Governance and Regulation: U.S. to Lead or Lag in the 21st Century

Visiting Speakers Program Event

Hosted by the
U.S. Department of Energy
Office of Health, Safety and Security
and the
National Academy of Public Administration

July 24, 2009
Washington, DC

NATIONAL ACADEMY OF PUBLIC ADMINISTRATION®

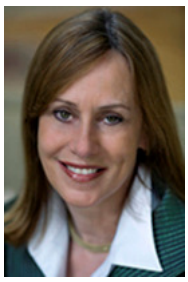
The National Academy of Public Administration is a non-profit, independent coalition of top public management and organizational leaders who tackle the nation's most critical and complex challenges. With a network of more than 600 distinguished Fellows and an experienced professional staff, the Academy is uniquely qualified and trusted across government to provide objective advice and practical solutions based on systematic research and expert analysis. Established in 1967 and chartered by Congress, the Academy continues to make a positive impact by helping federal, state and local governments respond effectively to current circumstances and changing conditions.

Federal agencies, Congress, state and local governments, academia, and foundations frequently seek the Academy's assistance in addressing both short-term and long-term challenges-including budgeting and finance, alternative agency structures, performance measurement, human resources management, information technology, devolution of federal programs, strategic planning, and managing for results.

The Academy's most distinctive feature is its membership of 550 Fellows. They include current and former Cabinet officers, members of Congress, Governors, Mayors, state legislators, diplomats, business executives, local public managers, foundation executives, and scholars. They form the heart of the Academy's studies-from inception through implementation-serving on project panels and guiding other major activities.

Individually, Fellows provide unparalleled insight and experience. Collectively, they are the Academy's primary vehicle for addressing emerging issues and contributing to intellectual and popular discourse on issues of governance. Fellows elect new members of the Academy each year. The principal criterion for selection is a sustained contribution to the field of public administration through public service or scholarship.

The Academy's Board of Directors provides overall guidance and leadership. Virtually all Academy activities are conducted through panels composed of Academy Fellows and others with expertise in the specific study topics. Projects are supported by the Academy's executive, administrative, and research staffs. In addition, the Academy has five Standing Panels that provide input to the Academy's agenda of studies and serve as collegial forums for Fellows to exchange ideas and to interact with experts outside the Academy, including senior government officials.



Jennifer L. Dorn
President and CEO

Office of Health, Safety and Security

The Office of Health, Safety and Security (HSS) is the Department of Energy's (DOE) corporate organization responsible for health, safety, environment, and security; providing corporate leadership and strategic vision to coordinate and integrate these vital programs. HSS is responsible for policy development and technical assistance; corporate analysis; corporate safety and security programs; education and training; complex-wide independent oversight; and enforcement. The Chief Health, Safety and Security Officer advises the Secretary and the Deputy Secretary on all matters related to health, safety and security across the complex.

Through its research on sustainability and industry's successful use of its concept, HSS has a clear idea of the types of organizations with which it would be beneficial to collaborate on sustainability. Such outreach efforts provide a cooperative advantage of sustaining an organization's efficiency and vitality by bringing together creative thought and diverse viewpoints toward common goals while demonstrating leadership's commitment to listening to and reflecting the concerns and issues of its shareholders and stakeholders.

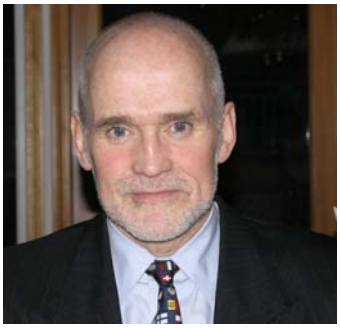
As the first phase of its outreach efforts, HSS created a Focus Group forum. The HSS Focus Group forum integrates senior HSS managers from across the organization to discuss and address topics and issues of interest to DOE managers and stakeholders. The objective of the Focus Group is to establish a means for responding to questions and concerns regarding HSS initiatives and activities for improving, the health, safety, and environmental and security performance within the Department and to maintain an ongoing dialogue with involved parties supportive of these efforts. HSS believes an outcome of these continuing discussions and collaborations will be improved worker health and safety programs and the solidification of a safety culture at DOE sites.

Glenn S. Podonsky
Chief Health, Safety and Security Officer

HSS Visiting Speaker Program

The next phase of HSS outreach activities is the creation of the Visiting Speaker Program. The Visiting Speaker Program consists of presentations by leaders drawn from a variety of disciplines to include business, organizational theory, performance management, sustainability, and organizational resilience, made to HSS management and selected attendees from other interested organizations (i.e., Office of Science, Office of Environmental Management, and the National Nuclear Security Administration).

The program is intended to focus agency attention at the management level to the emerging challenges and issues threatening the national security and economic prosperity of the United States. DOE's mission, supported by HSS and other agency organizations, requires the most efficient and resilient leadership and organizational structure for successful mission completion and the continued safety, security, and prosperity of the nation. By inviting and having presenters from the wide range of public and private sector organizations, HSS is encouraging the transformation of government and demonstrating the various stages for change. This includes understanding the depth of the global issues, need for change, tools and means for transformation, and knowing the appropriate performance measurements to determine success and implement evolving management initiatives.



Eugene G. Arthurs

Moderator

Topic: Analysis of U.S. Regulation; Economic Impacts, Export Controls, Effective Policy for U.S. Interests

Eugene G. Arthurs joined SPIE staff as Executive Director in November 1999. Prior to this he was President and CEO of Cleveland Crystals Inc. (CCI) He joined CCI, a closely held company, in 1997 and after reorganizing the company he marketed and sold it at the end of 1998.

In 1980 he joined Quantronix Corporation in New York, leading laser applications development and then managing its business for the semiconductor equipment market. From 1983 to 1997, Eugene was with Oriel Corporation in Connecticut, initially as Vice President of Technology and Marketing and from 1991, as President. Oriel, originally a privately held corporation, was acquired by a venture capital company in 1987. He changed the business of Oriel to emphasize systems and instruments and in 1996 ThermoElectron Corp. acquired an increasingly profitable Oriel. Eugene became involved in Thermo's growth-by-acquisition activities. During his time at Oriel, he played an active role on the Boards of Oriel Scientific Ltd., (London, UK), LOT Oriel GmBH, (Darmstadt, Germany) and he was a founder of Andor Technology Ltd. (Belfast, N.Ireland) a company initially owned mostly by Oriel.

Eugene received his B.Sc. (1st class honours) in 1972 in Physics, and his Ph.D. in 1975 in Applied Physics from Queens University Belfast, N.Ireland. His Ph.D. research was in generation and measurement of tunable ultrashort (1-2 ps in those days) pulses. In 1973, he taught the M.Sc. class in optoelectronics at Queens while continuing his research. He then moved to Imperial College in London where he conducted U.S. Air Force sponsored research on lasers.

An SPIE member from 1972 or so, Eugene has been active in the American Society for Lasers in Medicine of which he was a founding member, the Council for Optical Radiation Measurement, and the OSA at a local and national level. He is currently a member of SPIE, OSA, IEEE, and ASAE. He is a member of the boards of Edmund Optics, and the Council of Engineering and Scientific Society Executives and the Advisory Boards to the Photochemical Research Center at Bowling Green State University and to the Scottish University Physics Alliance. A former Congressional District Organizer, he remains active in Bread for the World, an educational and public policy organization working on the basic causes of world hunger.

SPIE

Robert D. Atkinson

Panel Member

Topic: What is the 21st Century Public-Private Partnership and Technology Transfer Perspective?

Robert Atkinson is President of the Information Technology and Innovation Foundation (ITIF). He has an extensive background in technology policy and has conducted ground-breaking research projects on technology and innovation.

Before coming to ITIF, Dr. Atkinson was Vice President of the Progressive Policy Institute and director of PPI's Technology & New Economy Project.

Previously Dr. Atkinson served as Executive Director of the Rhode Island Economic Policy Council, a public private partnership including as members the Governor, legislative leaders, and corporate and labor leaders.

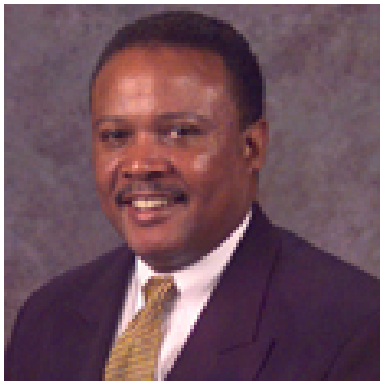
Prior to that he was Project Director at the former Congressional Office of Technology Assessment. While at OTA, he directed "The Technological Reshaping of Metropolitan America," a seminal report examining the impact of the information technology revolution on America's urban areas.

He is also author of the book, The Past and Future of America's Economy: Long Waves of Innovation that Power Cycles of Growth (Edward Elgar, 2005).

Dr. Atkinson received his Ph.D. in City and Regional Planning from the University of North Carolina at Chapel Hill in 1989.

The Information Technology & Innovation Foundation

ITIF



Johnny G. Barnes
Moderator
Topic: What is the 21st Century Public-Private Partnership and Technology Transfer Perspective?

Mr. Barnes has over 30 years of experience with IBM, holding a variety of product, solution development, staff, system architecture, management and executive positions. Mr. Barnes has been appointed to several IBM corporate staff positions, which have included a number of critical IBM product and strategy task forces responsible for establishing the future technical and business direction for IBM. Mr. Barnes has also worked to re-engineer IBM's internal hardware development, global computing and telephony environments and grow IBM's Public Sector transformation services business.

Mr. Barnes' professional experience includes several years of business and technical management of customer solution contracts and IBM worldwide organizations. Mr. Barnes was responsible for the definition of IBM's Manufacturing Industries' Worldwide Technical Strategy and the development of key components of the strategy. Throughout Mr. Barnes' career with IBM, he has received 8 patents, 3 IBM invention achievement awards, several IBM informal, divisional, and corporate awards for his technical and management contributions to IBM. Mr. Barnes has also been published on several occasions.

In an executive position as the Director of Hardware Common Tools, Mr. Barnes was responsible for transforming IBM's worldwide hardware and systems development strategy in support of IBM's re-engineered business process, Integrated Product Development (IPD). As Vice President of Global IT Infrastructure, Mr. Barnes was responsible for transforming IBM's global infrastructure to both a premier e-business computing and VOIP telephony environment ($2.5B budget).

As the Vice President and Deputy CIO, Mr. Barnes was responsible for IBM's worldwide intranet, application and information architecture, data and voice infrastructure, alliance management and advanced technology deployment within IBM ($3.5B budget). As the Vice President of Technology and Federal Solutions, Mr. Barnes was responsible for transforming a troubled strategic government agency infrastructure program into a success. Mr. Barnes' management responsibilities have included business management, strategy, architecture, design, development and deployment of both IBM and customer business solutions utilizing the latest HW, SW and development technologies and IT standards.

Johnny G. Barnes - Biography
Moderator
Continued

Mr. Barnes has an overall perspective of the computer industry and its applicability to business segments, as well as IBM's strategic plans to meet the distributed computing and e-business on demand market to satisfy future critical business requirements.

Currently, as General Manager Technology and Corporate Technology Officer, Mr. Barnes has responsibility for IBM's WW Public Sector Technical and Solution Strategy and expanding IBM's Public Sector transformation service business.

Mr. Barnes holds a B.S. in Electrical Engineering from the University of Houston and attended graduate school at the University of Texas concentrating on software engineering.

John S. Bresland

Panel Member

Topic: The Next Generation of Regulation for High-Reliability Organizations

The Honorable John S. Bresland was appointed by President George W. Bush as chairman and chief executive officer of the U.S. Chemical Safety Board in March of 2008.

Mr. Bresland previously served as a CSB board member from August 2002 until August 2007. Before joining the Board he was President of Environmental and Safety Risk Assessment LLC, a chemical process safety consulting company based in Morristown, New Jersey. In addition he was a Staff Consultant to the Center for Chemical Process Safety of the American Institute of Chemical Engineers, working as a project manager on two committees writing books on dust explosions and the management of reactive chemical hazards.

Until August 2000, he was Director of Environmental Risk Management for Honeywell International Inc. in Morristown, New Jersey. While working for Honeywell in Morristown he was responsible for their compliance with EPA's Risk Management Program regulation at 20 facilities in the United States.

From 1966 to 2000 he worked for Honeywell in West Virginia, Pennsylvania, Virginia and New Jersey. He held positions in process engineering, environmental compliance, project management and manufacturing. Before moving to Honeywell's headquarters in Morristown in 1995 he was Plant Manager of the Honeywell phenol and acetone manufacturing plant in Philadelphia.

In 2006, Mr. Bresland was appointed to be a member of the Department of Energy Hydrogen and Fuel Cell Technical Advisory Committee. He is also a member of U.S. Department of Transportation Pipeline and Hazardous Materials Safety Administration Technical Hazardous Liquid Pipeline Safety Standards Committee. He has served as Chairman of the Pennsylvania Chemical Industry Council and as Chairman of the Federation of State Chemical Associations.

John S. Bresland - Biography
Panel Member
Continued

Mr. Bresland graduated in Chemistry from Londonderry Technical College, Northern Ireland and from Salford University, England.

He is a member of the American Institute of Chemical Engineers, the American Chemical Society and a Fellow of the Royal Society of Chemistry.

Gerald W. Brock

Panel Member

Topic: Governance and Regulation for the 21st Century – Reform Not Relief/Increase

Dr. Gerald W. Brock is Professor of Telecommunication and of Public Policy and Public Administration at the Trachtenberg School of Policy and Public Administration, George Washington University. Prior to joining the George Washington University faculty in 1990, he served as Chief of the FCC Common Carrier Bureau from 1987-89.

Dr. Brock's research focuses on telecommunication policy, including the interaction of regulatory and other policy decisions with economic efficiency and technological progress. His current research examines the relationship between the regulated voice communication sector and the unregulated data communication sector, looking for insight regarding factors that facilitate technological progress and flexibility in economic institutions.

He teaches courses in telecommunication policy, the economics of the telecommunication industry, and economics for public policy.

Dr. Brock is the author of four books, of which the most recent is The Second Information Revolution (Harvard University Press, 2003).

He received his BA in Applied Mathematics and Ph.D. in Economics from Harvard University.

THE GEORGE WASHINGTON UNIVERSITY
WASHINGTON DC

Joseph J. Cordes

Panel Member

Topic: Governance and Regulation for the 21st Century – Reform Not Relief/Increase

Professor Cordes received his Ph.D.in Economics from the University of Wisconsin, Madison in 1977. He has been on the faculty of The George Washington University since 1975. He was a Brookings Economic Policy Fellow in the Office of the Assistant Secretary for Tax Policy, US Treasury Department in 1980-81. From 1989-1991 he was Deputy Assistant Director for Tax Analysis at the Congressional Budget Office. Professor Cordes currently directs the University's Ph.D. Program in Public Policy, and is an Associate Scholar at the Urban Institute. Professor Cordes is a member of the National Tax Association, and the American Economic Association.

Dr. Cordes is co-editor of the Encyclopedia of Taxation and Tax Policy (Urban Institute Press). He has published articles on tax policy, government regulation, and government spending in Economic Inquiry, Journal of Economic Perspectives, Journal of Public Economics, Journal of Finance, Journal of Law and Economics, National Tax Journal, Public Finance, Research Policy, Eastern Economic Journal, Journal of Policy Analysis and Management, Journal of Urban Economics, Space Policy, and the American Economic Review.

He has been a contributor to The Economics of Technological Change on Employment and Growth (Ballinger), State Taxation of Business (Praeger), Labor Market Adjustments in the Pacific Basin (Kluwer-Nijhof), Cooperative Research and Development: The Industry-University-Government Relationship (Kluwer-Nijhof), and Readings in Public Policy (Basil Blackwell).

Jerry Ellig

Panel Member

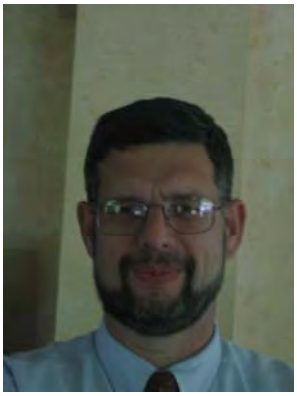
Topic: The Next Generation of Regulation for High-Reliability Organizations

Jerry Ellig is a senior research fellow at the Mercatus Center at George Mason University, where he has worked since 1996. Between August 2001 and August 2003, he served as deputy director and acting director of the Office of Policy Planning at the Federal Trade Commission. Dr. Ellig has also served as a senior economist for the Joint Economic Committee of the U.S. Congress and as an assistant professor of economics at George Mason University.

Dr. Ellig has published numerous articles on government regulation and business management in both scholarly and popular periodicals, including the Journal of Regulatory Economics, Managerial and Decision Economics, Antitrust Bulletin, Competitive Intelligence Review, Journal of Private Enterprise, Texas Review of Law & Politics, Wall Street Journal, New York Times, Barron's, and Washington Post. He has co-authored/edited several books, including Dynamic Competition and Public Policy (Cambridge, 2001), New Horizons in Natural Gas Deregulation (Praeger, 1996), and Municipal Entrepreneurship and Energy Policy (Gordon & Breach, 1994).

Dr. Ellig earned his Ph.D. and MA in economics from George Mason University in Fairfax, VA, and his BA in economics from Xavier University in Cincinnati, OH.

MERCATUS CENTER
GEORGE MASON UNIVERSITY



Robin Gaster

Panel Member

Topic: Analysis of U.S. Regulation; Economic Impacts, Export Controls, Effective Policy for U.S. Interests

Dr. Robin Gaster is President of Innovation Ecologies Inc. He is also Vice President for Research at the Alliance for Science and Technology in America (ASTRA) and Senior Fellow (nonresident) at the Innovation and Information Technology Foundation (ITIF).

Dr.Gaster founded Innovation Ecologies Inc. (IEI) in 2005. IEI has focused on the need to measure and understand the ecologies of economic innovation in the US and abroad. With funding from NIST and support from the National Academy, IEI has developed the Regional Innovation Index, a web-based tool for comparing the innovation capacity of US regions. He is also founder of the upcoming Innovation Policy Forum, a series of meetings to be held in conjunction with ITIF.

Since 2003, Dr.Gaster has been lead researcher on the National Academy of Sciences study of Small Business Innovation Grants. (http://www7.nationalacademies.org/sbir/) Dr.Gaster has authored many reports and publications covering a wide arrange of topics broadly related to technology, trade, and e-commerce, including a book on trans-Atlantic telecommunications issues, Bit by Bit.

His work has been published in Foreign Policyand The Atlantic, and his consulting clients include the European Commission, Deloitte and Touche, the Economist Intelligence Unit, TEKES (the Finnish National Technology Agency), VINNOVA (the Swedish National Technology Agency), and the Electric Power Research Institute, as well as many corporate clients such as Philips, Olivetti, Mitsubishi Research, and Dataquest, and think tanks such as the Berkeley Roundtable on the International Economy and the Economic Strategy Institute. A more extensive list of clients and publications is available at the web site of North Atlantic Research Inc., the consulting company he led from 1991 to 2005.

Robin Gaster - Biography
Panel Member
Continued

In addition, Dr.Gaster has founded several companies, focused on aggregating and deploying electronic information, targeting local and industry-specific information services.

Dr. Gaster received a Ph.D from U.C.Berkeley 1985, an M.A. from the University of Kent (UK), and a B.A. from Oxford University (U.K). His doctoral thesis won a national academic prize.

ASTRA

Christopher A. Hart

Panel Member

Topic: The Next Generation of Regulation for High-Reliability Organizations

Christopher A. Hart is the Deputy Director for Air Traffic Safety Oversight at the Federal Aviation Administration. Until recently he was the FAA Assistant Administrator for Office of System Safety. Reporting directly to the FAA Administrator, the Office of System Safety provided data, analytical tools and processes, safety risk assessments, and other assistance to support numerous FAA and worldwide aviation community safety programs; spearheaded industry-wide safety activities such as the Global Aviation Information Network (GAIN); and helped to identify key safety issues and emerging trends affecting aviation safety.

Mr. Hart's previous positions have included:

- Deputy Administrator for the National Highway Traffic Safety Administration (NHTSA),
- Member of National Transportation Safety Board (NTSB),
- Deputy Assistant General Counsel to the Department of Transportation,
- Managing partner of Hart & Chavers, a Washington, D.C., law firm, and
- Attorney with the Air Transport Association.

Mr. Hart has a law degree from Harvard Law School and a Master's Degree (magna cum laude) in Aerospace Engineering from Princeton University. He is a member of the District of Columbia Bar and the Lawyer-Pilots Bar Association, and he is a pilot with commercial, multi-engine, and instrument ratings.

Sean Heather
Panel Member
Topic: Analysis of U.S. Regulation; Economic Impacts, Export Controls, Effective Policy for U.S. Interests

Sean Heather is executive director for Global Regulatory Cooperation, an initiative of the U.S. Chamber of Commerce that seeks to address regulatory issues that act as barriers to international trade.

A member of the Chamber's staff for the past ten years, Mr. Heather previously led a project to identify emerging public policy issues of concern to the business community and served as part of the Chamber's Congressional Affairs division working on issues range of public policy issues.

Mr. Heather holds an undergraduate degree and an MBA from the University of Illinois.

Anne M. Khademian

Moderator

Topic: The Next Generation of Regulation for High-Reliability Organizations

Dr. Khademian is Professor, Center for Public Administration and Policy, Alexandria, Virginia Tech University with a research speciality in financial regulation, inclusive management, and organizations involved in homeland security.

She is the author of several books including; Working With Culture: How the Job Gets Done in Public Programs, CQ Press, 2002; *Checking on Banks: Autonomy and Accountability in Three Federal Agencies,* Brookings, 1996; *The SEC and Capital Market Regulation: The Politics of Expertise*, Pittsburgh, 1992.

Additionally, Dr. Khademian has contributed to several articles and book chapters including; (with William Berberich), "There's no security unless everyone is secure": The United States Coast Guard and a Port Security Network of Shared Responsibility;" "The Securities and Exchange Commission: A Small Regulatory Agency with a Gargantuan Challenge." *Public Administration Review* 62 (5): 515-526 (2002); and in Stephen Goldsmith and Donald Kettl (eds) *Innovations and Leadership: Networking for Improved Government Performance*. Brookings (Forthcoming 2009).

Dr. Khademian received her Ph.D. in Political Science from Washington University, and her MPA and B.A. in Political Science (cum laude) from Michigan State University.

Cynthia McIntyre

Panel Member

Topic: What is the 21st Century Public-Private Partnership and Technology Transfer Perspective?

Cynthia McIntyre, Ph.D., is a senior vice president at the Council on Competitiveness. She oversees strategic operations, planning and development. McIntyre is also leading the Council's High Performance Computing Initiative.

Prior to joining the Council, she served as chief of staff to the president, associate vice president for policy and planning at Rensselaer Polytechnic Institute, the nation's oldest technological research university. Her leadership and oversight of intellectual property, technology transfer and new ventures guided this portfolio to become a successful enterprise for Rensselaer. Additionally, McIntyre co-led the program and architectural design and development of a new research and performance platform, EMPAC, at Rensselaer. She managed the institutional performance planning process, monitored campus-wide progress on the university's strategic plan, and managed the budget for the Office of the President.

McIntyre is a theoretical condensed matter physicist and holds a Bachelor of Science in physics from the University of Texas at Austin, a Master of Arts in physics from Brandeis University and a doctorate in physics from the Massachusetts Institute of Technology.

Compete.
Council on Competitiveness

Arti K. Rai

Panel Member

Topic: Analysis of U.S. Regulation; Economic Impacts, Export Controls, Effective Policy for U.S. Interests

Arti Rai is an authority in patent law, administrative law, law and the biopharmaceutical industry, and health care regulation. Her current research on innovation policy in areas such as green technology, drug development, and software is funded by NIH, the Kauffman Foundation, and Chatham House. She has published widely in both peer-reviewed journals and law reviews, including Nature Biotechnology, PLoS Biology, PLoS Medicine, the Annals of Internal Medicine, and the Columbia, Georgetown, and Northwestern law reviews. She is currently editing a book on intellectual property rights in biotechnology and has also co-authored a casebook on law and the mental health system.

Rai has served as a peer reviewer for Science, Research Policy, the Journal of Legal Studies, various National Academy of Sciences reports on intellectual property, and various NIH study sections. She has also testified before the U.S. Senate on innovation policy issues. Rai is currently the chair of the Intellectual Property Committee of the Administrative Law Section of the American Bar Association.

Rai joined the Duke Law faculty in 2003. In the winter of 2007, Rai was the Hieken Visiting Professor in Patent Law at Harvard Law School. Prior to joining Duke, she was on the faculty of the University of Pennsylvania Law School, where she was also a visiting professor in Fall 2000.

Prior to entering academia, Rai clerked for the Honorable Marilyn Hall Patel of the United States District Court for the Northern District of California; was a litigation associate focused on patent litigation at Jenner & Block; and a litigator defending federal agencies at the United States Department of Justice, Civil Division, Federal Programs Branch.

Duke
UNIVERSITY

Larry E. Christensen

Panel Member

Topic: Analysis of U.S. Regulation; Economic Impacts, Export Controls, Effective Policy for U.S. Interests

Larry E. Christensen is a member in the firm's International Department and concentrates on export controls, sanctions and embargoes under the International Traffic in Arms Regulations (ITAR), Export Administration Regulations (EAR) and various regulations issued by the Office of Foreign Assets Control (OFAC). He focuses on the pre-acquisition due diligence, CFIUS reviews of foreign direct investment, and the defense of enforcement cases, as well as compliance processes, assessments and audits.

Mr. Christensen served in the Department of Commerce for eleven years in the Office of Chief Counsel of Export Administration and as Director of the Regulatory Policy Division (1986-1997). In that role, he headed the complete redrafting of the EAR in 1995-1996, the first such rewrite since 1949. He also authored the deemed export rule and coordinated the policy support for the rule prior to its publication.

Mr. Christensen has worked in export controls and trade sanctions for more than 29 years and has been counseling clients on ITAR since 1979. During his eleven years at the Commerce Department, Mr. Christensen was primarily responsible for the regulatory and interagency issues surrounding the State Department scope of jurisdiction under the ITAR and, on behalf of Commerce, negotiated with the State Department on the current standards for commodity jurisdiction under the ITAR. Since leaving Commerce in 1997, Mr. Christensen has dedicated more than half of his time to ITAR matters. While Vice President of Export Controls for JPMorgan Chase Vastera (1997-2007), he trained and supervised consultants and managed services employees that performed more than 10,000 self-determinations, more than 80,000 classifications and more than 100 export compliance assessments.

Mr. Christensen is the author of the EAR provisions regarding publicly available treatment, including the provisions regarding the scope of the academic exclusion under EAR. In addition, he led the US delegation to Coordinating Committee for Multilateral Export Controls in connection with the drafting of the General Technology Note.

He trains on all US export control and sanctions topics and has lectured on export controls in China, Brazil, Argentina, Singapore, Finland, Germany, the United Kingdom, and the United States. In the United States, he is a frequent speaker for the Practicing Law Institute and the American Conference Institute. He was a speaker during China seminars sponsored by the U.S. Department of Commerce.

Larry Christensen - Biography
Panel Member
Continued

Mr. Christensen has counseled firms in the development of compliance strategies, process assessments and audits. He has also assisted firms facing governmental administrative audits and criminal investigations.

While in government, Mr. Christensen co-authored the “Know Your Customer" Guidance and "Red Flags Under the EAR.” In multilateral control negotiations, he represented the U.S. in China and at the multilateral national security regime. He has advised corporations on the most challenging substantive areas of export controls, such as commodity jurisdiction, the outer limits of US re-export rules, encryption and OFAC restrictions on facilitation. In addition, he has substantial technical experience and classification experience in industries such as seismic, oil and gas, aerospace, night vision, navigation, special metals, information technology, telecommunications, machine tools, sensing devices, accelerometers, chemicals, and bio toxins. He has experience in technology transfer in avionics, gas turbine engines, missile development, telecommunications, computers, and chemicals.

Mr. Christensen is familiar with the export laws of many countries. He was on the team that trained the Government of Singapore before it implemented its export control laws.

Mr. Christensen has testified before the U.S. Senate and House of Representatives regarding export control legislative developments and drafted all Export Administration Act proposed legislation for the Reagan, Bush Senior and first Clinton administrations.

Mr. Christensen is globally and nationally ranked by Chambers and featured in Best Lawyers in America for his work in the International Trade: Export Controls & Economic Sanctions area. Since 1994, Mr. Christensen has been an adjunct professor of law at Georgetown University Law Center where he teaches export controls and trade sanctions.

Education
Duke University School of Law, 1972 J.D.
University of South Dakota, 1968 B.A.

MILLER CHEVALIER

Mihail C. Roco

Panel Member

Topic: The Next Generation of Regulation for High-Reliability Organizations

Dr. Mihail C. Roco is the founding chair of the National Science and Technology Council's subcommittee on Nanoscale Science, Engineering and Technology (NSET), and is the Senior Advisor for Nanotechnology at the National Science Foundation. He also coordinated the programs on academic liaison with industry (GOALI). Prior to joining National Science Foundation, he was Professor of Mechanical Engineering at the University of Kentucky (1981-1995), and held visiting professorships at the California Institute of Technology (1988-89), Johns Hopkins University (1993-1995), Tohoku University (1989), and Delft University of Technology (1997-98).

Dr. Roco is credited with thirteen inventions, contributed over two hundred articles and sixteen books including "Particulate Two-phase Flow" (Butterworth, 1993), "Nanostructure Science and Technology" (1999), “Societal Implications of Nanoscience and Nanotechnology” (2001 and 2006), and more recently “Managing Nano-Bio-Info-Cognition Innovations” (2007) and “Mapping Nanotechnology Knowledge and Innovation: Global and Longitudinal Patent and Literature Analysis” (2008).

Dr. Roco was a researcher in multiphase systems, visualization techniques, computer simulations, nanoparticles and nanosystems. He initiated the first Federal Government program with focused on nanoscale science and engineering (on Synthesis and Processing of Nanoparticles) at NSF in 1991. He formally proposed NNI in a presentation at White House/OSTP, Committee on Technology, on March 11, 1999. He is a key architect of the National Nanotechnology Initiative, and coordinated the preparation of the U.S. National Science and Technology Council reports on "Nanotechnology Research Directions" (NSTC, 1999) and "National Nanotechnology Initiative" (NSTC, 2000).

Dr. Roco is a Correspondent Member of the Swiss Academy of Engineering Sciences, a Fellow of the American Society of Mechanical Engineers, a Fellow of the Institute of Physics, and a Fellow of the American Institute of Chemical Engineers. He has been co-founder and Chair of the AIChE Particle Technology Forum and of the International Multiphase Flow Council. He has served as editor for Journal of Fluids Engineering and Journal of Measurement Science and Technology, and is Editor-in-chief of the Journal of Nanoparticle Research. He has been member in the several research boards in Americas, Europe and Asia including the S&T Council of the International Risk Governance Council in Geneva.

Mihail C. Roco - Biography
Panel Member
Continued

He was honored as recipient of the Carl Duisberg Award in Germany, “Burgers Professorship Award” in Netherlands and the “University Research Professorship” award in U.S. He was named the “Engineer of the Year” in 1999 and again in 2004 by the U.S. National Society of Professional Engineers and NSF. In 2002, he received the “Best of Small Tech Awards” (“Leader of the American nanotech revolution”).

Forbes magazine recognized him in 2003 as the first among “Nanotechnology’s Power Brokers” and Scientific American named him one of 2004’s top 50 Technology Leaders. Dr. Roco is the 2005 recipient of the AIChE Forum Award "for leadership and service to the national science and engineering community through initiating and bringing to fruition the National Nanotechnology Initiative".”

He received the National Materials Advancement Award from the Federation of Materials Societies at the National Press Club in 2007 for NNI leadership and “as the individual most responsible for support and investment in nanotechnology by government, industry, and academia worldwide”.

Thomas H. Stanton

Moderator

Topic: Governance and Regulation for the 21st Century – Reform Not Relief/Increase

Thomas H. Stanton is a Fellow of the Center for the Study of American Government at the Johns Hopkins University, where he received the award for Excellence in Teaching. Mr. Stanton serves on the board of directors of the National Academy of Public Administration and is a former member of the federal Senior Executive Service.

As a Washington, DC attorney, Mr. Stanton's practice relates to the capacity of public institutions to deliver services effectively, with specialties relating to organizational and program design, federal credit and benefit programs, government enterprises, and regulatory oversight. His writings on public administration have appeared in publications including *Public Administration Review*, *The Administrative Law Journal*, *American Banker*, and *the Wall Street Journal*. He edited, with Benjamin Ginsberg, *Making Government Manageable: Executive Organization and Management in the 21st Century*, Johns Hopkins University Press, 2004. He also edited, *Meeting the Challenge of 9/11: Blueprints for Effective Government*, M.E. Sharpe Publishers, 2006. Mr. Stanton's publications on government and the financial markets include two books on government-sponsored enterprises (GSEs). Concerns expressed in A *State of Risk: Will Government-Sponsored Enterprises be the Next Financial Crisis?* (HarperCollins, 1991) helped lead to enactment of several pieces of legislation and the creation of a new federal financial regulator in 1992.

Mr. Stanton's B.A. degree is from the University of California at Davis, M.A. from Yale University, and J.D. from the Harvard Law School. He is fluent in German and has conducted research in several different countries. The National Association of Counties awarded him its Distinguished Service Award for his advocacy on behalf of the intergovernmental partnership.

NATIONAL ACADEMY OF PUBLIC ADMINISTRATION®

Ralph Taylor-Smith

Panel Member

Topic: What is the 21st Century Public-Private Partnership and Technology Transfer Perspective?

Ralph Taylor-Smith has a background in engineering, applied-science and technology development, finance and business management. He gained his academic training from Princeton University and the Massachusetts Institute of Technology (MIT), receiving a PhD in Engineering (Chemical & Biomolecular Engineering focus) and an MBA in Finance (Corporate Finance & Strategic Planning focus). He is currently a General Partner of Battelle Ventures, a private equity investment firm which manages $255Million in venture capital funds. At Battelle, Ralph is a member of the firm's Investment Committee and he covers all aspects of the venture investment business, including deal sourcing, due-diligence, deal negotiation and transaction closing, Board of Director duties, start-up company development and financial exits.

Ralph has led various venture investments for Battelle Ventures and he currently serves on the Board of Directors for six Companies. Prior to entering the venture capital industry, Ralph gained significant experience in investment banking, business development and technology R&D. He worked previously as an Investment Banker on Wall Street at GoldmanSachs and JPMorgan focusing on mergers/acquisitions for technology-industry companies. Earlier in his career, Ralph worked as a Senior Research Scientist and Engineer at Bell Labs and in Business Development at Lucent Technologies.

He holds twelve patents for innovations in semiconductor microelectronic devices, optical-fiber & photonics, fuel cells, flat panel displays, and nanotechnology systems.

Ralph was selected as a Kauffman Fellow by the Center for Venture Capital Education & Entrepreneurial Leadership, affiliated with the Ewing Marion Kauffman Foundation.

Ralph Taylor-Smith - Biography
Panel Member
Continued

He was also appointed a Robert Toigo Foundation Fellow in Finance & Technology Entrepreneurship at MIT Sloan School of Business Management and appointed a PriceBabson SEE Fellow in Entrepreneurship Education & University Curriculum Development at Babson College Center for Entrepreneurship.

In addition to his several for-profit Corporate Board Directorships, Ralph currently serves various non-profit educational organizations, academic colleges and universities as Advisory Board Member or Board of Trustees Member; he also works regularly with the National Science Foundation (NSF) on SBIR (Small Business Innovation Research) and STTR (Small Business Technology Transfer) programs.

Charles W. Wessner

Panel Member

Topic: What is the 21st Century Public-Private Partnership and Technology Transfer Perspective?

Dr. Charles W. Wessner is a National Academy Scholar and Director of the Program on Technology, Innovation, and Entrepreneurship. He is recognized nationally and internationally for his expertise on innovation policy, including public-private partnerships, entrepreneurship, early-stage financing for new firms, and the special needs and benefits of high-technology industry. He testifies to the U.S. Congress and major national commissions, advises agencies of the U.S. government and international organizations, and lectures at major universities in the U. S. and abroad. Reflecting the strong global interest in innovation, he is frequently asked to address issues of shared policy interest with foreign governments, universities, and research institutes, often briefing government ministers and senior officials. He has a strong commitment to international cooperation, reflected in his work with a wide variety of countries around the world.

Dr. Wessner's work addresses the linkages between science-based economic growth, entrepreneurship, new technology development, university-industry clusters, regional development, small firm finance and public-private partnerships. His program at the National Academies also addresses policy issues associated with international technology cooperation, investment, and trade in high-technology industries.

Currently, he directs a series of studies centered on government measures to encourage entrepreneurship and support the development of new technologies and the cooperation between industry, universities, laboratories, and government to capitalize on a nation's investment in research. Foremost among these is a congressionally mandated study of the Small Business Innovation Research (SBIR) Program, reviewing the operation and achievements of this $2.3 billion award program for small companies and start-ups. He is also directing a major study on best practice in global innovation programs, entitled Comparative Innovation Policy: Best Practice for the 21st Century. A complementary analysis entitled Competing in the 21st Century: Best Practice in State & Regional Innovation Initiatives is now underway. The overarching goal of his work is to develop a better understanding of how we can bring new technologies forward to address global challenges in health, climate, energy, water, infrastructure, and security.

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21ST CENTURY REGULATION

DISCOVERING BETTER SOLUTIONS FOR ENDURING PROBLEMS

JANUARY 2009

MERCATUS CENTER
GEORGE MASON UNIVERSITY

About the Mercatus Center at George Mason University

The Mercatus Center at George Mason University is a 501(c)(3) education, research, and outreach organization that works with scholars, policy experts, and government officials to bridge academic learning and real-world practice.

Our mission is to generate knowledge and understanding of how institutions affect the freedom to prosper and hold organizations accountable for their impact on that freedom. The aim of our work is to enable individuals to live free, prosperous, and peaceful lives.

The Mercatus Center is located on George Mason University's Arlington Campus, along with the George Mason University School of Law, the Law and Economics Center, and our sister organization, the Institute for Humane Studies.

About the Regulatory Studies Program

The Regulatory Studies Program has begun a new series of research and discussions to engage some of the country's brightest scholars in a long-term research agenda designed to find innovative reforms and new approaches to the U.S. regulatory process help solve social problems more effectively.

As a first step in this initiative, the Regulatory Studies Program released six working papers at a Washington, D.C., conference, 21st Century Regulation: Discovering Better Solutions for Enduring Problems, on September 15, 2008. Those papers are now published in this compendium.

We are continuing to work in these areas and are looking for both scholars who wish to engage with us on these issues and academic and policy groups that would benefit from presentations of these ideas.

Cover image: Marcial Camilo Ayala /Courtesy Tyler Cowen Collection

January 2009

On behalf of the Mercatus Center at George Mason University, I am pleased to present *21st Century Regulation: Discovering Better Solutions to Enduring Problems*.

Our new president has the opportunity offered to all of his predecessors: the chance to put his stamp on regulation and the regulatory process. Every president in the last generation has modified the way the federal government uses regulation as a tool to address issues about which all Americans care, including a healthy environment, stable financial markets, safe consumer goods, and workplace health and safety. We are delighted that you are interested in exploring innovative ways of reforming regulatory and market institutions in order to better achieve lasting solutions to the problems of the 21st century.

In this publication, you will find five papers at http://www.mercatus.org by leading scholars in the Mercatus Center's academic network. These papers examine various reforms and new approaches to regulation that the new president could implement. We encourage you to read these working papers, and we welcome your feedback.

Far from being the last word on potential new regulatory approaches in the new administration, this publication is the kick-off document of a new series of research and discussions planned by the Mercatus Center. We intend to engage some of the country's brightest academic scholars in a long-term research agenda designed to break through political and ideological barriers and find solutions to those problems about which we all care.

As a university-based research center, the Mercatus Center works to blend theory and practice to advance new knowledge that can help to improve public policy. We do our best work when we can tap into multiple perspectives and expertise. If you would like to be involved in this work going forward, please feel free to contact me at rwilliav@gmu.edu.

We look forward to your feedback, and we trust you will find the ideas discussed in this compendium a valuable investment of your time and mind.

Sincerely,

Richard A. Williams
Managing Director, Regulatory Studies Program and Government Accountability Project

FIVE NEW IDEAS

During the last several decades, knowledge about the role of regulation in solving problems has advanced considerably. This compendium draws on that knowledge to offer new solutions to pressing social problems that our existing 20th century regulatory institutions cannot adequately address.

The current economic situation underscores the importance of considering the way in which policy decisions will affect the economy. We must identify regulatory decisions that solve important problems while enhancing, rather than impeding, economic opportunity.

This compendium presents several specific suggestions that do just that. To get started, consider the following five ideas to improve regulatory decision making:

IDEAS	PROBLEM	SOLUTION
PREVENT INDUSTRY CAPTURE.	Pressure from organized interest groups results in socially wasteful regulations that help one group at the expense of another and may not help consumers.	Require agencies to ensure that market-oriented options are considered first and in sequence from most market-oriented (e.g., requiring information or performance standards) to least market-oriented (command and control options) and justify less market oriented choices.
CHECK ON THE BIG ONES.	Regulatory choices are made outside of congressional intent due to vague or antiquated statutes and without sufficient attention to overall societal resources.	Require congressional approval for economically significant regulations and consider requiring offsetting cost-savings elsewhere.
MAKE SURE REGULATIONS BENEFIT SOCIETY.	The myriad internal and external pressures that agencies face when promulgating regulations creates mission creep, which leads to regulations that do not accomplish social goals.	Require agencies to identify outcome-based performance measures (such as GPRA goals) for each regulation and apply performance measurement.
GIVE NEW TECHNOLOGY A FAIR SHAKE.	New technologies (e.g., nanotechnology) with the potential to help lower risks, address environmental concerns, and enhance economic growth (and add jobs) are subjected to premature and unwarranted regulatory requirements that inhibit their development.	Establish a non-discriminatory policy toward new technologies that places them on the same scientific footing as existing technologies.
NEGOTIATE PROBLEMS.	Regulatory processes are slow, and decisions bound by old statutes do not address modern stakeholder needs.	Consider privately facilitated solutions that offer innovative, quick, and inclusive solutions to problems.

INTRODUCTION*

Momentous events in 2008 involving housing, financial markets, food safety, and government response to cataclysmic emergencies have generated a common response: Something is wrong with the rules of the game. Something is wrong with the way we regulate the economy.

While the need for new ways to regulate may be obvious, it may still seem premature to try to create a 21st century regulatory framework. But just eight years into this new century, the rules and regulations under which the American economy operates are not only a relic of the past, but a reflection of an economy that no longer exists. Indeed, many of the rules that once provided greater benefits than costs now constrain the competitiveness of the United States's participation in the global economy.

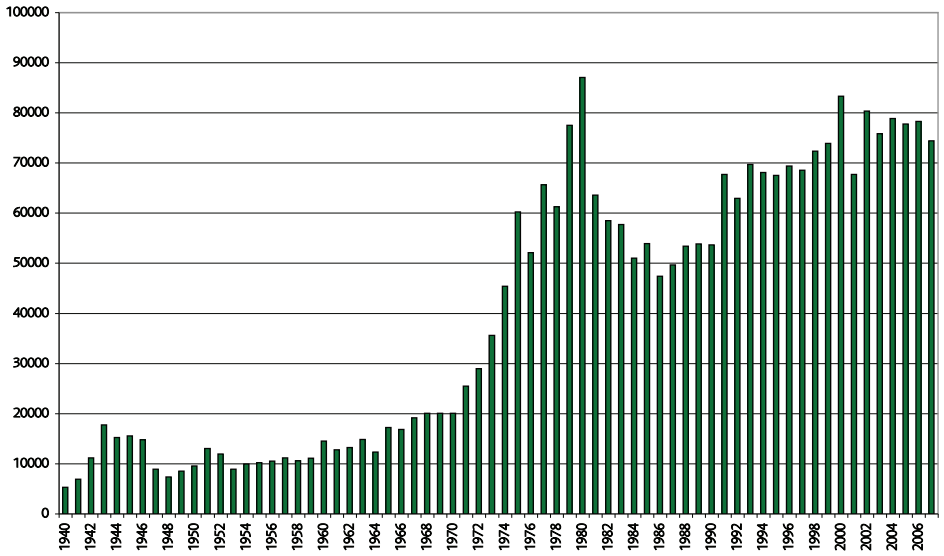
It is a time for change. Let us consider why this is so.

THE IMPRINT OF THE '70s

To find the origin of the federal regulations that helped build and now constrain the modern U.S. economy, we need to go back about thirty years. The 1970s represented a decade-long heyday for regulators. The number of pages added to the *Federal Register* during this time is one obvious indicator of the dramatic difference between this period and decades preceding and following it. Even the number of rules created during World War II, an era marked by strict price controls and command-and-control resource allocation, is vastly outnumbered by the quickly increasing rate of regulatory activity of the 1970s.

But the 20th century is also characterized by relatively steady economic growth. One can logically argue that a growing and larger economy requires accompanying growth in the number of *Federal Register* pages. However, if the number of pages is divided by annual GDP, one still observes the dramatic 1970s increase, unprecedented and unmatched since then.

TABLE 1: *FEDERAL REGISTER* PAGES PER BILLIONS OF DOLLARS OF GROSS DOMESTIC PRODUCT[1]



FEDERAL REGISTER
1940—2007

1. Compiled using data from the Office of the *Federal Register* and U.S. Department of Commerce Bureau of Economic Analysis.

**The ideas presented in this research are the authors' and do not represent official positions of the Mercatus Center at George Mason University.*

It was during the 1970s that the term "midnight regulations" first entered the regulatory vernacular. This phrase refers to the regulations pushed through at the end an administration's term in an attempt to create a lasting regulatory imprint in the little time that remains.

We now know that there were more regulations published systematically during this "midnight" period than there were during other times during a president's term, but there were even greater forces at play in the drive to write more federal regulations. During the 1970s, low-cost national television network advertising enabled producers of consumer goods to tap into the national market. National markets were forming like never before. As these national markets grew, manufacturers and distributors increasingly began to look to federal regulators to preempt and standardize state and local regulations that previously defined the rules of the game. Sellers preferred streamlined federal regulations to the panoply of rules they encountered across the fifty states.

Although this centralization of rulemaking theoretically reduced costs for business, centralization also created an ideal opportunity for rent-seeking among incumbent and dominant industry players. Because industry groups needed only gain approval of a single agency, it became easier for these groups to act like a cartel and lobby for rules that appeared to maximize social welfare but really served to limit competition. For example, firms could lobby for uniform, technology-based regulations and onerous safety and environmental standards that happened to match their already existing production processes. The result often raised the cost of entry for new firms and potential competitors.

AS TIME GOES BY . . .

Even if one assumes that all the regulations from the 1970s were necessary to achieve legitimate outcomes, a variety of changes in the economy since then make the overall structure of the past wholly inappropriate for today's world. Today's economy barely resembles its 1970s predecessor.

To begin with, the economy has disintegrated. Disintegration is a term of art among economists. Its opposite, integration, describes the process of including more steps of production within a single firm—more functions take place under one roof. Prior to the 1970s, the economy was characterized by integration, with increasingly larger firms, consolidation, and mergers. Since then, a growing share of the economy has been taken over by smaller firms, spin-offs from larger firms, and companies that specialize in specific parts of the production chain. This disintegration has gone so far that in 2002, nonemployer firms (single-person firms) made up 75 percent of firms in the U.S. economy.[2] If nonemployer firms represent the terminus of economic disintegration, the economy has not much further to go along this path. But there is far more to the story of change that has occurred since the 1970s.

Another significant change is the type of work Americans do. In 2007, 19 percent of private-industry employees worked in goods production, down from 39 percent in 1970. On the contrary, employment in professional services—the sector that could reasonably be called the "new economy"—the share nearly doubled from 9 percent to 16 percent. The contours of the traditional sectors have also changed in a way that may not be apparent in labor statistics. Manufacturing today is much more knowledge-intensive than it was thirty to forty years ago, with much more reliance on technology than on human labor.

2. U.S. Census Bureau, "Characteristics of Business Owners: 2002" (Sept. 2006), 1, http://www.census.gov/prod/ec02/sb0200cscbot.pdf.

CHART 1: U.S. EMPLOYMENT BY SECTOR: 1970[3]

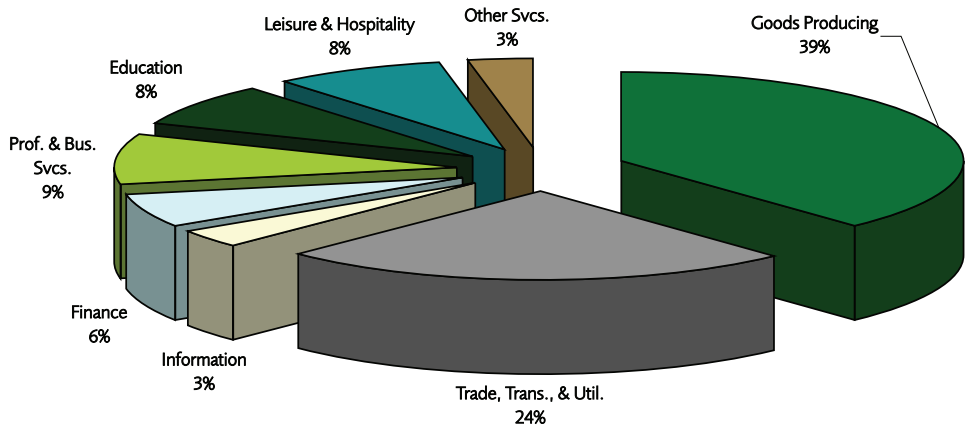
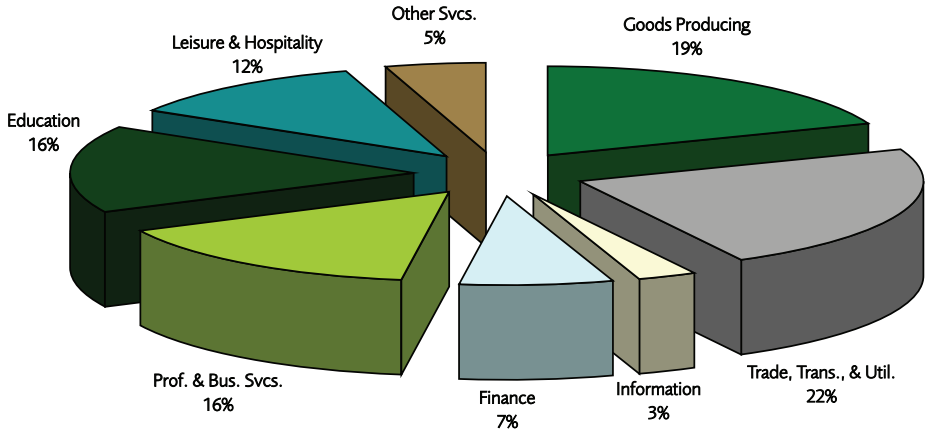


CHART 2: U.S. EMPLOYMENT BY SECTOR: 2007



Even information has become disintegrated. During the rise of the large broadcast networks, the delivery of information was concentrated in a relatively small number of media outlets. Back then, information was centralized in much the same way as regulation. Today, of course, information flows through highly disintegrated firms and outlets, along a dizzying number of channels and types of media.

3. Percentages calculated using Bureau of Labor Statistics industry data, available at http://www.bls.gov/iag/tgs/iag_index_naics.htm.

Economic growth over the last few decades has generated a wealthier economy. Per capita GDP, in real dollars, has increased from $18,000 in 1970 to $38,000 today.[4] The compositions of the population as well as the labor force have also changed. In the 1970s, the Baby Boomer generation was just entering the workforce. As a result, the overall population and workforce were younger and less experienced than today's counterpart.[5] In addition to being older and more experienced, today's population is significantly better educated. In 1970, 11 percent of people over the age of 25 possessed a college degree; today that number is just under 29 percent.[6]

Along with being disintegrated, wealthier, and more educated, today's economy is also more international. In the 1970s, trade restrictions and higher-cost transportation protected U.S. firms from the full forces of international competition. The typical domestic firm had few competitors outside the country. Today, international competitors abound and many countries have the potential to become the next economic superpower. Global competition demands more efficient and effective regulation. Rules that worked well for the old economy just don't get the job done today.

THE SONG REMAINS THE SAME

The United States needs a new regulatory framework that will better address the changed nature of the economy. Regulation that may have been appropriate in 1970 is simply inadequate in the 2000s and beyond. A population and workforce that is older, more experienced, more educated, and has much better and faster access to information is better equipped to confront and handle risks. Whereas before, observers worried about a "race to the bottom," today's consumers engage in a "race to the top;" their incomes and access to information lead them to demand products that are safer and cleaner.

The implicit demand for a more modern regulatory framework calls for change. But change will not come easily. Path-dependence has created a strong inertia to remain within the grooves created by those rules and the institutions that created them thirty years ago. Because of the nature of federal regulatory policymaking, the rulemaking agencies tend to provide little response to what MIT Professor Clayton Christensen calls the "innovator's dilemma." In any large organization, growth is evidence that the organization is succeeding and doing well. As growth continues, the organization becomes more hesitant to adopt new and innovative ways of doing things. Making significant change is antithetical to their previous success: Why change when things are going so well?[7]

In a competitive industry, innovations find a voice through either a spin-off from the larger company or as a completely new entrant into the market. In other words, the increasing disintegration of the economy can be

4. Figures obtained from Federal Reserve Bank of St. Louis data, "Series: GDPCA, Real Gross Domestic Product," http://research.stlouisfed.org/fred2/series/GDPCA?cid=106; U.S. Census Bureau, "Historical National Population Estimates: July 1, 1900 to July 1, 1999," http://www.census.gov/popest/archives/1990s/popclockest.txt; and U.S. Census Bureau, "Population, Population change and estimated components of population change: April 1, 2000 to July 1, 2007," http://www.census.gov/popest/national/files/NST-EST2007-alldata.csv.

5. Daniel Aaronson and Daniel Sullivan, "Regional Growth in Worker Quality" *Chicago Fed Letter*, no. 189 (May 2003), http://www.chicagofed.org/publications/fedletter/2003/cflmay2003_189.pdf.

6. U.S. Census Bureau, "Years of Schooling by People 25 and Over, by Age and Sex: Selected Years 1940 to 2004" Educational Attainment—Historical Tables, 2005, http://www.census.gov/population/socdemo/education/tabA-1.xls.

7. Clayton M. Christensen, *The Innovator's Dilemma: When New Technologies Cause Great Firms to Fail* (Boston, MA: Harvard Business School Press, 1997).

thought of as evidence of innovation. Within the federal agency structure, however, innovators cannot simply spin off into a new agency, but must appeal to the bureaucratic and political chain of command. And again, because of the long experience with older ways of doing things, these agencies are unlikely to accommodate proposals for radical change.

CONCLUSION

The need for new ways of regulating is predicated not upon the simple flipping of the calendar to a new decade, but because of an underlying decades-long evolution of the economy against a well-trodden regulatory structure. In any given year, these structural economic changes may have been hardly perceptible, but looking back over time, one can observe fundamental shifts in the composition of the workforce, the type of work that is being done, the nature of the typical firm, and the new international competitive landscape.

With capital now able to move fluidly among nations, economic growth will be the reward for regulatory schemes that can properly adapt to and accommodate the needs of today's economy. It's time for policymakers to open the door to a new era of 21st-century regulation.

CONTENTS

EXECUTIVE SUMMARY

Why should Americans care about regulation? We should care because regulations affect almost every aspect of our lives. We should care because the outcomes of regulatory policy matter. The quality of the environment, the safety of consumer goods and industrial processes, and the adoption of quality-of-life-enhancing technology all depend to a great degree on the goals of regulatory policy.

We should also care because regulations impose a significant cost on the economy. Estimating the precise scope of this burden is difficult. Regulatory compliance (or avoidance) often comes with implicit costs that are not easily summed across the economy. However, at least one estimate puts it at over $1 trillion.[1]

The next administration will have the opportunity to reformulate regulatory policy significantly. It could take steps that would greatly improve outcomes as well as minimize the costs imposed on firms and consumers. As the Mercatus Center launches a program to investigate ways in which to improve the regulatory process and policy in the 21st century, we offer a few brief ideas for new directions a new administration could take.

A NEW DAY, NEW PROBLEMS[2]

the 20th century saw significant gains in the quality of life. But the institutions and frameworks developed in the past are decreasingly relevant in the 21st-century world. The United States is shifting from a manufacturing-based economy to a knowledge-based one. Goods and services are increasingly subject to international movement. Productive capital faces international competition. Government needs to update existing regulatory policies to keep up with this changing world.

The papers that follow identify some of the specific problems with today's regulatory arrangement which include:

- insufficient feedback from elected officials;
- interest groups' pressure to write regulations to their advantages;
- vague and often antiquated authorizing statutes;
- lack of incentives for updating or eliminating older regulations;
- reliance on older, intrusive types of regulations when newer ones may be necessary;
- suspicion of new technologies;
- and failure to account for regulation's effect on competition.

These papers include proposals to help better achieve our goals while mitigating or even eliminating the problems mentioned above.

1. Clyde Wayne Crews, Jr., "Ten Thousand Commandments 2008: An Annual Snapshot of the Federal Regulatory State," (Competitive Enterprise Institute, July 10, 2008), http://cei.org/cei_files/fm/active/0/10KC_2008_FINAL_WEB.pdf.
2. This section based on Bruce Yandle, prepared remarks for "21st Century Regulation: Discovering Better Solutions for Enduring Problems," (September 15, 2008).

1. Performance-Enhanced Regulations

In order to assess whether the government should continue or modify current federal regulations, federal policy makers and the public need to understand whether these rules are performing well. Regulatory reform statutes and executive orders should, but woefully do not, provide a consistent means to answer questions like: What outcomes does the rule seek to achieve that produce concrete public benefits; how does the rule advance the mission and goals of the issuing agency; and, how does the agency measure the rule's success in achieving outcomes?[3]

Creating a framework that would answer these questions would require an executive order. That executive order must lay out clear requirements for performance metrics and align incentives with performance goals. Such an order would require agencies to:

- develop for each rule verifiable indicators of progress toward long-term goals, a benefit analysis demonstrating the effect of the rule on intended outcomes, and long-term performance goals that specify the outcome the rule is designed to achieve
- develop draft performance metrics along with the Office of Management and Budget (OMB) and in consultation with stakeholders
- report on performance measures each year
- adopt personnel practices (managerial contracts) that create incentives for agency management to support outcome-oriented performance measurement[4]

2. New Kid on the Block

In this century, the greatest gains in well-being are likely to come from emerging and heretofore unknown technologies. Biotechnology, nanotechnology, and other areas of ongoing research hold great potential to improve the environment, eliminate disease, and increase economic growth. Unfortunately, the current regulatory environment that governs adoption of these technologies discriminates against new technologies in favor of existing ones. In order to combat a regulatory agenda that is often motivated by stigma and emotion and suppresses advancement in potentially beneficial technologies, the following three policies should be pursued:

- Reject the precautionary principle. Generally regarded as an implementation of the "better safe than sorry" doctrine, this principle opens the door to regulation based on subjective and arbitrary political bias. Because there is no standard definition, despite having been adopted as official policy throughout the world, the precautionary principle is prone to application on anything but a principled basis.[5]
- Adopt a principle of non-discrimination that would prohibit regulatory discrimination against a product based on the process by which it was produced. Under this framework, regulation would be based solely on the evidence of risk of the individual product and not the technology used to produce it.[6]

3. Henry Wray, "Performance-Based Regulations," (working paper 08-25, Mercatus Center at George Mason University, August 2008), 1.
4. *Ibid*, 12–14.
5. Gary Marchant, "Lessons for New Technologies," (working paper 08-26, Mercatus Center at George Mason University, August 2008), 9–10.
6. *Ibid*, 11–12.

- Create a voluntary health and safety certification program. New and novel technologies, even if they are treated neutrally by regulators, may still inspire public hesitation and calls for oversight due to media portrayals and activist-group pressure. In order to provide public confidence without unfairly burdening the emerging technology, the government could offer a voluntary certification for manufacturers that undertake specific health and safety testing programs.[7]

3. Meeting of the Minds

While markets are surprisingly efficient at providing the goods and services we want, institutional constraints can sometimes limit their effectiveness. In some cases, stakeholders—corporations, regulators, public health officials, and the like—all agree that a problem exists, but the transaction costs are too high to reach a solution. Where that is the case, facilitated negotiations may provide relief from this coordination problem without deadening effects on innovation. In order to facilitate coordination within an industry to solve social problems, mediation firms could bring together different perspectives on an issue and give stakeholders the opportunity to voice their concerns, encouraging cooperation.[8]

Industry representatives may also have an incentive to reach an agreement to avoid regulation. For instance, internet service providers worried that regulation of web traffic may soon arrive in the form of heavy-handed regulation would be well served to enter a facilitated mediation with advocates of regulation (in this case, advocates of net neutrality). If they can come to an agreement that satisfies all parties, they could eliminate the perceived need for any formal regulatory action.

The government too, through the Administrative Procedures Act and the Negotiated Rulemaking Act, sometimes acts in this mediator capacity. Unfortunately, these government-led negotiations are often costly to stakeholders. Because they are public, participants fear that confidential or proprietary information brought forth will become a matter of record. This discourages the candid discussions that negotiations are supposed to foster.[9]

Privately mediated solutions do not suffer from this drawback. Mediators can guarantee confidentiality. Additionally, private facilitators are not bound by often outdated authorizing statutes. Though meditation firms are relatively new, they have been used to handle arms proliferation talks, to lead discussions of international oil pipeline construction, and to engage on environmental issues under the Clinton administration's sustainable development initiative.[10]

Sadly, outdated rules designed to prevent dangerous industrial collusion hamper this type of facilitated market solution. Having helped solve various other types of problems, facilitated market solutions offer a useful and immensely potent way to address regulatory problems going forward if the rules constraining them are reexamined. [11]

7. *Ibid*, 14.
8. Richard A. Williams and Andrew Perraut, "Facilitated Market Solutions for Social Problems," (working paper 08-31, Mercatus Center at George Mason University, August 2008).
9. *Ibid*, 2–5.
10. *Ibid*, 5–6.
11. *Ibid*, 9–10.

4. Competitors and Competition

The intent of regulation is almost always to protect consumers, society, or some other subgroup of the population from harm. However, a side effect of regulation is often that incumbent and well-connected firms use it to drive out competitors. For decades, firms have lobbied for regulations that raise competitors' costs and create an uneven playing field. They have even used antitrust regulation to prevent unwanted takeovers.[12]

Regulators then face two seemingly competing interests: consumer safety and business competition.[13] But if regulatory agencies would adopt some changes, these two interests need not remain mutually exclusive.

- Regulatory agencies should consider more market-oriented solutions (such as performance standards and economic incentives) first and command-and-control options last and perform an assessment of the effects of major regulation on competition.
- Independent regulatory agencies should be subject to a congressional oversight unit, similar to the Office of Information and Regulatory Affairs (OIRA).
- Agencies that develop voluntary standards should license the use of the agency's seal to be used on consumer products to signal approval.[14]

5. A New Regulatory Process is Born

Throughout the life cycle of the regulatory process, opportunities exist to substantially increase the net benefits of the entire system for both the near- and long-term. Starting with the strategic goals that government hopes to achieve and moving through the implementation phase, regulations evolve over time—they are constrained and shaped by this life cycle. Thus, improving the regulatory process depends substantially on understanding the steps in the process and identifying points of improvement overall.[15] Some of the proposed recommendations are:

- An agency must define at least two Government Performance Results Act (1993) performance measures when a major regulation is proposed and at least one must be related to economic performance such as cost-effectiveness or benefit-cost assessment.
- OIRA should develop and make public a report/score card that identifies the actionable elements of its guidance, rates major proposals on each item, and explains any failures or inconsistencies that are below its standard.
- At the time a regulatory proposal goes public, the agency shall create a public access, on-line, and editable (wiki) version of the regulation on which multiple parties can make edits.
- The Bureau of Economic Analysis (BEA), in conjunction with other professional organizations, should develop time-series data on actualized risks and their economic valuation—the typical subject of regulation.

12. Bruce Yandle, "Rethinking Protection of Competition and Competitors," (working paper 08-24, Mercatus Center at George Mason University, August 2008), 1–2.
13. *Ibid*, 2.
14. *Ibid*, 3.
15. Scott Farrow, "Improving the Regulatory Process Throughout its Lifecycle: Nine Recommendations to a New Administration," "(working paper 08-33, Mercatus Center at George Mason University, August 2008), 2–4.

- Regulations that impose costs of more than $100 million per year should be approved by the relevant portion of Congress.
- OMB should work with the BEA to determine whether a supplemental account to the National Income and Product Accounts can be developed for regulatory impacts, costs, benefits, and other features of regulatory impacts.[16]

A BOLD STEP FORWARD

Taken together, the papers included in this volume represent a major step forward in the way policymakers ought to think about and undertake regulation. The authors have all carefully considered existing problems as well as opportunities for productive changes in regulatory policymaking. If adopted, these proposals could lead to a regulatory regime which is uniquely adapted to the specific needs of a 21st century economy, resulting in a more dynamic American economy.

16. *Ibid*, 9–16.

PERFORMANCE ACCOUNTABILITY FOR REGULATIONS

Henry Wray

Federal rules greatly affect many components of daily life that most Americans take for granted, such as public health and safety, environmental quality, and the sound functioning of financial institutions and markets. The rules guiding behavior in these and many other areas are essential to maintaining a high standard of living in the United States, but they also impose costs on everyone that must comply with them and on the taxpayers that fund their implementation. These costs amount to about $1.1 trillion a year.

Despite the importance and expense of these rules, there is no sufficient framework to evaluate their effectiveness. Every rule should be scrutinized for the concrete benefits it produces for the public, for its relationship to the goals and mission of the issuing agency, for the meaningfulness of the standards used to measure its success, and for its performance against its regulatory goals.

The existing framework, as created through statutes and executive orders signed by the last seven presidents, has probably improved many existing rules and deterred other poorly conceived ones. However, studies by the Government Accountability Office (GAO) and others have identified important gaps and limitations in this framework. For example, the existing evaluation framework focuses primarily on the development of rules and largely overlooks their actual performance once they have been implemented. Further, where there have been retrospective reviews, agencies have conducted them sporadically, unevenly, and without sufficient transparency. Because overhauling the existing, limited review process would be time consuming, controversial, and complex, the federal government should implement an interim solution that does not require the enactment of new legislation.

An existing statute, the Government Performance and Results Act (GPRA), legislates accountability by federal agencies for the results (or lack thereof) achieved with tax dollars. The GPRA requires agencies to create comprehensive plans that include five-year goals and objectives (including outcome-related ones) and to measure and report their progress toward those goals to Congress and to the public every year. A new executive order could apply these requirements directly to important federal rules.

This paper first discusses the limitations of the existing system, then presents a framework for the new executive order. That framework includes (1) performance metrics for rules, (2) consultation with stakeholders and the Office of Management and Budget (OMB) review, (3) performance reporting, (4) guidelines for which rules would be covered, and (5) guidelines for which agencies would be covered. It then discusses how to bring a new executive order from mere implementation to actual success through two key steps: incentives to agency managers to support outcome-oriented performance measurement and accountability and ongoing stakeholder participation in the development and performance monitoring of the new goals and measures. Finally, this paper considers the likely challenges in the application of this accountability framework to the rules, offers suggestions for overcoming them, and proposes that the potential benefits of successful implementation could include a more transparent and accountable federal government, increased public confidence, and better rules that deliver superior results.

IMPROVING THE REGULATORY PROCESS THROUGHOUT ITS LIFE CYCLE: NINE RECOMMENDATIONS TO A NEW ADMINISTRATION

Scott Farrow

The procedural steps to develop the government regulations that affect what we hear over the airwaves, the cars we drive, the food we eat, and so much more are many, complex, and costly. While participants seem to agree that the regulatory process needs improvement, there is no consensus on what that means.

This paper sets out a life-cycle view of the regulatory process with suggested changes for the near and longer term. The life cycle begins with the strategic goals that government hopes to achieve, proceeds through several steps to the implementation and monitoring of a regulation, and continues to evolve over time. This paper provides nine distinct recommendations along with their purposes, backgrounds, reasons for adoption and challenges to implementation. A new administration in 2009 will have the option to change executive-branch aspects of the regulatory process and may work with Congress to improve regulation.

The five near-term and four longer-term recommendations, along with a leading reason for adopting each one, are listed below. In the text of the paper, one-page summaries of each recommendation provide more detail as well as explanations of key terms. Each recommendation is relatively high level and could have further implications for additional recommendations.

TABLE ES.1: RECOMMENDATIONS FOR IMPROVING THE REGULATORY PROCESS

RECOMMENDATION NAME	REASON FOR RECOMMENDATION
NEAR TERM	
1. Integrate Government Performance and Results Act and the regulatory process.	Establish performance criteria at the time of proposal for future evaluation of the regulation.
2. Create public scorecard of regulatory analyses.	Identify to the public and to agencies the requirements for and achievement of compliance with guidance.
3. Develop regulation-specific "wiki."	Establish an online dialogue and record of the suggested comments that may reach a community consensus.
4. Obtain performance audit guidance from the GAO.	Give responsibility for guidance to a neutral and credible source in government.
5. Establish a public financial education module.	Inspire a better-informed citizenry to participate in more actions such as regulatory comments or simply to vote.
LONGER TERM	
1. Create residual risk accounting data and reports.	Publish new information regarding what to regulate and the performance of existing regulation.
2. Require congressional approval for high-cost regulations.	Incorporate triggers for congressional review that the cost burden may be inappropriate.
3. Establish a public-private partnership to improve regulatory analysis methods.	Improve accomplishment of agency and OMB missions.
4. Integrate OMB annual regulatory reporting with National Income and Product Accounts.	Link regulatory reporting with standard economic reporting.

FACILITATED MARKET SOLUTIONS FOR SOCIAL PROBLEMS

Richard A. Williams and Andrew Perraut

Before the 20th century, private markets resolved social problems through methods such as third-party certifications and word of mouth. In the 20th century, government regulations designed to solve social problems, such as product quality, became popular; however, normal market processes are still often the most common and effective means to a solution.

There are situations, though, when government regulation is the best method for resolving social problems, such as when a firm cannot credibly signal safety or quality improvements to its products (and thereby reap the economic rewards of those improvements) or when industry standardization is needed but the transaction costs for individual firms to act are too high to drive the needed change. Without government assistance to solve such problems, entire industries can suffer.

The process of regulatory negotiation uses government agencies to bring together stakeholders to resolve a problem. Because stakeholders tend to have more information about a problem than the government, the two groups, working together, can create smarter regulations than if the government designed rules alone.

While this process sounds good in theory, in practice it has often been more burdensome than beneficial for stakeholders. The regulatory negotiation process, with its attendant bureaucracy, unnecessarily slows the resolution process. It also encourages companies to withhold crucial information in the name of protecting industry secrets because government negotiations must become public record.

To avoid the need for government intervention, companies could meet to solve such problems, but they would do so at serious risk of violating antitrust laws against collusion. A solution to these issues is nonprofit, third-party mediation firms, who specialize in solving challenging public policy problems by bringing corporate and social stakeholders together with privately negotiated solutions, or "facilitated market solutions." Unlike with regulatory negotiation, political bias does not become a factor in decision making; further, private solutions encourage a more open sharing of information, resulting in more effective solutions. Recognizing the shortcomings of its own system, even the government sometimes turns to private mediators, as it did when the Department of Health and Human Services needed to design new patient package inserts for prescription drugs.

Facilitated market solutions come at a price, however. While government regulation is already paid for with tax dollars, private negotiation must be paid for separately. As such, this process is only undertaken in situations where an impending law or regulation with a definitive time table does not seem like it will serve stakeholders' best interests or where a current problem does not seem like it can be handled effectively through the traditional avenues of legislation, regulation, and litigation.

This paper explains how the facilitated market solution process begins, who pays for the negotiation, what measures are taken to ensure that all affected parties are represented, how the process differs from regulatory negotiation, and how this method falls short. It then discusses an existing issue, that of improving health labeling on packaged food products, and how it is being handled through this process by a nonprofit intermediary (the Keystone Center).

RETHINKING PROTECTION OF COMPETITION AND COMPETITORS

Bruce Yandle

Regulation of all forms—social and economic—is a deeply engrained feature of modern life. But can the goals of regulation—for example, safer cars, cleaner air, and more dependable energy supply—be accomplished without simultaneously compromising competition in domestic and world markets? Put another way, can the protection and improvement of consumer well-being generated by competition be assured in the face of growing regulation?

There are at least two ways for an economy to reduce risks and provide environmental benefits. This can be achieved by competitive market forces where firms and organizations competing for consumer patronage struggle to provide what consumers value. Where competition is lacking, regulations that affect market outcomes can bring about improvements.

However, efforts to improve human well-being through regulation can often weaken competitive forces to the point where consumers may actually be harmed rather than protected. Expanding regulation can provide a valuable stimulus to interest groups seeking member contributions for successful efforts to gain favored government action. Regulation can also be a form of corporate welfare, with industries supporting regulations that would force out competitors or raise competitors' cost, which might in turn contribute to higher prices and lower quality of goods and services for consumers.

In the case of either interest group-driven regulation or corporate-driven regulation, an over-expansion of regulation may end up making society worse off. In many cases, consumer and environmental groups—which may not be familiar enough with the industry to understand the anti-competitive effects of a particular regulation—actually support industry positions and actions that may cause long-term difficulties for consumers.

The paper analyzes government involvement in the delicate balance between competition and regulation and offers recommendations for improvement. Focusing first on the incentives included in the various regulatory approaches that government might develop for accomplishing a given regulatory goal, this paper recommends that government always attempt to avoid specifying technology-based standards and favor instead goal-oriented rules that focus on outcomes and not on regulatory inputs.

Further, for independent regulatory agencies that operate outside the regulatory review process required of executive branch agencies, development of a regulatory review process within the Congressional Budget Office or as a separate congressional unit would close the regulatory review circle and raise the accountability of independent agencies to the public they seek to serve. When agencies decide to act, whether in issuing new rules or enforcing old ones, regulators should assess the costs and benefits of the action, taking into account the effects of the action on competition in the marketplace. In the global marketplace, clearing houses, conferences, and nongovernmental agencies are crucial in improving quality assurance and providing consumer protection.

Competition among firms, governments, and government agencies can improve human well-being, but regulatory actions taken to address important problems consumers face either can strengthen or weaken vital competitive forces. When agencies consider regulation, they should give critical attention to whether the benefits of regulation will be large enough to offset any anti-competitive effects such regulations may generate.

LESSONS FOR NEW TECHNOLOGIES

Gary E. Marchant

Emerging technologies such as biotechnology, nanotechnology, and several others have the potential to provide enormous economic, environmental, and health benefits. Yet, the discriminatory treatment and stigmatization of these technologies by regulators, sensationalized media coverage, and activist campaigns are blocking or restricting these benefits.

This paper considers the short history of such technologies—in particular the technologies of genetically modified foods, nanotechnology, and food irradiation—and the regulatory pressures placed upon them. It concludes that the exotic nature of these emerging technologies, media sensationalism, and activist campaigns create "risk cascades" that sensationalize and amplify the risk of some technologies to the point of stigmatization. Such stigmatization results in regulatory double standards that are unfair to the developers of beneficial new technologies and detrimental to public health and welfare.

Legislators and regulators should address this problem of discriminatory and undue regulation of beneficial emerging technologies. They need to resist pressure to adopt premature and unwarranted regulatory requirements based on stigma and emotion and instead pursue scientifically based risk assessment and weighing of costs and benefits of regulatory action. To that end, three specific policy options should be pursued: (1) reject the precautionary principle; (2) establish the principle of non-discriminatory treatment in U.S. law; and (3) create a voluntary health and safety certification program.

PERFORMANCE ACCOUNTABILITY FOR REGULATIONS

Henry Wray

INTRODUCTION

Regulation plays a vital role in the way the federal government carries out its functions. Federal rules are a key tool for implementing many important governmental policies that directly affect the lives of all people living in the United States in such areas as public health and safety, environmental quality, and the sound functioning of financial institutions and markets. At the same time, federal rules impose heavy costs and burdens on businesses and other organizations, state and local governments, individual citizens, and the economy as a whole. Because of both their importance and their cost, it is essential that these rules be effective. Regulators also must adhere to their statutory mandates and avoid "mission creep" by exceeding their authority in response to the myriad pressures they face, externally and internally.

Given the importance of regulation, federal policy makers and the public need to understand whether federal rules comply with statutory intent and how well they are performing in order to assess whether they should be continued or modified, or whether alternative approaches should be considered. Specifically, the following core performance-assessment questions must be answered:

- What outcomes that produce concrete benefits for the public does the rule seek to achieve?
- How does the rule comport with and advance the statutory mission and strategic goals of the agency that issued it?
- How does the agency measure the rule's success in achieving its intended outcomes?
- Once implemented, how well does the rule perform against its goals and measures?

Current regulatory reform statutes and executive orders do not provide a comprehensive and consistent means to answer these questions. The federal government needs a systematic, outcome-oriented assessment framework. This paper (1) examines several statutory and executive-order provisions enacted to improve the regulatory process, (2) offers a proposal for a new assessment framework, (3) articulates how this proposal will improve the process, and (4) makes recommendations for its implementation.

1. STATEMENT OF THE PROBLEM

The existing statutory and executive order provisions for regulatory oversight are plentiful, but they are not well-suited to provide for the systematic, outcome-oriented assessment of regulatory effectiveness. Indeed, they were developed in a piecemeal way and probably were not designed with this overall purpose in mind. Considering the pervasive importance and impact of federal rules, *there is a critical need to assess a rule's effectiveness and to hold the issuing agency accountable for how well it achieves its intended purpose.*

Leading federal agencies affirm the need for such assessments. The Office of Management and Budget (OMB) has observed that federal rules, like other tools of government policy, carry great potential for both good and harm. A well-designed rule can advance important public benefits; a poorly designed rule can produce excessive compliance costs and burdens, harm the economy, and divert attention from potentially better solutions to the problem it seeks to address.[1] The Government Accountability Office (GAO) asserts that a thorough review of the regulatory process is particularly timely now because of the long-term fiscal imbalance facing the United States. The GAO regards a broad reexamination of federal regulation as a first step in the long-term effort to transform what the federal government does and how it does it.[2]

1. Office of Management and Budget, Office of Information and Regulatory Affairs, *Report to Congress on the Costs and Benefits of Federal Regulations* (Washington, DC: Sept. 30, 1997), 10, http://www.whitehouse.gov/omb/inforeg/rcongress.html.
2. U.S. Government Accountability Office, *Regulatory Reform: Prior Reviews of Federal Regulatory Process Initiatives Reveal Opportunities for Improvements*, GAO-05-939T (Washington, DC: July 27, 2005), 11.

The enormous economic impact of federal rules reinforces the need for effectiveness assessments. One estimate places the aggregate cost to comply with federal rules at *$1.1 trillion annually*.[3] Other measures confirm the magnitude of federal regulation. The GAO reports that from March 29, 1996 through October 30, 2007, federal agencies submitted over 46,000 rules to Congress and the GAO pursuant to the Congressional Review Act, described hereafter.[4] Of these, 703 were so-called "major" rules having an annual impact on the economy of $100 million or more or producing other significant effects. According to a recent analysis, the president's fiscal year 2009 budget proposed $51.1 billion in spending on regulatory activities carried out by over 260,000 full-time federal employees.[5]

2. BACKGROUND ON THE NEED FOR CHANGE

2:A. Statutory and Executive Order Provisions for Regulatory Oversight

In recent decades, Congress and presidents of both parties have devoted considerable effort to scrutinizing federal rules. Major "regulatory reform" statutes enacted over this period include the Paperwork Reduction Act, the Regulatory Flexibility Act, the Unfunded Mandates Reform Act, and the Congressional Review Act. In addition to such statutory requirements, all presidents from Richard Nixon to George W. Bush imposed mandates for federal agencies to analyze the costs (in the beginning) and benefits (later on) of their rules. From the Reagan administration on, these mandates have been embodied in executive orders and implemented by the OMB's Office of Information and Regulatory Affairs (OIRA). The version now in effect is Executive Order 12866, originally issued by President Clinton in 1993 and revised by President Bush in 2002 and 2007. Appendix I provides a brief overview of these statutes and executive orders.[6]

2:B. Gaps and Limitations of Existing Provisions

The current statutory and executive order requirements undoubtedly bring more rigorous analysis to rulemaking. Presumably, many rules have been improved as a result of them, and their very existence probably serves to deter some ill-considered regulatory proposals that could not withstand the scrutiny they provide. However, a number of studies by the GAO and others have pointed out their gaps and limitations.

One major limitation is that the requirements focus primarily on the development of rules at the front end rather than on their actual performance once they take effect. While the Regulatory Flexibility Act and Executive Order 12866 address reviews of existing rules to some extent, their core regulatory analysis requirements target the development of new rules. The Unfunded Mandates Reform Act applies exclusively to the development of new rules.[7]

3. Jerry Brito and Jerry Ellig, "A Tale of Two Commissions: Net Neutrality and Regulatory Analysis," *CommLaw Conspectus* 16, no. 16 (2007): 8, see note 34, referring to the oft-cited study by W. Mark Crain, U.S. Small Business Administration, *The Impact of Regulatory Costs on Small Firms* (2005).

4. U.S. Government Accountability Office, *Congressional Review Act*, GAO-08-268T (Washington, DC: Nov. 6, 2007), 2.

5. See Veronique de Rugy and Melinda Warren, *Regulatory Agency Spending Reaches New Height: An Analysis of the U.S. Budget for Fiscal Years 2008 and 2009* (Arlington, VA: Mercatus Center at George Mason University, August 2008), 1.

6. For more on the evolution of the regulatory analysis requirements, see Brito and Ellig, "A Tale of Two Commissions," 7–14, and John D. Graham et al., "Managing the Regulatory State: The Experience of the Bush Administration," *Fordham Urban Law Journal* 33, no. 953 (2006), 955–965.

7. Even within the context of rule development, application of some requirements is limited. As the GAO noted in recent congressional testimony, the regulatory analysis provisions of the Unfunded Mandates Reform Act and the Regulatory Flexibility Act apply only to rules developed through the notice-and-comment proposed rulemaking provisions of the Administrative Procedure Act, *U.S Code* 5 (1946), § 553. The testimony further observed that it is common for agencies to issue "direct" and "interim" final rules without going through the proposed rulemaking process. U.S. Government Accountability Office, *Federal Rulemaking: Past Reviews and Emerging Trends Suggest Issues That Merit Congressional Attention*, GAO-06-228T (Nov. 1, 2005), 9–10.

The regulatory analyses required by the statutes and by Executive Order 12866, including cost-benefit calculations and other assessments of anticipated effects, are necessarily based on assumptions made at the time a proposed rule is being developed. These assumptions, of course, may or may not prove accurate once the rule is implemented. For this and other reasons, the analyses are subject to considerable technical debate over their methodologies as well as broader controversy over their fundamental credibility and value.[8]

Scope limitations also impact the statutes and executive orders. Both the Unfunded Mandates Reform Act and the principal regulatory analysis features of Executive Order 12866 exclude a major source of rules: those issued by "independent regulatory agencies."[9] Also, their key requirements are restricted to rules having an annual economic impact of $100 million or more or other significant economic effects. For example, the GAO identified fourteen definitional restrictions in the Unfunded Mandates Reform Act that severely limit its application.[10]

Another problem is ambiguity. For example, the Regulatory Flexibility Act does not apply to a rule if the issuing agency certifies that the rule will not have a "significant economic impact on a substantial number of small entities." However, the failure of the act to define the term "significant economic impact" has led to differing interpretations and inconsistent application across agencies.[11]

The provisions of the statutes and executive orders that require or at least encourage retrospective reviews of existing rules also have their limitations. In particular, they have been applied sporadically and unevenly by the agencies. Last year, the GAO reported on the results of a comprehensive study of retrospective reviews.[12] The GAO study covered agency reviews of existing rules pursuant to section 610 of the Regulatory Flex-

8. See, for example, U.S. General Accounting Office, *Regulatory Reform* (assessments often incomplete, inconsistent with general economic principles, and based on different assumptions for the same key economic variables; concerns expressed about the accuracy and completeness of agency cost estimates); Alan Carlin, "The New Challenge to Cost-Benefit Analysis," *Regulation* 18, no. 20 (2005); Robert W. Hahn and Patrick Dudley, "How Well Does the Government Do Cost-Benefit Analysis?" (working paper 04-01, AEI-Brookings Joint Center for Regulatory Studies, revised April 2005), 11 (finding that the quality of regulatory impact analyses varies within and across administrations and is generally low); Robert W. Hahn and Erin M. Layburn, "Tracking the Value of Regulation," *Regulation* 23, no. 3 (2003): 16–17 (observing that the OMB does not provide independent assessments of the quality of agency regulatory impact analysis submissions); and Robert W. Hahn and Cass R. Sunstein, "A New Executive Order for Improving Federal Regulation? Deeper and Wider Cost-Benefit Analysis," *University of Pennsylvania Law Review* 150, no. 5 (2002): 1492–93 (suggesting that the Executive Order 12866 regulatory impact analyses "have had little impact on what agencies actually do"). On the other hand, the former administrator of OIRA maintains that regulatory impact analyses have improved in recent years. John D. Graham et al., "Managing the Regulatory State: The Experience of the Bush Administration," *Fordham Urban Law Journal* 33, no. 4 (2006). See also the working paper by Richard Williams, "The Influence of Regulatory Economists in Federal Health and Safety Agencies" (working paper, Mercatus Center at George Mason University, May 2008).

9. The act defines "independent regulatory agencies" to mean the Board of Governors of the Federal Reserve System, the Commodity Futures Trading Commission, the Consumer Product Safety Commission, the Federal Communications Commission, the Federal Deposit Insurance Corporation, the Federal Energy Regulatory Commission, the Federal Housing Finance Board, the Federal Maritime Commission, the Federal Trade Commission, the Interstate Commerce Commission, the Mine Enforcement Safety and Health Review Commission, the National Labor Relations Board, the Nuclear Regulatory Commission, the Occupational Safety and Health Review Commission, the Postal Regulatory Commission, the Securities and Exchange Commission, and any other similar agency designated by statute as a federal independent regulatory agency or commission. *U.S. Code* 44, § 3502(5).

10. U.S. General Accounting Office, *Regulatory Reform*, 5. A more detailed GAO report on this subject describes the various exceptions, which include rules that enforce constitutional or civil rights, rules necessary for "national security," rules relating to "emergencies" designated by the president and Congress, and rules that do not result in annual "expenditures" (as opposed to "costs") of $100 million or more. See U.S. General Accounting Office, *Unfunded Mandates: Analysis of Reform Act Coverage*, GAO-04-637 (May 2004), 13–14 and 26–27.

11. Brito and Ellig, "A Tale of Two Commissions," 7–14; Graham et al., "Managing the Regulatory State," 955–965.

12. U.S. Government Accountability Office, *Reexamining Regulations: Opportunities Exist to Improve Effectiveness and Transparency of Retrospective Reviews*, GAO-07-791 (July 2007).

ibility Act, Executive Order 12866, and agency-specific statutes such as the Clean Air Act. The GAO found wide variation among agencies in how they conducted their retrospective reviews and the manner in which they reported on them. According to the GAO, agencies performed certain required reviews infrequently.[13] The mandatory reviews the agencies did conduct had little impact since they usually concluded that no changes were needed.[14]

Another problem the GAO highlighted was the lack of transparency in agency reviews and reporting practices; nonfederal parties told the GAO that they were rarely aware of the reviews.[15] Still another problem was that agencies said they lacked the data necessary to conduct effective reviews.[16] As the GAO noted, other studies have likewise identified problems limiting the effectiveness of retrospective reviews.[17]

The GAO offered a series of recommendations to improve retrospective reviews, including the following:

- When developing new rules, agencies should consider how they will measure the performance of the rule and what data they will need for this purpose.
- The transparency of reviews should be enhanced by developing mechanisms to communicate review results to the public.
- Agency managers should give sustained attention to supporting and improving regulatory reviews.
- OIRA and regulatory agencies should identify opportunities for Congress to revise the timing and scope of existing review requirements and perhaps consolidate such requirements.[18]

Looking more generally at the regulatory reform statutes and executive orders, the GAO suggested two avenues to make them more effective. One was to "broadly revisit the procedures, definitions, exemptions, and other provisions of existing initiatives to determine whether changes are needed to better achieve their goals." The other was to put more emphasis on evaluations of existing rules, using lessons learned from such evaluations "to keep the regulatory process focused on results and inform future action to meet emerging challenges."[19]

3. A NEW APPROACH AND HOW IT CAN HELP

The studies described above indicate that the current regulatory reform statutes need a general overhaul. This general revision could incorporate a statutory process to ensure outcome-oriented performance measurement and accountability for individual rules. However, revising the current statutes will be a complex, controversial, and time-consuming undertaking. In the interim, an alternative approach could be implemented in far less time that offers great potential to enhance regulatory accountability and effectiveness. This approach does not require the enactment of new legislation. Rather, it takes advantage of a law already on the statute books, albeit one that tends to be overlooked as a tool for regulatory reform: the Government Performance and Results Act of 1993 (GPRA). [20]

13. Brito and Ellig, "A Tale of Two Commissions," 7–14; Graham et al., "Managing the Regulatory State," 955–965.
14. Ibid.
15. U.S. General Accounting Office, *Federal Rulemaking*, 9–10.
16. Ibid. Agency officials also asserted that they had insufficient time and staff resources to devote to the reviews and complained of overlapping and duplicative review requirements.
17. See Brito and Ellig, "A Tale of Two Commissions," note 26. See also Congressional Research Service Report for Congress, *Reexamining Rules: Section 610 of the Regulatory Flexibility Act*, RL 32801 (Jan. 14, 2008), and studies cited.
18. U.S. Government Accountability Office, *Reexamining Regulations*, 53–54.
19. U.S. Government Accountability Office, *Regulatory Reform*, "Highlights" page.
20. Public Law no. 103-62, *U.S. Statutes at Large* 107 (August 3, 1993),§ 285.

As its name suggests, the GPRA was designed to shift the focus of federal performance management and accountability from process to results. Rather than measuring success by activities and outputs (e.g., number of rules issued or inspections conducted), the act sought to emphasize the outcomes resulting from these activities and outputs (e.g., safer workplaces and healthier food). The late Senator William Roth, principal sponsor of the GPRA, observed during Senate debate that the legislation represented a fundamental reform in the way the federal government does business, bringing about a new form of accountability to American taxpayers: accountability by federal agencies for the results they achieve when they spend tax dollars.[21]

The act's findings and purposes section noted that federal program managers were "seriously disadvantaged in their efforts to improve program efficiency and effectiveness, because of insufficient articulation of program goals and inadequate information on program performance" and that "congressional policymaking, spending decisions, and program oversight are seriously handicapped by insufficient attention to program performance and results."[22] To address these shortcomings, the act was intended to accomplish four main goals:

- systematically hold federal agencies accountable for achieving program results
- improve program effectiveness and accountability by promoting a new focus on results
- help federal managers improve service delivery by requiring them to plan for meeting program objectives and by providing them with information about program results
- improve congressional decision making by providing more objective information on achieving statutory objectives and on the relative effectiveness and efficiency of federal programs and spending

The GPRA covers virtually all executive-branch departments and agencies, including independent regulatory agencies, and thus reaches the full range of agencies having significant regulatory functions.[23] It requires each agency to develop a comprehensive mission statement along with long-term (five-year) strategic goals and objectives, including outcome-related goals and objectives, covering the agency's major functions and operations.[24] Agencies must also prepare annual performance plans containing goals and measures for each of their program activities, which must include indicators assessing outcomes.[25] Finally, agencies must report to Congress and to the public annually on their performance results against these goals and measures.[26]

The GPRA operates at a higher level than individual rules, focusing on federal departments and agencies as a whole.[27] However, the act's analytic framework, along with its established reporting mechanism, is well-suited to assessing and tracking the effectiveness of federal program activities at virtually any unit of analysis. As described above, the GPRA has three core elements:

21. Congressional Record 139 § 13833 (1993). Senate Report no. 103-58 (June 16, 1993) and House Report no. 103-106 (May 25, 1993) provide additional legislative history on GPRA.
22. GPRA, Section 2, Statute 107 § 285.
23. See *U.S. Code* 5 § 306(f).
24. *U.S. Code* 5 § 306(a) and (b).
25. *U.S. Code* 31 § 1115(a). The act defines "outcome measure" as "an assessment of the results of a program activity compared to its intended purpose." *U.S. Code* 31 § 1115(f)(2).
26. See generally *U.S. Code* 31 § 1116.
27. For this reason a regulatory agency's GPRA plans and reports do not now contain the detailed information needed to assess the performance effectiveness of individual rules, although they would be relevant. In particular, the agency's GPRA strategic plan would provide the source for determining whether an individual rule supported the agency's overall mission and strategic goals.

- one or more long-term goals for the unit of analysis, expressed as measurable outcomes that clearly identify the intended public benefits
- annual performance measures that provide a valid and verifiable basis for tracking progress toward long-term goals
- annual reports on performance results against the goals and measures for the applicable year

In order to be valid, a performance measure must credibly link the actual impact of the unit of analysis (for example, a rule) to the intended outcome, so as to establish cause and effect. In the regulatory context, this is one reason why retrospective analysis of the performance of rules is so important. Developing credible outcome-oriented performance metrics is certainly challenging. However, as illustrated by the specific examples taken from federal agency performance reports listed in appendix II, it can be done.

The OMB's Performance Assessment Rating Tool (PART) illustrates how the GPRA framework can be adapted to individual federal programs and activities. PART rates the effectiveness of specific federal programs, including regulatory programs, using standard sets of questions:[28]

- Does the program have a limited number of specific, long-term performance measures that focus on outcomes and meaningfully reflect the purpose of the program?
- Does the program have ambitious targets and time frames for its long-term measures?
- Does the program have a limited number of specific annual performance measures that demonstrate progress toward achieving the program's long-term measures?
- Does the program have baselines, ambitious targets, and time frames for its annual measures?

Both the GPRA and PART tend to be viewed primarily as tools for performance budgeting. Neither has achieved much success in this arena so far, largely because congressional appropriators have yet to take an interest in outcome-oriented performance information.[29] However, outcome-oriented performance management and accountability principles have applications well beyond budgeting and appropriations. They should prove particularly useful in the context of federal rules, which are already subject to extensive scrutiny and where there is no shortage of interested parties eager to engage on a wide range of performance-effectiveness issues.

28. For background on PART, including its assessment criteria and specific program assessments, see http://www.whitehouse.gov/omb/part. For additional background, see Eileen Norcross and Joseph Adamson, *An Analysis of the Office of Management and Budget's Program Assessment Rating Tool (PART) for Fiscal Year 2008* (Arlington, VA: Mercatus Center at George Mason University, 2007); John B. Gilmour, *Implementing OMB's Program Assessment Rating Tool (PART): Meeting the Challenges of Integrating Budget and Performance* (Washington, D.C.: IBM Center for the Business of Government, 2006).

29. See, e.g., Maurice McTigue, Henry Wray, and Jerry Ellig, *8th Annual Performance Report Scorecard: Which Agencies Best Inform the Public?* (Arlington, VA: Mercatus Center, 2007), 28: "[M]any congressional oversight and appropriations committees have shown scant interest in using . . . performance information to make decisions on program design and budgeting. Republicans and Democrats, liberals and conservatives, might rightfully disagree based on values, priorities, or honestly different assessments of whether particular results are worth the cost. But surely they could muster a bipartisan consensus to examine the performance information before they decide." See also Office of Management and Budget, *Budget of the United States Government, Fiscal Year 2009, Analytical Perspectives* (February 2008), 14, noting that congressional use of PART information "has been limited." A similar problem exists at the state level, according to a recent "report card" by the Pew Center on the States' Government Performance Project. While strategic planning and developing results-oriented performance information have become a routine and accepted part of governing, "[o]ne of the biggest obstacles to progress in managing for performance is the disconnect between the production of performance information and its use in the budgeting process, particularly by legislators." Katherine Barrett and Richard Greene, "Measuring Performance: The State Management Report Card for 2008," *Governing* (March 2008): 26–27. On a positive note, the report, at page 28, predicts, "Nobody expects a legislative turnaround to happen soon or without snags. But it will come."

4. RECOMMENDED NEAR-TERM SOLUTION

The initial and immediately actionable way to adapt the GPRA framework to federal rules is through the issuance of a new executive order. Specifically, the executive order should require that (1) those individual rules intended to achieve significant public benefits incorporate GPRA-type, outcome-oriented performance metrics and (2) performance against these metrics be systematically tracked and reported using GPRA annual performance reports.[30]

4:A. Proposed Executive Order

The key elements of the proposed executive order are as follows:

1. **Performance metrics for rules.** The executive order should require agencies to develop for each of their covered rules (see below) the following performance metrics:

- one or more long-term performance goals that clearly specify the outcome(s) the rule is designed to achieve in terms of measurable public benefits
- a concise explanation of how the rule's goals advance the issuing agency's mission and strategic goals as set forth in its GPRA strategic plan
- a benefit analysis presenting evidence that the rule is likely to create the intended outcomes, accompanied by quantification, where possible, of the rule's likely effect on the performance goal
- annual performance measures that provide valid and verifiable indicators of progress toward achieving the rule's long-term goals

2. **Consultation with stakeholders and OMB review.** Agencies would consult with their stakeholders in developing draft performance metrics for a covered rule. Such consultation should of course be part of, but not limited to, notice-and-comment rulemaking processes. At a minimum, the agency would be required to make the proposed goals and measures publicly available when drafted and to invite public participation in reviewing and finalizing them. The agency also would be required to provide the proposed goals and measures to the OMB for review. The OMB's reviews would focus primarily on (1) whether the proposed goals were expressed as measurable outcomes and (2) whether the annual measures were valid and verifiable indicators of progress toward the outcome goals. The OMB would not be expected to substitute its judgment for the agency's concerning the substantive merits of the goals and measures. Rather, its role would be to ensure that the goals were appropriately outcome oriented and subject to credible measurement.[31] The OMB would approve the proposed goals and measures under these criteria or return them to the agency for further consideration. The goals and measures would be finalized through a transparent process involving the agency's stakeholders.

3. **Performance reporting.** Once rules were finalized, the issuing agency would report performance results for them each year as part of its annual GPRA performance reports. As is the case for other GPRA goals and measures, the agency's reports would explain any performance shortfalls affecting covered rules and describe improvement strategies. The goals and measures for rules would be subject to adjustment from time to time, as are other GPRA goals and measures.

30. A similar system was recommended in 2005 by the GAO in the report, U.S. General Accounting Office: *Economic Performance: Highlights of a Workshop on Economic Performance Measures*, GAO-05-796SP, July 2005. The report was more of a cost-benefit analysis to evaluate overall government programs rather than what is suggested in this paper—tying individual regulations to mission goals.
31. Ideally, specific and measurable outcome goals would be set forth in authorizing legislation as well.

4. **Rules covered.** The ultimate objective of the executive order would be to cover all new rules that lend themselves to outcome-oriented performance measurement and accountability and that are significant enough (i.e., have a substantive effect on achieving important public benefits) to justify it.[32] This would be a larger universe than those rules that satisfy the current definition of "economically significant" (i.e., rules with an annual economic impact of $100 million or more). Many rules would not qualify, such as those dealing with internal agency practice and procedures. The OMB should be responsible for determining, in consultation with agencies and stakeholders, the rules to be covered. It could start by tasking the agencies, in consultation with their stakeholders, to develop and submit to the OMB recommendations on which rules should be covered. Given the implementation challenges (discussed later), it would be best to begin with a pilot approach targeting a limited number of representative rules from a range of agencies. The rules initially selected should be the best candidates for testing the executive order's concepts and implementation techniques and thereby developing best practices for general application.

5. **Agencies covered.** The executive order should cover all agencies with significant regulatory responsibilities, including independent regulatory agencies. The OMB generally does not review independent regulatory agency rules. However, independent regulatory agencies are fully subject to the GPRA, and the rationale for the executive order proposed here applies equally to them. Omitting the independent regulatory agencies would create a serious gap. Moreover, the limited nature of the OMB's reviews would not impinge upon their independence. In this context, the OMB's responsibility would be to ensure that the agency has adopted valid and verifiable performance metrics to support a rule's intended outcomes—not to second guess whether those outcomes should be pursued or whether the rule should be issued. Any possible concern in this regard, however, could be eliminated by incorporating into the executive order an escape clause modeled on the Paperwork Reduction Act, which permits an independent regulatory agency to override a negative response from the OMB by a majority vote of its members.[33]

4:B. Key Implementation Steps

Simply issuing an executive order along the foregoing lines will not guarantee success. Rather, success in bringing about effective performance measurement and accountability for rules will turn on two key implementation steps.

1. **Agency incentives.** The executive order must be accompanied by agency personnel practices (including Senior Executive Service contracts and bonuses) that provide the agency's managers with incentives to support outcome-oriented performance measurement and accountability. Research shows that high-performing, public-sector organizations create a clear "line of sight" between individual performance and organizational success and that they link individual performance expectations and rewards to agency missions, strategic goals, and results.[34] Individual managers cannot be held directly account-

32. Existing rules could be phased into this process to the extent practical.
33. See *Public Information Collection Activities*, *U.S. Code* 44, § 3507(f).

able for mission outcomes that are beyond their control. However, performance within the scope of their responsibilities should directly align with and support the accomplishment of mission outcomes:

- Performance expectations, assessments, and rewards for agency managers who are responsible for developing and implementing outcome-oriented performance metrics for rules should take into account (1) the quality of the goals and measures they produce, (2) the accuracy of performance reporting, and (3) the actions they take in response to reported performance results.
- Performance expectations and rewards for agency managers of regulatory programs should also be aligned with and structured to achieve the substantive outcome goals and measures to the greatest extent consistent with their individual responsibilities.

2. **Ongoing stakeholder participation.** It is essential that agency stakeholders actively develop the goals and measures as well as monitor reported performance results. Agencies should affirmatively encourage and facilitate stakeholder participation at each stage of the process. Active engagement from a range of stakeholders with contrasting viewpoints will be particularly valuable in the case of controversial and highly contested rules. Stakeholders also should pay close attention to the results and related analyses provided by agencies in their annual GPRA performance reports. The GPRA has yet to achieve its potential in the budget arena largely due to the failure of Congress to engage in this process. By contrast, the regulatory arena already is populated by many intensely interested stakeholders with diverse viewpoints who already engage in vigorous debate over the merits of federal rules. Presumably, they will prove more than willing to take advantage of new tools that offer the opportunity to enhance the quality of debate through the infusion of outcome-oriented, fact-based performance data.

4:C. Application and Overcoming Challenges

Bringing outcome-oriented performance management to federal rules will take patience and thoughtfulness. The Mercatus Center has evaluated and issued "scorecards" for the GPRA performance reports of cabinet departments and major agencies for each year since the first reporting cycle was completed in fiscal year 1999. As the most recent Mercatus scorecard notes, the average scores for the reports have increased since 1999, albeit gradually and with occasional slippage from year to year.[35] The scorecard evaluations confirm that most federal agencies face conceptual and practical challenges when it comes to devising and implementing outcome-oriented performance metrics. These challenges will carry over into the regulatory arena. If they are to be overcome, the good cannot become the enemy of the perfect. Developing meaningful, outcome-oriented goals and measures will necessarily proceed incrementally, often by trial and error.

Agencies should be able to clearly articulate the intended long-term results a rule seeks to achieve and how those results advance the agency mission and strategic goals. Thus, developing outcome goals for

34. The GAO's considerable work in this area documents the importance of these principles. See generally: U.S. General Accounting Office: *Results-Oriented Cultures: Creating a Clear Linkage between Individual Performance and Organizational Success*, GAO-03-488 (March 2003); U.S. General Accounting Office, *Results-Oriented Cultures: Insights for U.S. Agencies from Other Countries' Performance Management Initiatives*, GAO-02-862 (August 2002); U.S. General Accounting Office, *Managing for Results: Emerging Benefits From Selected Agencies' Use of Performance Agreements*, GAO-01-115 (October 2000); U.S. General Accounting Office, *Human Capital: A Self-Assessment Checklist for Agency Leaders*, GAO/OCG-00-14G (September 2000).

35. McTigue, Wray, and Ellig, *9th Annual Performance Report Scorecard*. Indeed, this most recent year was one of retrenchment.

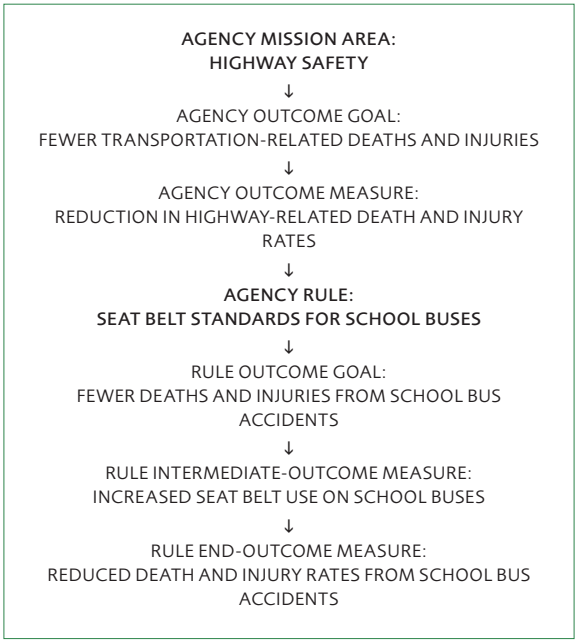
rules should not be problematic. The proposal envisions goals that are expressed as tangible and measurable results—not abstract rhetorical assertions of the public interest that sometimes pass for statements of purpose. A far greater challenge is to convert those results into specific performance measures that are valid (i.e., relevant to rule's goals and attributable to its effects) and verifiable (i.e., capable of documentation through credible data).

Not all measures can be expressed as end outcomes. So-called intermediate-outcome measures and other measures that logically indicate progress toward the end outcome are useful and often essential. For example, the end outcome of healthier air might be subject to intermediate-outcome measures expressed as annual reductions in harmful emissions. Also, given the many external factors that come into play, it is often difficult to attribute outcomes to federal actions. Agencies should, however, be able to identify links between their actions and social outcomes and maximize their ability to achieve those outcomes through such tools as influence diagrams. These diagrams include all other entities and actions that play a role in the final desirable outcome.

Agencies and their managers must be encouraged to be innovative, take reasonable risks, and, most of all, be candid. The worst approach is to create perverse incentives that inhibit these qualities and instead encourage "gaming" the system by setting nonchallenging goals and measures that may be easily documented and achieved but have little bearing on outcomes. In this regard, the scorecard work shows that agency performance reports indicating perfect or near-perfect performance are cause for skepticism rather than celebration. They usually signify that the goals and measures were not challenging, that the reporting was not candid, or both.

Figure 1 provides a hypothetical example of what the performance metrics for a rule might look like. Figure 2 gives examples of actual performance goals and measures for federal regulatory programs.[36] While not broken down to specific rules, they illustrate the kinds of goals and measures that could be applied to rules.

FIGURE 1



5. CONCLUSION

The conclusions of this paper may be summarized as follows:

- As key tools of federal policy implementation that impose major economic impacts, federal rules need to be mission related, effective, and accountable for their results.
- Current regulatory reform statutes and executive orders do not provide for the comprehensive performance assessment of federal rules.
- The GPRA provides a framework for articulating and measuring regulatory outcomes and for holding rules accountable for those outcomes.

36. The examples are taken from PART assessments published on the OMB's web site, http://www.expectmore.gov.

- An executive order should be issued requiring GPRA-type, outcome-oriented performance goals and measures for rules with significant public policy objectives.
- The success of the executive order will depend upon holding federal regulatory officials accountable for its effective implementation and actively engaging agency stakeholders in the development of performance metrics as well as the assessment of performance results.

While the implementation challenges are considerable, so too are the potential benefits. In the near term, federal regulation should become more transparent and accountable, thereby enhancing public confidence. Also, the information developed should improve the quality of prospective and retrospective reviews of rules under the current regulatory reform processes. The most important longer-term benefit will be more effective rules that deliver better performance results for the public in terms of enhanced health, safety, security, economic well-being, and the other important public outcomes that the rules and their issuing agencies exist to serve.

APPENDIX I
Overview of Major Regulatory Reform Statutes and Executive Orders

The Paperwork Reduction Act[37] requires agencies to provide advance public notice and to obtain OMB approval for rules that involve the collection of information (including recordkeeping requirements) from ten or more nonfederal persons. The act applies to virtually all executive-branch agencies with regulatory responsibilities, including the so-called "independent

FIGURE 2

AGENCY/ PROGRAM	STRATEGIC OUTCOME GOAL	ANNUAL PERFORMANCE GOALS/MEASURES
Agriculture Department: food safety and inspection	Reduction in the prevalence of foodborne illnesses from meat, poultry, and egg products	Prevalence of salmonella on raw meat and poultry products (annual targets expressed as percentage reductions) Percentage of ready-to-eat meat and poultry products testing positive for listeria bacteria (annual targets expressed as percentage reductions)
Transportation Department: Railroad Safety Program	Reduction in transportation-related deaths and injuries	Fewer rail-related accidents and incidents per million train-miles Fewer grade-crossing incidents per million train-miles Fewer train accidents per million train-miles, broken down by cause: human factors, track, and equipment
Treasury Department: national bank supervision	Percentage of national banks with high ratings according to industry standards	Percentage of problem banks rehabilitated, as measured by industry standards (annual targets expressed as percentage of such banks) Percentage of banks that are well capitalized (annual targets expressed as percentage of such banks)

37. The act was originally enacted in 1980 and is codified as amended at *U.S. Code* 44 § 3501–3520. For additional background on the act, see Jeffrey S. Lubbers, "Paperwork Redux: The (Stronger) Paperwork Reduction Act of 1995," *Administrative Law Review* 49 (1997): 111.

regulatory agencies."[38] However, the act contains an escape clause permitting an independent regulatory agency to override the OMB's disapproval of an information collection by majority vote of its members.[39] The act also created the Office of Information and Regulatory Affairs (OIRA) within the OMB.

The Regulatory Flexibility Act[40] requires agencies to conduct a "regulatory flexibility analysis" of proposed rules that have a significant economic impact on a substantial number of small entities, including small businesses as well as small governmental units and not-for-profit organizations. The analyses must consider, among other things, alternative ways of accomplishing the objectives of the rule in a way that would minimize its impact on small entities. Also, section 610 of the act[41] requires agencies to review within ten years existing rules that have a significant impact on small entities to determine whether they should be continued or altered so as to minimize their impacts. This act was amended in 1996 by the Small Business Regulatory Enforcement and Fairness Act, which added, among other things, the ability of affected small entities to pursue legal challenges to various provisions of the act.

Title II of the Unfunded Mandates Reform Act of 1995[42] requires agencies to prepare a "qualitative and quantitative assessment of the costs and anticipated benefits" of proposed rules containing federal mandates that impose annual costs exceeding $100 million on state, local, or tribal governments or on the private sector.[43] The act does not apply to independent regulatory agencies.[44]

The Congressional Review Act[45] requires agencies to submit reports on new rules to Congress and to the GAO. The reports to the GAO must include, among other things, a copy of any cost-benefit analysis the agency did for the rule.[46] Agencies generally must delay the effective date of "major" rules for sixty days in order to give Congress the opportunity to disapprove them by enactment of a joint resolution.[47] The act defines a "major" rule as one that will have an annual economic impact of $100 million or more or other specified economic impacts.[48]

Executive Order 12866 ("Regulatory Planning and Review") was originally issued by President Clinton in 1993 and was amended by President Bush in 2002

38. The act defines "independent regulatory agencies" to mean the Board of Governors of the Federal Reserve System, the Commodity Futures Trading Commission, the Consumer Product Safety Commission, the Federal Communications Commission, the Federal Deposit Insurance Corporation, the Federal Energy Regulatory Commission, the Federal Housing Finance Board, the Federal Maritime Commission, the Federal Trade Commission, the Interstate Commerce Commission, the Mine Enforcement Safety and Health Review Commission, the National Labor Relations Board, the Nuclear Regulatory Commission, the Occupational Safety and Health Review Commission, the Postal Regulatory Commission, the Securities and Exchange Commission, and any other similar agency designated by statute as a federal independent regulatory agency or commission. *U.S. Code* 44 § 3502(5).
39. *U.S. Code* 44 § 3507(f).
40. This act also dates from 1980. It was amended in 1996 by the Small Business Regulatory Enforcement Fairness Act and is codified as amended at *U.S. Code* 5 § 601–612.
41. *U.S. Code* 5 § 610.
42. Public Law no. 104-4, *U.S. Statutes at Large* 109 § 48 (March 22, 1995). Title II of the act is codified at *U.S. Code* 2 § 1531–1538. Title I deals with congressional legislative proposals containing unfunded mandates.
43. *U.S. Code* 2 § 1532(a).
44. *U.S. Code* 2 § 1502(1) and 658(1).
45. Public Law no. 104-121 title II, subtitle E, *U.S. Statutes at Large* 110 § 847, 868 (Mar. 29, 1996), codified at *U.S. Code* 5 § 801–808.
46. *U.S. Code* 5 § 801(a).
47. The congressional disapproval process, which is described in *U.S. Code* 5 § 802, has been invoked only once in the act's history. The joint resolution in that case disapproved an ergonomics rule submitted to Congress in the waning days of the Clinton administration; it was signed into law by President Bush shortly after he took office. See Public Law no. 107-5, *U.S. Statutes at Large* 115 § 7 (Mar. 20, 2001).
48. *U.S. Code* 5 § 804(2). The other specified impacts are "a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic and export markets."

and 2007.[49] Executive Order 12866 requires agencies to prepare and submit to OIRA regulatory impact analyses of "significant" proposed regulatory actions, which are defined to include rules likely to have an annual economic effect of $100 million or more or to "adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local, or tribal governments or communities." [50]

Among other things, the agency analysis must include the following: an assessment of the potential costs and benefits of the proposed regulatory action; an explanation of how it is consistent with a statutory mandate; and, to the extent feasible, a quantification of its anticipated costs and benefits. The executive order also requires each agency to submit to OIRA a program to review significant existing rules, "consistent with its resources and regulatory priorities."[51]

Executive Order 12866 includes provisions encouraging government-wide coordination and a federal, unified regulatory agenda. It instructs agencies to prepare an annual agenda of all rules they are considering and a regulatory plan covering the most significant regulatory actions that each agency expects to issue in a given fiscal year.[52] The plan is to include, among other things, a summary of the legal basis for the rule and a statement of the need for it. The executive order's regulatory-impact analysis requirements for significant proposed and existing rules do not apply to independent regulatory agencies. However, the independent agencies are subject to the executive order's unified regulatory agenda and regulatory planning requirements.

49. The current text of Executive Order 12866 as amended appears at *U.S. Code* 5 § 601 note. While this is the most significant executive order dealing with federal rules, a number of other executive orders apply to federal rules and regulatory activities. Examples are: Executive Order 12630 ("Government Actions and Interference with Constitutionally Protected Property Rights"), *Federal Register* 53 § 8859 (Mar. 15, 1988), *U.S. Code* 5 § 601 note; Executive Order 12988 ("Civil Justice Reform"), *Federal Register* 61 § 4729 (Feb. 7, 1996), *U.S. Code* 28 § 519 note; Executive Order 13132 ("Federalism"), *Federal Register* 64 § 43255 (Aug. 10, 1999), *U.S. Code* 5 § 601 note; and Executive Order 13272 ("Proper Consideration of Small Entities in Agency Rulemaking"), *Federal Register* 67 § 53461 (Aug. 16, 2002), *U.S. Code* 5 § 601 note.
50. See generally Executive Order 12866 § 6; the definition of "significant regulatory action" is contained in section 3(f).
51. See generally Executive Order 12866 § 5.
52. See generally Executive Order 12866 § 4.

APPENDIX II
Examples of Outcome-Oriented Goals and Measures

AGENCY	GOAL	MEASURE(S)	SOURCE
Environmental Protection Agency	Healthier outdoor air	Cumulative percentage reduction in ozone in monitored counties from 2003 baseline	FY 2007 Performance and Accountability Report (PAR), p. II–34
Department of Homeland Security	Eliminate the flow of undocumented migrants via maritime routes to the United States	Percentage of undocumented migrants who attempt to enter the United States via maritime routes that are interdicted or deterred	FY 2007 Performance Highlights, p. 14
Labor Department (Occupational Safety and Health Administration)	Improve workplace safety and health	Workplace fatalities per 100,000 workers (for sectors covered by the Occupational Safety and Health Act)	FY 2007 PAR, p. 122
Labor Department (Mine Safety and Health Administration)	Reduce mine fatalities and injuries	Mine industry fatal injury incidence rate (per 200,000 hours worked) Mine industry all-injury incidence rate (per 200,000 hours worked)	FY 2007 PAR, p. 125
Nuclear Regulatory Commission	Ensure protection of public health and safety and the environment	Number of significant adverse trends in industry safety performance with no trend exceeding Abnormal Occurrence Criterion 1.D.4	FY 2007 PAR, p. 9
Transportation Department	Reduction in transportation-related deaths and injuries	Number of fatal general aviation accidents Rail-related accidents and incidents per million train miles Transit fatalities per 100 million passenger-miles traveled	FY PAR, p. 103

IMPROVING THE REGULATORY PROCESS THROUGHOUT ITS LIFE CYCLE: Nine Recommendations to a New Administration

Scott Farrow

STATEMENT OF THE PROBLEM*

This paper identifies regulation as a governmental tool for managing risk and sets out a life-cycle view of regulation with suggested changes for the near and longer term. The life cycle of regulation begins with the establishment of strategic goals that government hopes to achieve, continues through the implementation and monitoring of a regulation, and evolves over time. In general, U.S. laws begin the process, such as by establishing standards for consumers and businesses. Some congressional laws explicitly require agencies to act in precise ways. Other laws require further agency development, resulting in enforceable federal administrative law. These laws affect what we hear over the airwaves, the planes we fly in, the cars we drive, the air we breathe, how we act in the workplace, the food we eat, the drugs we take, the companies we buy from, the sports our children play in school, and more.

The total benefits and costs of the regulatory system are considerable but uncertain. Estimates of the benefits of recent regulations far exceed their costs in aggregate.[1] One cost estimate puts the burden at about 10 percent of the economy.[2] Other cost measures are direct government administrative costs, which are relatively low at about $44 billion, but involve about 75,000 pages of *Federal Register* notices covering all areas of government.[3] However, regulatory systems are thought by many to hinder development abroad and to be a source of periodic problems domestically. Examples of recent problems include the regulatory aspects of new types of credit lending, disaster response, antiterrorism efforts, and emerging markets for new commodities such as those related to energy or the environment.

The procedural steps to develop a regulation are numerous and complex. The regulatory development and review process, which involves numerous steps and agencies, can be found in Dudley[4] (reproduced in the appendix). Dudley's account of the process follows the initiation of a regulation from the agency through over a dozen steps or decisions until the rule becomes final and the regulation has the force of law.

A new administration will have the option to change executive-branch aspects of the regulatory process and may work with Congress to improve regulation. Unfortunately, there is no agreement on what "improve" means.[5] Some participants in the policy process are focused on improving the mission outcomes of agencies—improving the efficacy of actions to reduce crime, improve health, and so on. Other participants focus on the efficiency of the actions, whether they are produced at the lowest cost or designed to balance incremental benefits and costs.

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1. U.S. Office of Management and Budget, *Annual Regulatory Reports to Congress*, multiple years, http://www.whitehouse.gov/omb/inforeg/regpol-reports_congress.html.
2. Mark W. Crain, "The Impact of Regulatory Cost on Small Firms" *Small Business Research Summary* (Small Business Administration Office of Advocacy) 264 (September 2005), http://www.sba.gov/advo/research/rs264tot.pdf.
3. Susan Dudley and Melinda Warren, "Moderating Regulatory Growth: An Analysis of the U.S. Budget for Fiscal Years 2006 and 2007" *Regulators' Budget Report* (Mercatus Center at George Mason University) 28, http://www.mercatus.org/repository/docLib/20060511_Moderating_Regulatory_Growth_An_Analysis_of_the_US_Budget_for_Fiscal_Years_2006_and_2007_Dudley_and_Warren_May_2006_Final_as_Posted.pdf.
4. Susan Dudley, *Primer on Regulation* (Arlington, VA: Mercatus Center at George Mason University, 2005), http://www.mercatus.org/publications/pubid.2331/pub_detail.asp.
5. Margot Brown, Granger Morgan, and Scott Farrow, "Expert Assessment of the Performance of the U.S. System for Environmental Regulation" *Journal of Risk Research* 7, no. 5 (2004): 507–521.

Still others focus on competing interests involving fairness across the income distribution or on race, gender, or health status. Some aspects of the regulatory process are designed to bring information on these issues to the decision maker's attention. Other laws or aspects of the regulatory process go further and identify relatively more or less weight to place on different dimensions of improvement. The author's perspective on improvement is that of a policy-oriented economist with a strong interest in efficiency. There is an element suggesting that markets and economic information, broadly conceived, are useful and important, but recognition that there are multiple perspectives on the nature of "improvement."

Noll describes an "incoherency" in regulation that is related to the challenge in identifying directions and tools for improvement.[6] He describes attempts to discipline the regulatory process as attempting to bell the political cat, as there are strong forces resisting such disciplining efforts. In 2005, the Government Accountability Office (GAO) reviewed attempts to improve the administrative law/regulatory process.[7] It concluded that attempts to reform regulation had often been less effective than anticipated due to "(1) limited scope and coverage of various requirements, (2) lack of clarity regarding key terms and definitions, (3) uneven implementation of the initiatives' requirements, and (4) a predominant focus on just one part of the regulatory process, agencies' development of rules."[8] Consequently, many of the recommendations presented here have aspects of broad scope and coverage across agencies, support the implementation of requirements, and suggest processes that clarify terms or create new information. They are also spread across a cycle of regulatory activities from conception to implementation and monitoring.

REGULATION AS A TOOL OF RISK MANAGEMENT

Regulation is one government tool for managing risk. It is well understood that government has many tools at its disposal, such as direct expenditures, taxes, encouraging voluntary actions, and coercion—perhaps mutually agreed upon—through laws and regulation. In addition, most government actions can be viewed as working to reduce risk from someone's perspective, whether a citizen, a company, an interest group, or a government. The risks may be related to such areas as health, employment, security, or finances. Increasingly, risk management through *any* of the means available to government has been viewed as a repeating cycle of activity that involves (1) a strategic choice of direction and knowledge of constraints, (2) risk assessment, (3) evaluation of alternatives, (4) management selection—the choice by decision makers, and (5) implementation and monitoring. Risk communication is sometimes viewed as a cross-cutting element.[9] The GAO espoused this cycle most clearly in regard to Homeland Security but also applies it in a broader perspective.[10] Figure 1 illustrates this risk-management cycle.

6. Roger Noll, "Reforming Risk Regulation" *Annals of the American Academy of Political and Social Science* 545 no. 1 (1996): 165–175, http://aei-brookings.org/admin/authorpdfs/redirect-safely.php?fname=../pdffiles/phptZ.pdf.

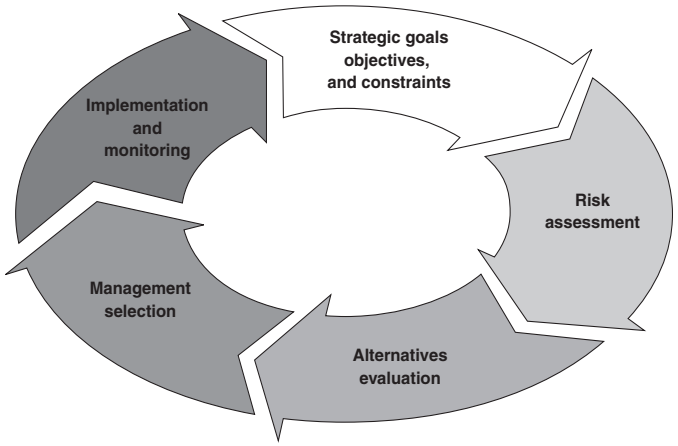
7. The reform attempts since 1980 include the following: (1) Paperwork Reduction Act (PRA), (2) Regulatory Flexibility Act of 1980 (RFA), (3) Small Business Regulatory Enforcement Fairness Act (SBREFA), (4) Unfunded Mandates Reform Act of 1995 (UMRA), (5) Congressional Review Act (CRA), (6) Government Paperwork Elimination Act (GPEA), (7) Truth in Regulating Act (TIRA), (8) Information Quality Act (IQA), (9) E-Government Act, and (10) Executive Orders 12866 (Regulatory Review) and 13132 (Federalism).

8. U.S. Government Accountability Office, *Regulatory Reform,* GAO-05-939T (2005), http://www.gao.gov/new.items/d05939t.pdf, 2.

9. Presidential/Congressional Commission on Risk Assessment and Risk Management, *Framework for Environmental Health Risk Management* 1 (1997), http://www.riskworld.com/Nreports/1997/risk-rpt/pdf/EPAJAN.pdf.

10. U.S. Government Accountability Office, *Risk Management: Further Refinements Needed to Assess Risks and Prioritize Protective Measures at Ports and Other Critical Infrastructure,* GAO-06-91 (2005), http://www.gao.gov/new.items/d0691.pdf; J. Valverde and Scott Farrow, "Federal Decision Making for Homeland Security, in *Real-Time and Deliberative Decision Making for Homeland Security*, eds. Igor Linkov, Elizabeth Ferguson, and Victor S. Magar (Netherlands: Springer, forthcoming).

FIGURE 1: RISK MANAGEMENT CYCLE



Source: GAO, (2005C)

This paper presents nine near- and longer-term recommendations, linked to the risk-management cycle, to improve the regulatory process. However, there is no unifying theme as their source is generally the author's research or experience in the executive or congressional branches. The recommendations are presented in table 1 and further context for the cycle and organizational actions are provided in table 2. Following table 2, a series of one-page outlines present and briefly describe each recommendation, the issue it is designed to address, how it improves the regulatory process, and the challenges to its implementation. Each recommendation is relatively high level and could have further implications for additional recommendations and would benefit from additional development. For instance, the recommendation for executive-branch agencies and the Office of Management and Budget (OMB) to work with external professional groups to improve standards omits the many specific areas that such a partnership might investigate, although examples are discussed in the text. However, such a partnership could easily lead to a new source of specific recommendations for improvement.

TABLE 1: RECOMMENDATIONS FOR IMPROVING THE REGULATORY PROCESS

RECOMMENDATION NAME	REASON FOR RECOMMENDATION
Near term	
1. Integrate Government Performance and Results Act and the regulatory process.	Establish performance criteria at the time of proposal for future evaluation of the regulation.
2. Create a public scorecard of regulatory analyses.	Identify to the public and to agencies the requirements for and achievement of compliance with guidance.
3. Develop regulation-specific "wiki" for public comments.	Establish an online dialogue and record of the suggested comments that may reach a community consensus.
4. Obtain performance-audit guidance from the GAO.	Give responsibility for guidance to a neutral and credible source in government.
5. Establish a public financial-education module.	Inspire a better-informed citizenry to participate in more actions such as regulatory comments or simply vote.
Longer term	
1. Create residual risk accounting data and reports.	Publish new information regarding what to regulate and the performance of existing regulations.
2. Require congressional approval for high-cost regulations.	Incorporate triggers for congressional review that the cost burden or other performance measures may be inappropriate.
3. Establish a public-private partnership to improve regulatory analysis methods.	Improve accomplishment of agency and OMB missions.
4. Integrate OMB annual regulatory reporting with National Income and Product Accounts.	Link regulatory reporting with standard economic reporting.

TABLE 2: RISK MANAGEMENT, INSTITUTIONAL ACTIONS, AND RECOMMENDATIONS SUMMARY

RISK-MANAGEMENT CYCLE	ILLUSTRATIVE INSTITUTIONAL ACTIONS		NEAR-TERM RECOMMENDATIONS	LONGER-TERM RECOMMENDATIONS
	CONGRESS	EXECUTIVE BRANCH		
Strategic goals, objectives, constraints	What to regulate (yes, no, how much?) What to fund	What to regulate within mission	GPRA requirement	Congressional approval for high-cost regulations
Risk assessment	Legislative development Budgetary development	Agency development Stakeholder review (including Executive Office) Management choice (judicial review)	GAO performance-audit guidance	BEA: residual-risk accounts public/private standards- partnership
Evaluation			Public scorecard Regulatory wiki GAO performance-audit guidance	Public/private standards- partnership
Management selection				Congressional approval for high-cost regulations
Implementation and monitoring	Authorization and appropriation Oversight	Implementation and monitoring Budget	GPRA requirement: financial-literacy module	BEA/OMB economic reporting Public/private standards- partnership

NEAR-TERM RECOMMENDATION 1

Integrate the Government Performance and Results Act (GPRA) and the regulatory process.

Suggested action

An agency must define at least two GPRA performance measures when a major regulation is proposed and at least one must be related to economic performance such as cost effectiveness or benefit-cost assessment.

Background/issue addressed

Although the regulatory process currently focuses on predicting the impacts of regulation, there is little retrospective assessment of existing regulations,[11] particularly related to their performance. Furthermore, the GPRA measures produced by the agencies typically ignore economic performance,[12] although committee language for the GPRA clearly includes at least cost-effectiveness measures and benefit-cost measures appear consistent with intent. Finally, integrating the GPRA with budget allocations has been an initiative of the OMB through the Program Assessment Rating Tool (PART) process. This recommendation brings

11. U.S. Government Accountability Office, *Regulatory Reform*; Thomas McGarity, *Reinventing Rationality: The Role of Regulatory Analysis in the Federal Bureaucracy* (New York: Cambridge University Press, 1991).
12. U.S. Government Accountability Office, *Economic Performance* GAO-05-796SP (2005), http://www.gao.gov/new.items/d05796sp.pdf.

regulation into the GPRA/budget connection by linking measures identified for regulatory review based on executive orders with implementation. It also provides incentives for retrospective analysis.

How the recommendation improves regulation and reasons for adoption

- It establishes performance criteria for the retrospective assessment of a regulation based on the regulation's expected performance at the time of its proposal.
- The forecasting efforts of the agency and review by the regulatory part of the OMB (Office of Information and Regulatory Affairs, OIRA) are integrated with performance-based aspects of the federal budget process that the budgetary part of OMB implements, most recently through PART.
- The prior analysis of large regulations should provide benchmarks against which actual outcomes and performance measures can be addressed.
- An established expectation can create incentives to design regulatory evaluation into the early stages.
- It builds information for an adaptive approach to modify regulatory implementation depending on results.

Challenges to improving regulation this way

- Agency and OMB resources are scarce.
- It is difficult to evaluate programs due to confounding factors.

Step in the risk-management process

Monitoring and strategic review

NEAR-TERM RECOMMENDATION 2

Create a public scorecard of regulatory analyses.

Suggested action

The OIRA should develop and make public a report/score card that identifies the actionable elements of their guidance, rates major proposals on each item, and explains any failures or inconsistencies that are below its standard.

Background/issue addressed

Several nongovernmental analysts have investigated the quality of Regulatory Impact Analyses based on their interpretation of OMB/OIRA guidance.[13] Their research has identified numerous weaknesses. However, neither agencies nor the public appear to know what the minimum or other standards are for acceptability. Requiring the OMB to be explicit about its analytical criteria (as distinct from any policy criteria) and having the agencies justify departures from those criteria could improve quality through transparent and explicit attention to analytical practices.

How the recommendation improves regulation and reasons for adoption

- It identifies to the public and to agencies requirements and achievement of compliance with guidance.
- It communicates more explicitly the basic analytical requirements in OMB guidance.
- OMB guidance exists, and no new executive order or legislation would be required.
- External researchers have demonstrated its feasibility.

13. Robert Hahn and Paul Tetlock, "Has Economic Analysis Improved Regulatory Decisions?" *Journal of Economic Perspectives* 22, no. 1 (2008): 67–84; Richard Belzer, *CSAB Project on Regulatory Oversight* (St. Louis: Center for the Study of American Business, 1999), http://wc.wustl.edu/csab/regulation/PROStudyProtocol.pdf.

Challenges to improving regulation this way

- Case-specific issues may lead to a number of exemptions.
- A possible desire to keep analytical and policy issues merged during regulatory review.
- Defining a minimum threshold may drive agencies to achieve just the minimum.

Step in the risk-management process

Quality control at the risk-assessment and evaluation stage

NEAR-TERM RECOMMENDATION 3

Develop a regulation-specific "wiki" for public comments.

Suggested action

At the time a regulatory proposal goes public, the agency should create a public-access, online, and editable (wiki) version of the regulation to which multiple parties can make changes.

Background/issue addressed

The public-comment period is currently based on a noncomputerized model of communication. In many cases, it is difficult to determine exactly what changes parties are suggesting because of the regulatory wording. Using a newly created Wikipedia-type system where multiple parties can enter changes, the agencies could possibly obtain a clearer understanding of what different groups are recommending and see whether a community consensus emerges. In addition, a wiki approach can help to facilitate stakeholder understanding and communication with other stakeholders. While many details would remain to be worked out on shared editing, the wiki community on the web has developed a number of protocols.[14] Such protocols may be modified for community commenting on a regulation (in contrast to a neutral, encyclopedia-type entry). For instance, different stakeholders could create an additional document and stakeholders could specialize in editing the one they most prefer. In addition to community editing of text, it may also be possible to provide analytical summaries of regulations online in which different groups may edit assumptions.

How the recommendation improves regulation and reasons for adoption

- It creates an online dialogue and record of the suggested comments that may reach a community consensus.
- It increases specificity and transparency of public comments on regulation.
- The cost to implement and to monitor (e.g., control "vandalism," "reverting," or excessive editing) is relatively low.

Challenges to improving regulation this way

- Contradictory or other incorrect information may appear in the edited versions.
- Documents evolve and can contain factual errors.

Step in the risk-management process

Evaluation of alternatives/public comment

14. See Wikipedia's editing policy at http://en.wikipedia.org/wiki/Wikipedia:Policies_and_guidelines.

NEAR-TERM RECOMMENDATION 4

Obtain performance-audit guidance from the GAO.

Suggested action

That GAO provides expanded, government-wide guidance for the performance audit of regulatory programs.

Background/issue addressed

GAO produces *Government Auditing Standards*," known as the "Yellow Book."[15] An important part of that guidance distinguishes financial audits from performance audits:

> Performance audits are defined as engagements that provide assurance or conclusions based on an evaluation of sufficient, appropriate evidence against stated criteria, such as specific requirements, measures, or defined business practices. . . . Performance audit objectives may vary widely and include assessments of program effectiveness, economy, and efficiency; internal control; compliance; and prospective analyses.[16]

The GAO has been considered for broader involvement in the regulatory process, through the Truth in Regulating Act that involved pilot evaluations. The GAO has resisted taking on a larger role in the absence of additional funding. However, the GAO may be an appropriate source of government-wide guidance on specific types of performance audits given its expertise in evaluation, accounting, economics, and statistics and its credibility in convening third parties to assist in developing guidance.

How the recommendation improves regulation and reasons for adoption

- It gives responsibility for guidance to a neutral and credible source in government.
- As the source of Generally Accepted Government Auditing Standards, the GAO appears to have the authority to develop guidance related to performance audits.
- The GAO has an established advisory system that could be expanded.
- The GAO has a neutral, credible reputation suited to providing guidance.
- GAO guidance is likely to be influential with agency inspector general offices.

Challenges to improving regulation this way

- Providing guidance and convening advisory groups are costly activities.
- Government agencies may not agree that they are conducting "performance audits" and avoid using guidance.

Step in the risk-management process

- Prospective activity: risk assessment/evaluation of alternatives
- Retrospective activity: monitoring

NEAR-TERM RECOMMENDATION 5

Establish a public financial-education module.

Suggested action

Develop a public finance and regulation module as part of efforts to increase public financial literacy.

15. U.S. Government Accountability Office, *Government Auditing Standards* GAO-07-731G (2007), http://www.gao.gov.
16. Ibid, 12.

Background/issue addressed

Concern for the financial literacy of the citizenry has lead to the formation of the U.S. Financial Literacy and Education Commission and the President's Council on Financial Literacy. Members of the commission include the Departments of Treasury, Education, and Health and Human Services, and the Social Security Administration, among others.

While an important part of financial education is personal finance, another important part is the issues at the intersection of governmental budgeting, taxation, and regulation. The commission's web site (http://www.mymoney.gov/) already provides information on personal finance as it relates to budgeting and taxes, credit, financial planning, home ownership, kids, paying for education, privacy, retirement, saving and investing, and starting a small business.

Additional modules on a citizen's financial connections to the government, including taxes, tax expenditures, regulation of financial markets, and regulation in general, should be an important if perhaps secondary part of personal financial literacy. Agencies such as those already listed but also including the OIRA could develop educational materials related to public finance and education for the commission's web site.

How the recommendation improves regulation and reasons for adoption

- A better-informed citizenry may participate in more actions, such as regulatory comments, or be better informed to vote.
- It extends the concept of personal financial knowledge to knowledge of governmental finances and actions and their impact on an individual.
- Adoption could be relatively simple since a commission and website with a purpose complementary to the recommendation already exist.
- The cost of implementation would be relatively low.

Challenges to improving regulation this way

- It may be difficult to get agreement on content.

Step in the risk-management process

Risk communication that cuts across steps in the process; feedback from citizenry to strategic planning

LONGER-TERM RECOMMENDATION 1

Create residual risk accounting data and reports.

Suggested action

The Bureau of Economic Analysis (BEA), in conjunction with other professional organizations, should develop time-series data on actualized risks and their economic valuation that are the typical subject of regulation.

Background/issue addressed

How much and what to regulate could be better informed by risk data that cut across specific areas. Congress and agencies are often said to be reactive to the crisis of the moment, and regulation can follow that reaction. Information is not currently compiled in a way that illustrates the scale and monetized value of residual risks across various outcome issues, such as crime, bankruptcy, health, education, environment, or natural hazards.

Residual, actualized risks are those actual risks that occur even though citizens take their own avoidance actions and a regulatory system is in place for many events. Risk laws and regulations often result from high-profile risk events placing pressure on Congress and regulatory agencies to act. In many cases, there may not be easily obtainable data to place the new

risks in context with existing risks, particularly in an actuarial sense—that is, measured injuries, illnesses, and deaths. Having both the risks and their monetized value to society in a single location could help legislators and regulators quickly place new risks in context.

The Bureau of Economic Research is the lead agency in the development of the National Income and Product Accounts (NIPA) that, for instance, lead to measures like gross domestic product. New work combined with existing data could create information on both quantities of risks that occur, such as accidental deaths or high-school dropouts, and their value in dollar terms. These data would represent a maximum value on the historical benefits that a "perfect" regulation would have achieved, while also informing discussions on prioritizing and assessing the effectiveness of proposed laws and regulations. Measures of the variability in outcomes and values could also be addressed.

How the recommendation improves regulation and reasons for adoption

- It creates new information regarding what to regulate and the performance of regulation.
- It structures information so that risks are both quantified in their natural units (e.g., dropouts) and in monetary units (their dollar value).
- Significant research has been done on component parts.

Challenges to improving regulation this way

- The precision of estimates may vary by type of risk.
- There are differences of opinion about values attached to outcomes.

Step in the risk-management process

Information for strategic direction, risk assessment, and evaluation.

LONGER-TERM RECOMMENDATION 2

Require Congress to approval high-cost regulations.

Suggested action

Regulations that impose total costs of more than $100 million per year should be commented upon by the relevant committees prior to finalization and Congress should jointly confirm approval if the Congressional Budget Office (CBO) or the (GAO) certify that key regulatory performance measures exceed preapproved levels. High-cost regulations could also be offset by cost reductions elsewhere under the agency's control and so certified by the CBO or GAO.

Background/issue addressed

Regulations that generate costs and benefits in the economy are often based on broad delegation given to agencies from Congress. For major regulations, the ambiguities behind such delegation often lead to high-cost litigation or wide discretion in design. This recommendation requires feedback from Congress to the executive branch by establishing benchmarks for congressional approval of high-cost or other outlying types of regulation. Low-cost or cost-neutral regulations would not require such approval.

Although individual members have commented on regulations and Congress has the power to review regulations prior to their finalization through the Congressional Review Act (CRA), the disapproval power of the CRA is rarely invoked. Further, the CRA weakly distinguishes high from low impact regulations and action is taken only if sufficient congressional interest exists to overcome the default action of approving.

The first part of this recommendation requires input from the appropriate committees following the formal proposal of a major regulation. The input could be the result of hearings or the committee may simply have no comment. Secondly, this recommendation seeks positive congressional action on regulations that are performance outliers when they reach final publication. Recognizing that significant legal and procedural issues surround positively re-approving delegated authority,[17] an alternative is that an automatic resolution of disapproval is submitted in the case of high cost or performance outlier regulations.

The additional element allowing cost offsets in the determination of a high-cost regulation would implement an incremental, regulatory budget check in the spirit of PayGo legislation.[18] There is a history of suggestions to create a regulatory budget[19] that would limit agency and total regulatory spending. This element essentially implements a case-by-case regulatory budget for major regulations to provide some encouragement for agencies to find low-cost alternatives or regulatory efficiencies elsewhere, or, failing that, to confirm approval from Congress to impose the regulatory cost.

How the recommendation improves regulation and reasons for adoption

- It creates a process for regulatory feedback from Congress to the executive branch.
- It incorporates triggers for congressional review when the cost burden or other performance measures may be unusual.
- It incentivizes retrospective review by agencies in order to find cost savings in their current activities.

Challenges to improving regulation this way

- It may encourage agencies to strategically game cost savings in other areas.
- It imposes a new congressional review process for major regulations that is a sensitive area of delegation and review.

Step in the risk-management process

Management selection and evaluation of alternatives

LONGER-TERM RECOMMENDATION 3

Establish a public-private partnership to improve regulatory analysis methods.[20]

Suggested action

Create and fund an interagency, executive branch task force to work with professional organizations on cross-cutting principles and standards for regulatory analysis.

Background/issue addressed

The OIRA and some individual agencies have produced guidance on implementing some aspects of regulatory review. The most detailed guidance has

17. Jeffrey Lubbers, *A Guide to Federal Agency Rulemaking: 4th Edition* (Chiago:.American Bar Association, 2006); Richard Beth, "Disapproval of Regulations by Congress: Procedure Under the Congressional Review Act," Congressional Research Service, RL-31160, October 10, 2001, www.senate.gov/reference/resources/pdf/RL31160.pdf .
18. Peter Orszag, *Issues in Reinstating a Statutory Pay-As-You-Go Requirement*, testimony for the Committee on the Budget, Congressional Budget Office, July 25, 2007.
19. Chris DeMuth, "Constraining Regulatory Costs: The Regulatory Budget" Regulation (March/April 1980), http://www.chrisdemuth.com/id29.html.
20. This recommendation may be combined with development of GAO guidance (near-term recommendation 4).

generally been for benefit-cost analysis (through OMB circulars A-94 and A-4 and from agencies such as the EPA, DOT, and DHS). However, such guidance is relatively terse and may be improved with added detail in some areas and updating in others. Further, OIRA lacks an advisory group to assist in guidance development such that certain issues, such as identifying some specific regulations as transfers, may not be consistent with professional standards. Academic economists and organizations such as the National Science Foundation, the National Bureau of Economic Research, the Society for Benefit-Cost Analysis, and the Society for Risk Analysis may usefully inform analytical practice in a partnership with executive branch agencies.

Issues that might be addressed include:

- analytical integration of risk assessment and benefit-cost analysis
- comparisons between benefit-cost analysis and multi-attribute utility
- development of guidance on the quantification of risk and/or uncertainty
- clarification of issues such as transfers, default values (shadow prices), reporting quantities as well as individual values, and so on
- development of benefit-cost electronic templates for classes of analysis, such as occupational safety, transportation regulations, air quality, and so on

How the recommendation improves regulation and reasons for adoption

- Public-private partnerships may produce more thorough, consistent, and analytically grounded guidance with wider acceptance than currently exists.
- Guidance on methods and practice may come from a neutral source.
- External groups could advise, but adoption would be up to the OMB and the agencies.

Challenges to improving regulation this way

- Government (the OMB and agencies) may give up some power to external groups.
- It requires new monetary or time resources.

Step in the risk-management process

Guidance for risk assessment and alternative evaluation

LONGER-TERM RECOMMENDATION 4

Integrate OMB annual regulatory reporting with NIPA.

Suggested action

The OMB should work with the BEA to determine whether a supplemental account to the NIPA can be developed for regulatory impacts, costs, benefits, and other features of regulatory impacts.

Background/issue addressed

The OMB produces an annual report on regulation. That report now contains the start of a reporting form for annual regulatory impact. The BEA, other data-oriented agencies of the federal government, and scientific organizations have considered developing supplemental accounts to the NIPA in many areas. Although it is doubtful that a meaningful measure of the total benefits and costs of cumulative regulations over all time could be constructed, the BEA is familiar with inventory adjustment and other methods that may increase the information content of the OMB's reports. Further, the expansion of benefit-cost reporting to include quantitative and nonquantitative benefits and costs may help communicate underlying information that supports regulatory benefit-cost analysis.

How the recommendation improves regulation and reasons for adoption

- It links regulatory reporting with standard economic reporting.
- Congress has asked for an annual accounting for regulation, but it is not clear that the major economic data-generating agency has been brought into design discussions.
- It may improve a report requested by Congress.

Challenges to improving regulation this way

- Supplemental accounts are time consuming and may be expensive to develop.
- The BEA is not an expert in regulations.

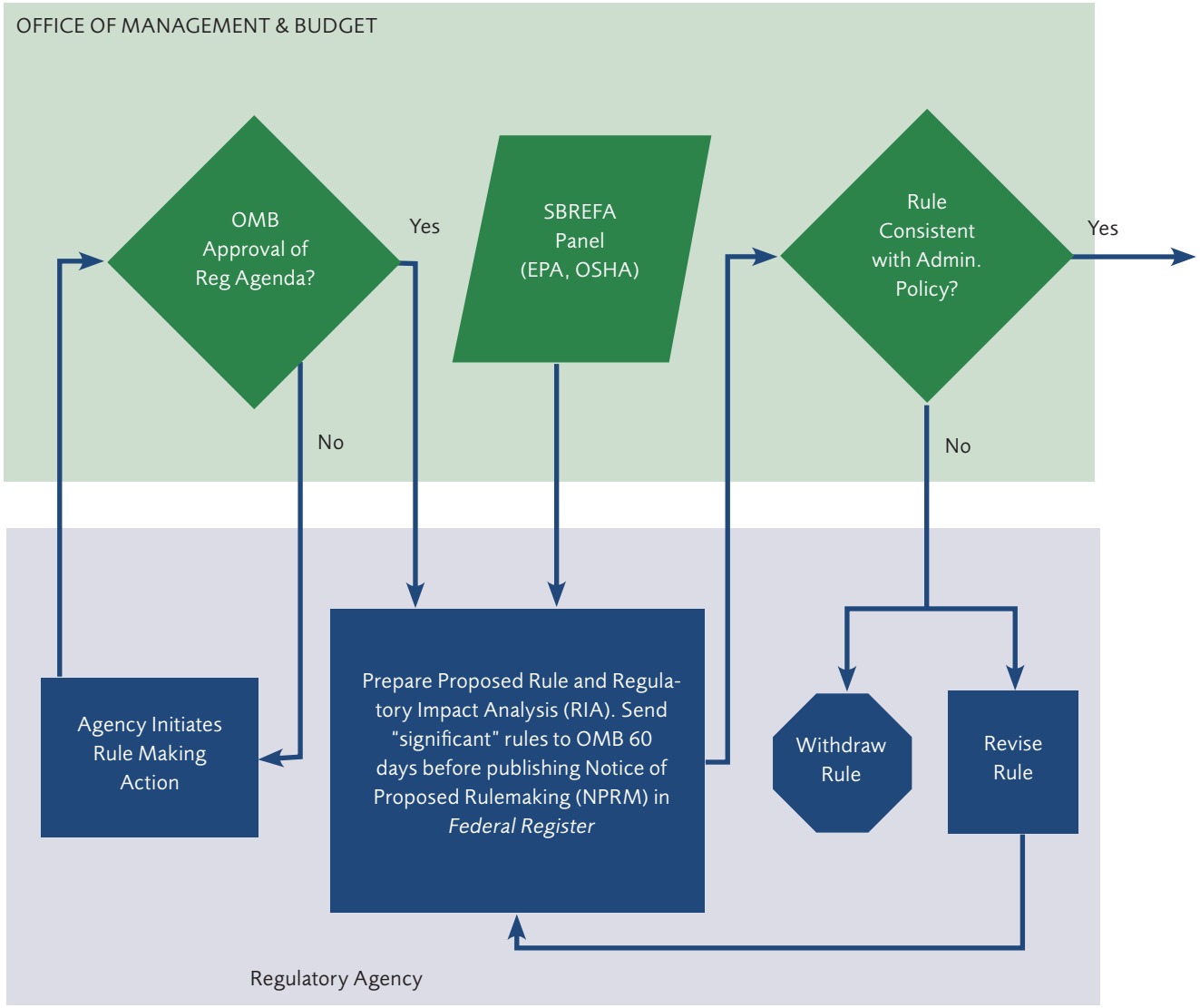
Step in the risk-management process

Information for monitoring and strategic review

CONCLUSION

This paper identified the challenges inherent in identifying a single direction for "improvement" in the regulatory process, the relevance of a full-cycle risk-management approach, and the weaknesses in past attempts at reform such as limited scope and coverage, lack of clarity, uneven implementation, and a predominant focus on the development part of regulatory process. The nine recommendations developed here address elements of those weaknesses and the risk management cycle. The recommendations are presented for discussion and elaboration knowing, like the regulatory process, that proposals evolve and that many stakeholders have different views that can improve upon an initial concept.

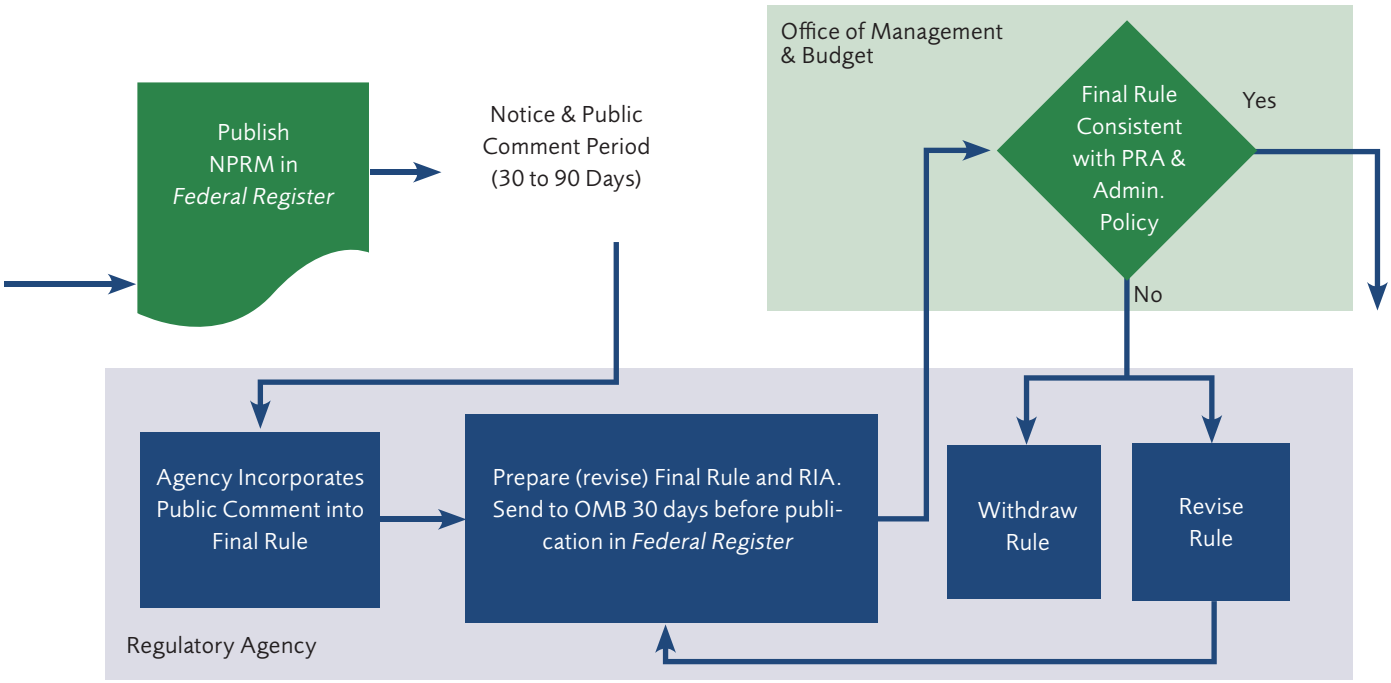
APPENDIX:
THE REGULATORY PROCESS: PART I (DUDLEY 2005)



This figure illustrates the regulatory development process. Agencies announce the initiation of a rulemaking through the semi-annual Unified Agenda of Federal Regulations (a list of all forthcoming and ongoing regulatory actions). The Office of Information and Regulatory Affairs (OIRA) in the Office of Management and Budget has a role in determining the content of the Unified Agenda. Agencies often spend years developing a regulation before beginning to draft a proposal. Once drafted, regulations that are considered significant must be reviewed by OIRA, and draft regulations of the EPA and OSHA are subject to a SBREFA review if they have the potential to affect small entities.

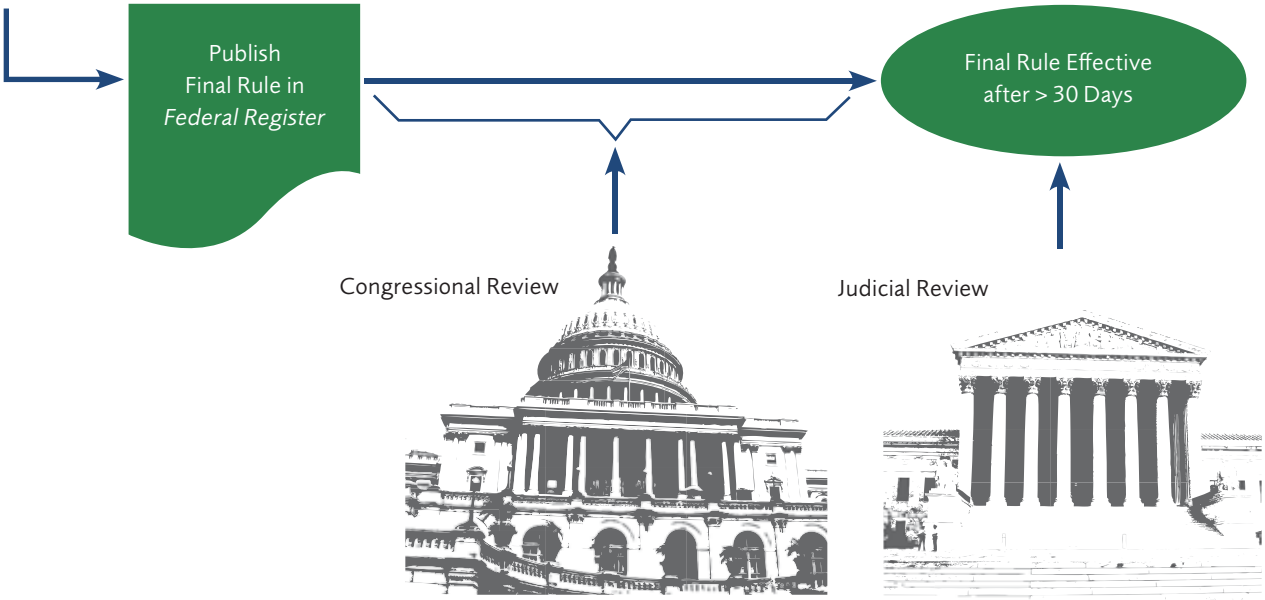
THE REGULATORY PROCESS: PART II (DUDLEY 2005)

NOTICE, COMMENT, & FINALIZATION



Once a draft regulation has passed these reviews, it is published in the *Federal Register*, and the public has an opportunity to comment on it. After reviewing public comment, the agency must submit the draft final rule to OIRA once again before a final rule can be published in the *Federal Register*. Regulations do not take effect for at least 30 days after final publication. Congress has an opportunity to issue a joint resolution of disapproval after a final regulation has been published, and regulations are also subject to judicial review: affected parties can sue to have regulations overturned by the courts.

PUBLICATION & POSSIBLE REVIEW



FACILITATED MARKET SOLUTIONS FOR SOCIAL PROBLEMS

Richard A. Williams and Andrew Perraut[1]

Prior to the wave of regulations that began sweeping the country in the 20th century, virtually all solutions to social problems were solved by private markets. For example, third-party certification, like the Good Housekeeping seal still used today, helped ensure the quality and integrity of products. Word of mouth also spread information about good and bad products. Today, Internet RSS feeds, blogs, and other information on the Web have amplified the effects of word-of-mouth information sharing.

Normal market processes still solve most of the social problems confronting society today, matching society's productive resources to the particular demands of consumers. If, for example, there is a way to increase the quality of a product (say, widgets), a market leader will generally improve its widgets to capture an additional share of the widget market, which forces its competitors to follow.[2] Even where an industry's products have "negative" attributes, markets work through a process called "unfolding."[3] In this process, the product with the least "bad" attributes advertises that it is better than the next-best product, which forces that product to innovate. The most famous example of such an "unfolding" process may come from the auto industry. Many manufacturers were reluctant to advertise their cars' safety features for fear of drawing attention to the inherent dangers of driving. Volvo, a Swedish company, broke that stalemate by introducing drastic safety improvements and informing consumers—leaving American brands to play catch-up in the early 1990s. Following the Volvo ad campaign, American companies were forced to compete to make their cars safer as well. That case was fairly typical: Once a product then advertises that it is better than the third-best product, this process continues until the last product innovates or is forced off the market by lack of demand.

But resolving some social problems requires intentional management of markets. In these cases, the normal interaction of firms and consumers does not work, and government intervention is assumed to be necessary. Welfare economists call these kinds of problems "market failures." They have identified several specific types, such as externalities (e.g., a factory emitting pollution) where there are impacts on parties who cannot signal their preferences as part of the normal market transaction. Historically in these cases, it has been presumed that governments both can and should be responsible for solving these problems. More recently, however, economists have begun to understand that given the reality of political institutions, government may not always provide a solution that improves the market's "failure." Such government failures are a widely recognized phenomenon. To take a recent example, it has long been the policy of Congress to "correct" the market by encouraging homeownership through tax incentives and other means, policies which have likely contributed to the severity of the current fiscal crisis. Political failures aside, it may be folly to assume that government will always have the necessary expertise or resources for solving every problem in an increasingly technical society. In some cases, a better solution may lie with ad hoc organizations of market participants and stakeholders.

One problem with such ad-hoc organizations is that any time competing firms engage with one another, they run the risk of running afoul of antitrust prohibitions against collusion. To steer clear of this issue, many firms have employed nonprofit mediation organizations like the Keystone Center, which uses "expert science, careful convening, and skilled process . . . [to enable] . . . leaders from governmental, non-governmental, industrial, and academic organizations to find productive solutions to controversial and complex public policy issues."[4] We call the results of this process "facilitated market solutions."

1. Thanks to Brad Stone and Peter Adler of the Keystone Center for their helpful comments.

2. George Akerlof, "The Market for 'Lemons': Quality Uncertainty and the Market Mechanism," *Quarterly Journal of Economics* 84, no. 3 (1970): 488–500.

3. Sanford J. Grossman, "On the Impossibility of Informationally Efficient Markets," *American Economic Review* 70, no. 3 (1980): 393–408.

4. The Keystone Center, "Center for Science & Public Policy," http://www.keystone.org/spp/index.html.

REGULATORY NEGOTIATIONS

Some argue that industries need not seek the assistance of third-party organizations like Keystone because the federal government can perform this function due to an amendment to the Administrative Procedures Act (APA), otherwise known as notice-and-comment rulemaking. Under the APA, the government does occasionally perform a function similar to private negotiation called "regulatory negotiation," but these are not common and suffer from some constraints that do not affect private solutions.

The facilitated market solutions described in this paper are, in one sense, quite similar to regulatory negotiation, a tool used by executive agencies since the early 1980s and officially codified in the Negotiated Rulemaking Act of 1990.[5] Regulatory negotiations were devised as a means of improving the regulatory process by bringing together stakeholders to discuss pending rulemakings. An agency can summon the corporate and social stakeholders that it believes have valuable points of view or information about a topic and ask them to reach a consensus about a given problem. In a normal scenario, once consensus has been reached, the agency publishes the agreed-upon text as it would any other proposed rule, thus opening it for public notice and comment.

Proponents hoped that regulatory negotiation would be more successful than traditional agency-originated rules for several reasons. In most cases, stakeholders have more information about a given topic than regulators do (this is particularly true in very technical situations). By consulting with them, regulators would be able to put forward "smarter" rules that create less of a burden on businesses and the economy as a whole. Further, because interested parties are given a chance to voice their concerns, the regulatory negotiation process is supposed to be faster than traditional rulemaking and less prone to challenges in the courts.

Regulatory negotiation continues to be used today, and some agencies have more fully embraced it than others (the EPA in particular was, at least for a time, enamored of this procedure). On the whole, though, negotiation has not lived up to its promise. Some anecdotal accounts indicate that stakeholders found very little benefit in the process.[6] At base, the problem seems to be that regulatory negotiation can be very time consuming and burdensome for stakeholders, with the costs to participants outweighing the benefits.

Empirical studies have been mixed. Cary Coglianese examined regulatory negotiations over thirteen years and concluded that such negotiations had saved little or no time over traditional processes and that the final rules emerging from such negotiations were just as likely to be challenged in court.[7] Other studies have found just the opposite: Regulatory negotiation participants were more satisfied and less likely to challenge the results, and the process was significantly speedier.[8] Still others question regulatory negotiation at a more fundamental level. Whether or not regulatory negotiations result in faster action, for some observers they leave open troubling questions about undue corporate influence which, unmonitored, has the potential to undermine important democratic safeguards.[9]

5. *Government Organization and Employees*, Negotiated Rulemaking Procedure, U.S. Code 5, §§ 561–570.
6. See Lynn Sylvester and Ira Lobel, "The Perfect Storm: Anatomy of a Failed Regulatory Negotiation," *Dispute Resolution Journal* 59 (May-July 2004); See also Ellen Siegler, "Regulatory Negotiations and Other Rulemaking Processes: Strengths and Weaknesses from an Industry Viewpoint," *Duke Law Journal* 46, no. 6 (1997): 1429–1443.
7. Cited in Shi-Ling Hsu, "A Game-Theoretic Approach to Regulatory Negotiation and a Framework for Empirical Analysis," *Harvard Environmental Law Review* 26, no. 1 (2002): 33–40.
8. See Laura Langbein and Cornelius Kerwin, "Regulatory Negotiation versus Conventional Rule Making: Claims, Counterclaims, and Empirical Evidence," *Journal of Public Administration Research and Theory* 10, no. 3 (2000): 599–632; See also Jody Freeman and Laura Langbein, "Regulatory Negotiation and the Legitimacy Benefit," *New York University Environmental Law Journal* 9, no. 1 (2000): 60.
9. See Susan Rose-Ackerman, "Consensus versus Incentives: A Skeptical Look at Regulatory Negotiation," *Duke Law Journal* 43, no. 6 (1994); See also William Funk, "Bargaining Toward the New Millennium: Regulatory Negotiation and the Subversion of the Public Interest," *Duke Law Journal* 46, no. 6 (1997): 1351–1388.

While the evidence might be inconclusive, it seems clear that regulatory negotiation has not entirely lived up to its initial promise and has become more of an anomaly than a commonly used mechanism. Although similar in nature, privately negotiated solutions offer advantages over the government-run system of regulatory negotiation. Some of these advantages include avoidance of the political bias that may drive regulatory decisions as well as problems associated with "capture" of regulatory agencies, which occurs when private partisan interests have undue influence over the regulatory process. For example, many observers have noted that there is a marked shift in the types and stringency of regulations produced depending upon which political party holds executive office. In addition, members of regulatory agencies will also bring their biases to rulemaking. These biases may come from philosophical beliefs or from a sector of the economy in which they have previously worked, such as industry or advocacy, that can continue to drive their preferences.

Finally, it takes an agency a long time to produce a regulation under the Administrative Procedures Act. Over the years, the analytical and review requirements that have been inserted into the process, while useful, have added many months to the overall promulgation of regulations. All of these problems have been explored at length in the legal and economic literature. Each of these problems may exist, to some degree, for regulatory negotiation as well.

CONDITIONS FOR FACILITATED MARKET SOLUTIONS

A FACILITATED MARKET solution is a deliberate assembly of stakeholders led by a private professional organization to solve a specific social problem. Because stakeholders must pay for these solutions, over and above what they pay in taxes to fund regulatory agencies, there are unique conditions that must exist to make participation and consensus worthwhile. First, for any negotiated settlement to take place, there must be a policy driver such as an impending law or regulation with a definitive time table that stakeholders believe will not, left to the normal political process, serve their best interests, either procedurally or substantively. Stakeholders may also seek private negotiation if they believe that their views will not be given appropriate consideration or if they believe the traditional ways of handling these problems—legislation, regulation, and litigation—are unlikely to solve the problem. When these two conditions hold, stakeholders have a strong incentive to come together to find solutions quickly. Notice-and-comment rulemaking, for example, generally results in a one-way conversation: Each stakeholder submits comments to an agency and receives no communication back unless they are able to find some mention of their comment in a final rule. Additionally, in a privately mediated case, the stakeholders are the decision makers; in a government case, the government makes all the decisions behind closed doors.

Independent mediation and facilitation organizations offer discrete, candid, and creative discussions where all views are aired and a multiparty dialog takes place around every idea. It also offers protection of industry secrets, whereas negotiations directly facilitated by an agency and culminating in a legally binding regulation necessarily must be made a matter of public record, creating an incentive for private actors to hold back important information that could lead to better outcomes.[10] Further, private facilitators are not bound by (sometimes outdated) authorizing statutes or legal and cultural precedents unless they choose to be. They are free to come up with creative, progressive, and innovative solutions.

In some cases, it is actually the government that turns to private mediators for solutions. This may be the case if it sees the need for a faster solution, perhaps driven

10. As noted by a reviewer, agencies can hold information submitted privately to them if the meetings are "preparatory" for decision meetings governed by the Federal Advisory Committee Act. However, that information would not be shared with a larger group, only with regulators.

by a statutory mandate or because of an understanding that stakeholders are reluctant to speak candidly on certain issues when presenting their views directly to the government. For example, the Department of Health and Human Services employed private mediation to come up with new patient package inserts for prescription drugs because the agency was under a statutory deadline that it did not believe could be meet by conventional methods. Stakeholders from industry, academia, and consumer groups came together and found a solution relatively quickly. While this solution was not the end (there still needed to be formal rulemaking), this process moved the solution forward at a much faster rate than would have happened otherwise.

Private mediation firms are relatively new, having emerged about thirty years ago, primarily to handle site-specific environmental issues. They have been used internationally in dispute resolution between countries, such as in nuclear disarmament talks with the Soviet Union and in discussions regarding where to construct oil pipelines. More recently, these firms have engaged on environmental and energy issues such as the Sustainable Growth Initiative under President Clinton. This mechanism offers a tremendous untapped potential to solve many, many more problems.

HOW IT WORKS

Initiating a facilitated dialogue on complex marketplace solutions can happen in a variety of ways. Any prospective client—an NGO, a corporation, or a government entity—may approach an intermediary group or mediation company. Sometimes, the intermediary group might see an opportunity to approach multiple clients in various sectors with an idea for a facilitated discussion. Funding for mediation must come from the stakeholders or some acceptable subset thereof. The intermediary group must take great care to identify the right mix of participants with the goal of including all relevant views (and people).

Mediators must also figure out how best to represent consumers at these meetings—whether through consumer organizations or some other type of representation. Facilitators also must identify and ensure the representation of the divergent interests of the thousands of small businesses in a given industry. Note that even though regulatory dockets are public, the affected small businesses are not always aware of rulemaking as agencies generally do not actively seek out all relevant viewpoints. There is also a concern about new entrants to the industry who did not participate or have their views represented in the negotiation. However, they would have the same problems with the regulation process.

Another concern that might be raised is the issue of whether paying for the mediators pays for an outcome. While this might be of genuine concern if mediation companies adjudicated only one issue, reputation quickly provides an enormous incentive to remain being seen as a neutral party. No mediation firm that is perceived as "for sale" would survive very long in a marketplace where participation was voluntary. To survive, mediation companies must take an absolutely neutral position on the outcome.

Once all the affected parties have been identified and brought together, the first area for consensus is exactly what goals or problems need to be solved and what principles will be used to solve those problems. The group must establish rules for participating, such as whether the discussions will be confidential and how the parties will come to agreement (e.g., voting by unanimous agreement versus simple majority). Once the ground rules have been set to everyone's satisfaction, the negotiation can take place and the parties will attempt to resolve the problem at hand. One mediator has noted that there is an extremely high rate of successful resolution of issues.[11]

A word of caution: facilitated market solutions of this kind are *not* a regulatory activity. Unlike regulatory negotiations, even when the stakeholders reach con-

11. Conversation with Brad Sperber of the Keystone Center, June 2008.

sensus in a mediation, that outcome is not legally binding. In *A.L.A. Schechter Poultry Corp. v. United States*, the Supreme Court ruled that Congress may not delegate its regulatory powers to private organizations, stating that "such a delegation of legislative power is unknown to our law and is utterly inconsistent with the constitutional prerogatives and duties of Congress."[12] Still, private mediation has the potential to be a powerful tool for solving social problems. When issues arise that might necessitate regulation, the government may encourage stakeholders to engage in private mediation to solve the social problem. If mediation successfully resolves the issue, agencies would be free to devote their resources to other projects.

While the nonbinding nature of the agreements sounds like a weakness, it is actually a source of strength. Because mediation is fundamentally a nongovernmental solution, participants are not bound by the same rules, procedures, and institutional culture of regulatory bodies. With fewer constraints, they are freer to find optimal solutions. If that process fails, however, the government remains the ultimate safety net and can compel compliance if it believes that mediation has not resolved the underlying problem.

While these groups may reach agreement more rapidly than government negotiators, compliance may be a different manner. In a situation where the evidence for compliance is years off and an issue urgently needs a resolution (e.g., to protect public health), mediation might not be a good solution if it is uncertain that a large enough percentage of the market will comply to significantly move forward in addressing the problem. In those instances, the government may feel compelled to act given its unique powers to enforce rules. In addition, some firms try to use government rules to provide a shield to avoid liability and for them, a private voluntary solution will not provide that same shield.

Finally, American regulations are often incorporated into international trade agreements and become binding on commerce between nations. Where no clear U.S. rule exists, international regulatory bodies often step in to fill the void, applying their standards to any products that American manufactures wish to export. It is possible, however, that privately mediated agreements (by U.S. stakeholders) might also be used in the text for international agreements.

AN EXISTING ISSUE

One of the issues currently before the Keystone Center is the placement of nutritional health symbols on packaged food products to signal to consumers that a labeled product is a healthier choice than related alternatives. These symbols are a response to consumer demand for a faster, more comprehensive indication of the healthiness of the product without having to decipher the nutrition facts printed on the package.

Symbols like these are already on the market, but their proliferation has generated some confusion for consumers. Currently, some symbols signal the presence of nutrients such as whole grains, some address a particular health condition (e.g., the American Heart Association logo), some are particular to supermarket chains (the Hannaford Supermarket chain's "Guiding Stars"), some appear only on individual manufacturers' products (Kraft's "Sensible Solutions"), and some are found only in restaurants (the Weight Watchers symbol in Applebee's restaurants). All have different nutrition criteria—some are all encompassing, and some point to specific macronutrients or calories. Competition does not seem to be driving the market toward a single, superior solution, probably because the sheer number of food producers creates a coordination problem.

For consumers, this presents a somewhat bewildering jumble of signals. In addition, manufacturers might find themselves in a position where they will need to have multiple labels and multiple formulations to sell in different supermarkets if each decides on a different symbol.

12. 295 U.S. 495 (1935) at 537. Cited in Rose-Ackerman, "Consensus versus Incentives," 1216.

The Keystone group is now working with manufacturers, retailers, academics, and consumer organizations to produce a universal symbol that will help consumers to select healthier products. The social benefits of replacing this jumbled patchwork with a single standard are potentially enormous. The Centers for Disease Control and Prevention estimates that in the United States, the cost of treating cardiovascular diseases and strokes will amount to over $448 billion by the end of 2008.[13] Unhealthy diets contribute to this cost, since excess weight and obesity often leads to these ailments. In addition, poor nutrition has been linked to osteoarthritis, type 2 diabetes, and some cancers. The overall benefits of this labeling program (which will depend on how much these icons influence food choices) are likely to vastly exceed the costs.

ANTITRUST

Despite the enormous potential for mediatory groups like Keystone, they may be considerably underutilized. This may be due to the barrier placed between companies by the government to prevent antitrust violations. "Competitor collaboration" comprises a set of one or more agreements, other than merger agreements, between or among competitors to engage in economic activity, and the economic activity resulting therefrom.[14] In order to avoid antitrust concerns, an agreement between firms must not either raise prices or reduce output; these are "per se" violations of the act. Other restricted activities include agreements that reduce quality, service, or innovation to below what would likely occur if the companies did not make such an agreement. Alternatively, some collaborations can benefit consumers if they result in more valuable or less expensive goods. This exception leaves some space for facilitated market solutions, but the wording remains too subjective. Clearer boundaries would help to promote these sorts of beneficial mediations.

An amendment to Executive Order 12866, which requires benefit-cost analysis of all new regulations, could require that before government agencies determine that they will promulgate regulations where a privately mediated solution is possible, they should examine the possibility of encouraging this type of solution. In a single document, perhaps produced by the Department of Commerce in concert with the Federal Trade Commission and the Office of Management and Budget, the U.S. government could describe how to avoid any antitrust problems and simultaneously discuss the past successes of such agreements. It could encourage petitioners to various agencies to consider private negotiation first, inspiring a new way of thinking about resolving complex social problems that have at least part of their solution in the marketplace.

HOW THESE SOLUTIONS WILL HELP

The advantages of privately negotiated settlements include:

- Quicker solutions: Because all of the relevant parties are present and agree to a set of rules beforehand, solutions to social problems can come much more quickly than through the cumbersome notice-and-comment rulemaking.
- More creative solutions: The involved stakeholders are not bound by antiquated laws or precedents that must be stretched; they are free to come up with novel solutions.
- Necessary expertise readily available: The stakeholders often have all of the relevant data that needs to go into decision making and, as

13. Division for Heart Disease and Stroke Prevention, "Addressing the Nation's Leading Killers 2008," Centers for Disease Control and Prevention, February 2008, http://www.cdc.gov/nccdphp/publications/AAG/pdf/dhdsp.pdf.
14. The Federal Trade Commission and the U.S. Department of Justice, "Antitrust Guidelines for Collaborations Among Competitors," April 2000, 2, http://www.ftc.gov/os/2000/04/ftcdojguidelines.pdf.

questions arise, can quickly pool that data in a form that preserves company privacy.

- No special influence: The process does not involve bureaucrats or oversight bodies making decisions that may advance their own utility at the expense of the stakeholders and society. In particular, agreements reached by these bodies can be made independently of whoever is in political power.
- Focus on solving problems, not addressing them: Many regulations result from intense pressure on bureaucracies to respond to a problem even when they do not have a good solution. They will produce something just to appear to be doing something about a problem without actually solving it. If all sides are well represented in a privately mediated agreement, this problem is unlikely to arise.

ADDITIONAL LONGER-TERM RESEARCH

In order to move these solutions forward, some questions remain to be answered, such as precisely how government can "encourage" facilitated market solutions or how government may otherwise be a relevant player. Also, it would be worthwhile to compare solutions reached by these groups and government regulatory solutions based on their efficacy at solving problems.

CONCLUSION

Facilitated market solutions hold a great deal of potential, but they have yet to be implemented on a large scale. Especially in a world where the regulatory bodies are constrained by the number of issues they can address at one time, private mediation might help resolve important social problems and lead to significant benefits for consumers. Obviously, there is only so much that the government can do to promote more of this type of mediation—since the process is voluntary—but regulators can smooth the road. First, they should reexamine antitrust rules to ensure that, in an attempt to stop oligarchic collusion, they are not also preventing beneficial arbitrations. Second, where social problems that must be addressed are identified, regulators might notify stakeholders about their concerns and recommend private mediation to resolve the problem. These might be regarded as the first steps to the regulatory process, instead of government agencies leaping directly into rulemaking procedures.

RETHINKING PROTECTION OF COMPETITION AND COMPETITORS

Bruce Yandle

THE REGULATION PROBLEM

Regulation of all forms—social and economic—is a deeply engrained feature of modern life. Social regulation covers health, safety, and environmental quality and specifies how particular goods and services will be designed, produced, and sold.[1] Economic regulation deals with energy, finance, securities, transportation, and communication and specifies who will operate in designated markets and how products and services will be priced. Almost inevitably, it seems, every rule written can limit competition and affect the fortunes of industries, firms, and agents that compete in the regulatory process.

Can the goals of regulation—for example, safer cars, cleaner air, and more dependable energy supply—be accomplished without simultaneously compromising competition in domestic and world markets? Put another way, can the protection and improvement of consumer well-being generated by competition be assured in the face of growing regulation? In other words, there are at least two ways for an economy to reduce risks and provide environmental benefits. This can be achieved by competitive market forces where firms and organizations competing for consumer patronage struggle to provide what consumers value. And where competition is lacking, improvements can be generated by regulations that affect market outcomes. But we know that regulation is not generated in a noncompetitive vacuum. Firms and organizations compete for regulation too.

There is strong demand for regulation. Consumers seek to improve the functioning of markets by harnessing government forces. Expanding regulation can also provide a valuable stimulus to interest groups that seek member contributions for successful efforts to gain favored government action. And regulation can become a form of corporate welfare. In the cases of interest-group or corporate-driven regulation, an over-expansion of regulation may end up making society worse off. Evidence shows that many regulations supported by industry can force competitors from the market and raise competitors' cost. Raising competitors' cost through regulation may contribute to higher prices and lower quality of goods and services for consumers. In many cases, consumer and environmental groups—which may not be familiar enough with the industry to understand the anti-competitive effects of a particular regulation—actually support industry positions and action that may cause long-term difficulties for consumers. For example, the 1990 Clean Air Act amendments that, among other things, required expanding coal-fired power plants to install scrubbers, even if clean coal was burned, were strongly supported by clean air advocates.[2] Left in the dust, so to speak, were electricity consumers who paid higher power bills. The amendments did not recognize that clean air could be achieved by simply switching fuels, and this was very pleasing to producers of dirty coal in the Eastern United States. Restrictions on the cutting of timber from public land in the Pacific Northwest were much celebrated by environmental groups who sought to protect northern spotted owl habitat. The restrictions significantly raised timber prices and the cost of building homes but also increased profits for timber companies who cut more timber from private land.[3]

At times, industrialists seek to replace widely varying state and local regulations with uniform federal rules, arguing that the playing field needs to be level. While getting the same rules for all parties may be helpful to firms that operate nationwide, the result can eliminate innovative lower-cost state regulations that are achieving useful regulatory outcomes. What is often presented to regulators as a way to level the playing

1. On this point, see Brito and Warren's review of federal regulation activity, Jerry Brito and Melinda Warren, *Growth in Regulation Slows* (Arlington, VA: Mercatus Center at George Mason University, 2007), 5. They report that the 2008 budget request to fund regulator activity came in at $46.6 billion. Of this, 85 percent was for social regulation, which would employ some 215 thousand workers, and the remaining 15 percent for economic regulation, where there were some 35 thousand proposed employees.
2. On this, see Bruce Ackerman and William T. Hassler, *Growth in Regulation Slows* (Arlington, VA: Mercatus Center at George Mason University, 1981).
3. "Owls, of all things, help Weyerhaeuser Cash in on Timber Profits," *The Wall Street Journal*, A1, 1992.

field in fact is a way of unevenly tilting the playing field (leveling the players in the field) in favor of those best positioned to influence regulatory bodies. Lost economic well-being is the result of these anti-competitive activities.

BACKGROUND OF THE REGULATION-COMPETITION PROBLEM

From the Magna Carta's thirteenth century specification of standards for cloth woven and sold in the kingdom (that just happened to match the looms of London weavers but no others), to the New London Colony's seventeenth century rules for bread baking (that just happened to shuffle more business to particular bakers), to the U.S. Environmental Protection Agency's 2004 settlement with domestic medium diesel engine producers (that opened the door to larger market share for Mercedes, Volvo, and other European producers), government regulation seem inevitably to provide favors to some competitors at the expense of others.[4]

When firms in an industry use regulation strategically, they are able to raise competitors' costs or shut out competition entirely.[5] Paradoxically, even antitrust law enforcement can fall victim to anti-competitive behavior.[6] Firms already operating in a market, perhaps inefficiently, can use antitrust merger reviews as a way to fend off unwanted takeovers.[7] Even more blatant blunting of competition emerges if firms within an industry call for federal action when competitors cut prices in a market battle to gain customer patronage. And while outright collusion by private firms to cartelize markets is generally prohibited by antitrust law, an even more durable result can be achieved legally through regulation.[8] For example, the regulation of rates and entry by firms in an industry by the Federal Communications Commission, Interstate Commerce Commission, and state public utility commissions historically accomplished the same end as a private cartel. Prices are set high enough to maintain profits for the least efficient firms and entry is blocked so that profits continue. Environmental regulations that set stricter standards for new sources than for older ones accomplish the same thing. The stricter standards serve as a legal barrier to entry, which enables existing firms to earn higher profits.

QUICK AND NOT-SO-QUICK SOLUTIONS TO THE PROBLEM

In the short term, the executive branch can offer agencies clearer guidance regarding which type of regulation will best enhance consumer welfare without restricting competition or innovation. For exam-

4. Economists refer to human action designed to gain political favors as rent-seeking behavior. For an excellent compendium on the topic see James Buchanan, Robert D. Tollison, and Gordon Tullock, *Toward a Theory of the Rent-Seeking Society* (College Station: Texas A&M Press, 1980. On the early history of the use of regulation to raise competitors' costs, see Bruce Yandle, "Intertwined Interests, Rentseeking, and Regulation," *Social Science Quarterly* 65 (December 1984): 1004–1012. The diesel engine analysis is found in Andrew Morriss, Bruce Yandle, and Lea-Rachel Kosnick, "Regulating Air Quality Through Litigation: The Diesel Engine Episode," (PERC Research Studies, Property and Environment Research Center, Bozeman, MT, 2002. The three examples cited here illustrate Yandle's Bootlegger-Baptist theory of regulation (Bruce Yandle, "Bootleggers and Baptists: The Education of a Regulatory Economist," *Regulation* 7, no. 3, (1983): 12–16). which argues that durable consumer protection and environmental regulation emerges when supported politically by one group (Baptists) that take the moral high ground and argue for consumer benefits and another group (Bootleggers) who seek the same regulation for financial gain.

5. For an early but extensive review of this, see Federal Trade Commission, *The Political Economy of Regulation: Private Interests in the Regulatory Process* (Washington, DC: Federal Trade Commission, 1984).

6. See Fred McChesney and William Shughart II, The Causes and Consequences of Antitrust: *The Public Choice Perspective* (Chicago: The University of Chicago Press, 1995).

7. Ibid.

8. Cartelization of markets by agricultural producers is not just a legal option, but it required when USDA marketing orders dictate collusive action. U.S. antitrust agencies are prohibited from enforcing antitrust laws in the agriculture production sector.

ple, performance standards that provide incentives to compete may be preferred to the "one size fits all" command-and-control regulations that reduce competition. In addition, the executive branch can instruct agencies to identify not just overall benefits and costs, but also which groups stand to win and which to lose should a given regulatory option be enacted. To be more specific, the Office of Management and Budget's Office of Information and Regulatory Affairs (OIRA) located in the Executive Office of the White House, is charged with reviewing newly proposed regulations in an effort to reduce their burden while accomplishing regulatory goals. In addition to monitoring and reporting on federal regulation and assessing regulations on a benefit/cost basis, OIRA might ask agencies to address the effects of new rules on domestic and international competition.

Competition and regulation can be balanced in other ways as well. In many cases, regulatory goals can be enhanced by tort law or government-assisted quality assurance. For example, common law protections afforded by the law of nuisance and fraud provide for a cause of action against actors who damage consumers. Common law rules provide for actions that might be taken by private parties who are damaged or by public defenders who sue on behalf of a larger number of similarly affected individuals.[9] In other cases, government as a low-cost provider of information may use its information-gathering and -dissemination powers to enhance the operation of markets. For example, the Singapore government licenses firms to use a government seal of approval on consumer products that satisfy what the government perceives to be the appropriate standard of quality based on surveys.[10] However, no firm is required to meet the government standard. Products with and without government seals compete in the marketplace. Government regulators expect the products with government seals to command a higher price. When that does not happen, the regulators go back to the drawing boards.

Longer-term regulatory-competition balance may be secured if Congress develops regulatory legislation that avoids technology-based standards entirely and encourages the use of economic incentives. For example, reauthorization of major environmental and consumer product safety statutes provides an opportunity to allow the use of outcome-based regulation along with or instead of technology-based command-and-control regulation. Then, instead of setting precise engineering standards for improving water and air quality and for the production of consumer products, the regulatory agencies would set outcome-based standards and then impose sanctions when performance is achieved. Alternately, revised statutes could allow the use of prices, fees, and taxes as incentives for reducing unwanted harms. Taking this broader approach will be particularly important for international standard setting.

Further, OIRA should specify the order in which regulatory options must be considered, thereby strengthening the relative importance of performance standards and economic incentives in relation to command-and-control regulation. This action could be supported by the development and passage of complementary legislation.

By enacting these proposals, Congress and the executive branch can lower the overall cost of regulations substantially and facilitate increased competition in regulated industries. Implementation of these and similar proposals will both achieve regulatory goals and promote the competition that generates less expensive goods and services and improved social well-being for U.S. consumers.

ENACTING SOLUTIONS: REAL-WORLD SOLUTIONS

Consider now some recommendations that are designed to grease the rails for securing balance between regulation and competition.

9. Bruce Yandle, *Common Sense and Common Law for the Environment* (Lanham, MD: Rowman & Littlefield Publishers, 1997).

10. Bruce Yandle and Simon Rottenberg, *The Regulation of the Quality of Traded Commodities and Services in Developing Countries* (World Bank discussion paper no. IDP-11, Latin and the Caribbean Region Series, Washington, D.C., 1987).

- Performance standards (outcome-based regulation) or economic incentives should serve as the foundation for regulation in any legislative initiative. Technology-based, command-and-control regulation should be avoided where possible. The order of consideration for regulatory options should be required by executive order.
- A congressional regulatory review unit similar to OIRA should be authorized to oversee the regulatory activities of independent regulatory agencies.
- To satisfy OIRA's review, agencies should be required to perform an assessment of the effects of major regulation on competition.
- OIRA should be authorized to require executive branch agencies to obtain OIRA review of litigated settlements when the settlement includes regulation.
- All regulatory agencies should be required to assess the effect of enforcement on the competitiveness of the U.S. economy before taking enforcement actions.
- All regulatory agencies should maintain an office devoted to reducing the cost of global regulation by reducing anti-competitive effects of regulations. Further, each agency should be required to provide an annual report of international activities to OIRA.
- Agencies that develop voluntary standards should license the use of an agency seal to be used on consumer products that signals agency approval and puts the agency's "brand" at risk.

DISCUSSION OF SOLUTIONS

To flesh out the solutions identified above, this paper explores the following three questions:

- How can the legislative process be reformed to give regulators more flexibility for achieving regulatory outcomes when interpreting directives from Congress?
- How can we ensure that regulations designed to address competition and consumer protection focus exclusively on consumer welfare?
- Given the growing importance of global trade, how can we best reduce costs of compliance with multiple sets of regulatory rules from different countries, thus promoting trade?

A. How Can the Legislative Process Be Reformed to Give Regulators More Flexibility for Achieving Regulatory Outcomes when Interpreting Directives from Congress?

When Congress passes legislation that is designed to achieve a particular regulatory goal, affected firms may have an incentive to behave anti-competitively. This anti-competitive behavior may result when firms use regulatory agencies to limit competition by, for example, raising existing or potential rivals' costs, or by persuading agencies through the use of differential standards to block entry of new competitors. As mentioned earlier, current regulations that impose stricter standards on newly constructed factories than on existing ones serve as barriers to entry.

Some regulatory instruments provide greater opportunities for anti-competitive behavior than others. Moreover, some regulations may prompt competitive responses in the domestic economy while reducing global competition and stifling innovation. The choice of regulatory instrument—listed below from most- to least-restrictive—will determine the likelihood that competition is reduced. Technology-based standards are the riskiest for reducing competition; performance standards (outcome-based regulation) are the least risky.

- Technology-based, command-and-control regulation
- Economic incentives (fees and taxes)

- Cap-and-trade
- Requiring information/labeling
- Performance standards

Technology-Based, Command-and-Control Regulation

Both the U.S. Clean Air Act and Federal Water Pollution Control Act, passed in 1970 and 1972 respectively, provide classic examples of technology-based, command-and-control regulation. These two acts instruct the U.S. Environmental Protection Agency to define best-available, best-practicable, and other specified technologies that, when installed and operated, reduce otherwise uncontrolled emissions by predictable amounts. Once specified by the agency, every firm in a regulated industry, generally speaking, must apply the specified technology fix to designated discharge points. The clean air and clean water legislation carries command-and-control one step further by requiring differential treatment of old and new pollution sources.

As a regulatory package, these pieces of legislation establish enormous potential gains for firms that successfully influence the choice of technologies required across their industry. Operators of existing plants have an additional incentive to influence stiffer standards for newly constructed pollution sources built by competitors. From a firm's standpoint, appropriately designed technology standards can raise competitors' costs. Indeed, if a firm is successful in imposing its own practices on other firms that operate differently, the successful firm will encounter no cost effects. Like the London weavers mentioned in the introduction, however, the resulting rule will raise competitors' costs—a development that enables the favored firm to gain market share and additional profits. From an industry standpoint, an appropriately specified differential standard for new sources can reduce future output growth and enable higher prices and profits to be sheltered by regulation.

When Congress legislates technology-based, command-and-control regulation, the regulator is constrained to adopt particular regulatory solutions. Once in place, the resulting rules can effectively cartelize industries and protect existing firms from new competition. While this approach may indeed reduce pollution or some other unwanted risk, it may also weaken the beneficial effects of competition and the longer-run ability to install cleaner or safer technologies. Such a regulatory choice freezes technologies that may be used for pollution control or other risk-reduction purposes; reduces the search for cleaner and safer production processes; raises consumer prices for goods; and, unless otherwise blocked, invites lower-cost, global competition. When combined with differential standards between new and old sources, command-and-control further cartelizes an affected industry and further reduces consumer well-being. Again, it is possible that these actions simultaneously reduce unwanted pollution or other risks, evidencing the possibility of gains on one side of the consumer well-being ledger and losses on the other side.

Command-and-control regulation emerged in the 1970s during America's "smokestack era," a period when heavy manufacturing dominated the industrial scene and one set of rules for steel making, foundries, and copper smelters might be devised and required across somewhat homogeneous industries. Whether the problem under consideration was pollution, worker safety, safer lawn mowers, or more efficient appliances, Congress more often than not moved in the direction of technology-based standards. The smokestack era has passed, but smokestack regulations and their high potential for anti-competitive effects are still with us.

Economic Incentives

Using taxes and fees to ration undesired activities generates an entirely different set of incentives. For example, instead of telling industrial users of treatment services how to construct their plants, most municipal operators of sewage treatment plants require industrial firms that discharge into sewer lines for

later treatment to pay a fee based on the costs of treating the discharged waste. The higher the fee, the more likely the discharger will pretreat waste or reduce discharge. Thus, the fee provides a powerful incentive to protect environmental quality. California's South Coast Air Quality Control Region uses emission fees, together with required federal technology, to reduce unwanted emissions and simultaneously generate the revenue needed to operate the regulatory agency. Affected firms in the south-coast region receive a fee schedule explaining that higher emissions require higher total payments to the regulator. Thus, the outcome produced by command-and-control is achieved via neutral economic incentives that do not inhibit innovation or competition. The agency does not tell a firm how to reduce emissions, does not charge different fees for new and old sources, and does not protect competitors.

A much-celebrated early twentieth century example of the use of economic incentives was the use of effluent fees to control water pollution in the Ruhr River basin of Germany.[11] The Ruhr River Association gave waste discharging firms seeking to locate or expand in the region a price schedule that would determine the amount to be paid per unit when discharging into the river. The fee system gave firms an incentive to find low-cost ways to avoid discharging waste and encouraged the discovery of superior technologies, harnessed competitive forces to improve the environment, and did not reduce competition in product markets. As a result, industries and municipalities reduced discharge into the river, thereby improving the environment. The fees system further improved the environment because the revenue from collected fees paid for building water treatment plants and improving the region's environment in other ways. These present-day and historic examples indicate that the use of economic incentives reduces unwanted pollution (providing consumer benefits) without imposing costs on the other side of the consumer ledger. Of course, the potential use of economic incentives extends far beyond environmental regulation. Fees based on excess occurrence of accidents or product defects in consumer goods can substitute for technology-based standards, thereby avoiding the technology-freezing aspect of command-and-control.

Further, economic incentives focus on outcomes, not on inputs. They seem to be adaptable to a diverse economy not dominated by heavy industry. When using economic incentives—vital because they preserve the consumer benefits that flourish in a competitive marketplace—regulators must emphasize the importance of monitoring performance and measuring overall outcomes.

Cap-and-Trade Regulation

The U.S. approach to limiting sulfur dioxide emissions in the eastern half of the nation provides an excellent example of cap-and-trade regulation. The 1990 Clean Air Act amendments that spawned this regulatory approach instructed the EPA to develop regulations that would reduce total emissions by a specified amount. It also instructed the EPA to allocate the reduction burden across coal-fired electric utilities roughly on the basis of emissions in an earlier baseline period. Plant operators were given the option of reducing emissions at the plant level to meet the target or paying a plant in a different location to make reductions beyond its allocated reduction burden.

The cap-and-trade process spawned a search for lower-cost ways to reduce sulfur dioxide emissions. By its very nature, cap-and-trade is an output restriction; by restricting emissions it leads to reduced output and higher electricity prices. But the instrument itself provides profit opportunities to firms that produce more emission reductions and penalizes those that produce fewer reductions. The instrument does not inherently raise competitors' costs or impede expansion from new competitors. Indeed, prior to implementation of cap-

11. David W. Riggs and Bruce Yandle, "Environmental Quality, Biological Envelopes, and River Basin Markets for Water Quality" in *Water Quality in the Next Generation*, eds. Terry L. Anderson and Peter J. Hill (Lanham, MD: Rowman & Littlefield Publishers, 1997), 147–167.

and-trade legislation, Congress required coal-fired utilities to install scrubbers on all newly constructed plants, even if the plant could achieve clean air goals by burning low-sulfur coal. This earlier, technology-based approach eliminated competition from low-sulfur coal producers, required installation of a particular high-cost technology and thereby reduced incentives to discover lower-cost ways to produce cleaner air.

Cap-and-trade regulatory instruments induced competition for cleaner production, spur discovery of lower cost producers of clean air, and put market-determined prices on expansion of output by new or existing firms. All producers face an emission constraint. While both pollution and output are reduced, the competitive search for pollution reduction approaches tends to minimize the cost of achieving the regulatory goal.

When using cap-and-trade as a regulatory instrument, the regulator is challenged to determine a baseline level of pollution or unwanted risk from which to require reductions. Because of the baseline challenge, cap-and-trade is more likely to be applied across well-identified, large producers of pollution or risk. Once the regulations are in force, the regulator must focus on outcomes.

Requiring Information/Labeling

Point-of-sale information requirements are commonplace for many consumer goods. For example, instead of specifying standard recipes for food products and over-the-counter drugs, regulatory agencies require producers to list ingredients and nutrition content. In some cases, the agency specifies a glossary of terms that must be used when developing labels and advertising language.

For its part, the U.S. Department of Energy requires producers of certain electrical appliances to estimate and report annual energy use, the EPA requires auto companies to label prominently the fuel economy expected for new cars based on EPA testing, and the Federal Trade Commission requires textile and apparel product manufacturers to provide permanently attached care labels for consumer products. In each of these cases, the regulator assumes the technical burden of being the source of the information or approving the information supplied by producers.

While generally placing fewer restrictions on competition and innovation than technology-based standards, labeling requirements carry the risk that open-market competition will be biased in favor of certain producers. Given this risk, regulators may wish to consider adopting a voluntary approach for improving consumer information. The widespread use of ecolabels in the European Union, for example, attempts to highlight products that have low environmental impact. To use them, producers must provide technical product information that is then compared with government-approved standards to determine whether the product satisfies the standard. Because no producer is actually required to meet the environmental standard, competition between labeled and unlabeled products remains intact.

Performance Standards

The simplest tool (with the least anti-competitive baggage) available to Congress, should it wish to achieve a particular regulatory goal, is the performance standard approach. Instead of specifying how to accomplish a goal, performance standards announce the goal to be achieved, describe how results will be measured, and stipulate penalties imposed for regulatory failure. Of course, Congress could pass performance-standard legislation that specifies different standards for particular products or sectors and, in so doing, induce anti-competitive effects.

Corporate average fuel economy (CAFE) standards provide an example of performance standards and also illustrate how differential performance standards can be used to raise competitors' costs. When CAFE standards were first required for new cars sold in the United States, Congress specified a required outcome rather than instructing the U.S. Department of Transportation to specify the kind of engines, carburetors, and ignition systems that might accomplish

the same goal. In fact, Congress specified the end-period standard to be met for the new U.S. car fleet and instructed the Department of Transportation to specify standards for intervening years.

Since the pace for achieving performance standards was determined in the resulting rulemaking, competitors behaved strategically when lobbying for reduction timing that favored them. For example, firms with a high-mileage fleet favored an earlier schedule for heavier fuel economy gains. Those firms already meeting the fuel economy standard faced no new costs. Those performing below the standard had to alter vehicle design to meet the standard. However, the redesign was unconstrained. Producers could change ignition, weight, fuel, tires, and other vehicle features to gain fuel efficiency; thus competitive forces played through the process. Initial positions, model mix, and technical advantages helped some firms achieve the standard at lower costs than others.

Of course, fuel-efficiency standards were not quite so simple. Different rules were in force for domestic and foreign fleets as well as for trucks and cars. This distinction required regulators to define what constituted a truck versus a car and a domestic- versus foreign-produced car. As it turned out, SUVs became hugely popular because CAFE standards for trucks were set lower and SUVs more readily satisfied consumer demand for larger higher-powered vehicles. In the final analysis, CAFE standards induced differential effects across vehicle types; manufacturing firm specialization (large, as opposed to small, vehicles); and domestic versus foreign producers. In addition, and most controversial of all, implementation of CAFE standards led to lighter, less-safe automobiles and, as a result, an increase in highway fatalities.

CAFE standards notwithstanding, performance standards are generally neutral with respect to firms and technologies. When applied without special treatment for product or producer types, performance standards bring no particular bias to the marketplace. Indeed, they encourage competition at every margin. If the Clean Air Act, for example, had been based on performance standards (the approach used in earlier versions of the act developed in committee[12]), rather than technology-based, command-and-control standards, a case can be made that clean air goals would have been accomplished sooner and at much lower cost. The same statement can be made for safety and health legislation that call for technology-based standards.

Performance standards are better suited for a highly diverse economy not dominated by large, easily targeted industries; thus they seem far better suited to America's service economy than other regulatory instruments. The critical elements required for a performance standard to work are a well-defined standard and a readily measurable metric to monitor and report progress toward meeting that standard.

Establishing Priorities: Ordering Regulatory Options

In general, agencies should examine the existing market and regulatory structure—not only to gain a sense of the existing problem, but to assess how the market is likely to evolve in the near future. (By the time a regulatory agency is aware of a problem and can actually act on it, it is possible that the market has moved ahead of the agency.) Moreover, agencies should consider providing guidance regarding how market participants might use agency research and expertise to solve a problem without agency intervention. If, in fact, the agencies do not believe that solutions exist, they should consider not regulating in favor of investing in research to discover solutions. Third, agencies should consider encouraging, or actually engaging in, facilitated market solutions. Fourth, agencies should consider mandatory provision of information to solve social problems. Following these options, agencies should consider—in order—performance standards, cap-and-trade rules, and economic incentives as regulatory instruments. As

12. On this, see John C. Whitaker, *Striking a Balance: Environment and Natural Resources Policy in Nixon-Ford Years* (Washington D.C.: American Enterprise Institute, 1976).

a last resort, if none of these solutions will achieve the regulatory objective, specific requirements (command-and-control) should be considered.

B. How Can We Ensure that Regulations Designed to Address Competition and Consumer Protection Focus Exclusively on Consumer Welfare?

The discussion of incentives to engage in anti-competitive behavior illustrates how regulations designed to provide consumer benefits (e.g., cleaner water or more fuel-efficient cars) can simultaneously reduce consumer well-being in another area by chilling innovation and by reducing competition and competitive entry. How, given this possibility, can regulatory procedures can be improved so that innovation, competition, and—ultimately—consumer well-being remain strong?

Cases discussed in the previous section suggest that, broadly speaking, Congress should focus more on the goals of legislation that benefits consumers rather than specifying the precise means for achieving the goals. Practically speaking, this means avoiding technology-based standards and encouraging the use of performance standards or economic incentives in regulatory legislation. Then, when legislation-driven regulations are drafted, regulatory review should assess effects on consumers, including the effects on domestic and global competition, and on innovation. Another step to ensure that regulation generates overall consumer benefits occurs when regulatory agencies exercise discretion regarding enforcement action. Fostering changed behavior depends on a combination of legislative and executive branch actions. Whether written into law or initiated by presidential executive order, regulators can be instructed to ask a second question—What about competitive effects?—before initiating actions intended to protect consumer welfare. Let us consider how this might work.

Asking a Second Question When Regulating

Regulatory agencies may provide consumer benefits by issuing new rules and enforcing existing rules. In either case, the agency must demonstrate the legal authority to act, which is to say any action taken must be consistent with the agency's statutory authority. Assuring this to be the case relates to the first question to be answered. If the matter relates to issuing a new regulation, the agency must show that Congress authorizes the action. The question for the regulator is this: Are we authorized to initiate a rule? When proposing new rules that have a substantial effect on the economy, executive branch agencies must pass muster with OIRA's regulatory review authority, which stems from executive orders that have evolved since the Ford administration initiated the first regulatory review process in 1974.

Current OIRA authority rests on amendments to Executive Order 12866 issued by the Clinton administration in September 1993. It is noteworthy that the order requires agencies to "identify and assess available alternatives to direct regulation, including providing economic incentives" and to consider "incentives for innovation." The order goes on to require that agencies "to the extent feasible, specify performance objectives, rather than specifying the behavior or manner of compliance that regulated entities must adopt."

However, the current executive order does not emphasize the importance of considering effects on competition—as did the original Ford administration order issued in 1974.[13] To recognize the critical importance of the potential anti-competitive nature of regulation, the OIRA executive order should be amended to stipulate that agencies ask a second, but vital, question: What are the possible effects on global and domestic competition? In fact, they should be required to make a separate, distinct, thorough assessment of the effects of a proposed regulation on competition, domestic and global. The order should be further amended to

13. See Executive Order 11821, *Code of Federal Regulations*, title 3 (November 27, 1974) which states: "the Director must consider . . . [the] effect on competition."

require agencies to provide a final tally of the total welfare effects of a proposed rule that takes account of the expected net benefits to consumers and the negative effects, if any, generated by reduced competition.

Even if OIRA's review process is strengthened by asking such a "second question," there is a remaining matter of review coverage to consider. OIRA's required reviews apply only to executive branch agencies. Independent agencies such as the Federal Trade Commission, Federal Communications Commission, and Consumer Product Safety Commission are not included in the review process. Recognizing that independent agencies cannot be made subject to OIRA's demands requires development of a second review procedure. Such a procedure could involve adding a regulatory review process to the responsibilities of the Congressional Budget Office (CBO), which some have suggested serve as a Congressional Office of Regulatory Analysis.[14] If this approach were taken, the CBO should establish review requirements similar to those of OIRA. While CBO would not have the same administrative authority that OIRA exercises when requiring responses from executive branch agencies, CBO could be required to publish its reviews and provide recommendations to congressional oversight committees. Requiring this CBO activity would bring parallel treatment and equal transparency to regulatory actions taken by independent regulatory agencies.[15] The beneficial effects of public debate and discussion would follow.

Asking a Second Question When Enforcing Regulations

When it comes to enforcing existing regulations, an agency's first question is, "Has the law been broken?" Its second question, then, is, "Are the expected benefits of action greater than the costs imposed by action?" Answering this second question in enforcement matters requires the agency to confront the consequences of any action it may plan to take.

If the matter is enforcement of existing regulations, the agency must demonstrate first that the law has been broken. The second question in enforcement matters requires the agency to confront the consequences of the action it may take. Will the expected benefits of action be greater than the costs imposed by taking action? Regulators must consider the resource cost expended by the agency in bringing action and the costs imposed on the economy—including such costs as competitive effects. Given scarce agency resources, there will always be more opportunities to go after rule violators than there are resources for doing so.

An additional problem arises when firms in an industry attempt to blow the whistle on competitors in the hope of raising competitors' costs. Enforcement of the Robinson-Patman Act may provide an example of using regulation to reduce competition. This piece of antitrust legislation addresses price discrimination, which can be broadly interpreted as cutting prices for one customer or group of customers but not for all. There are defenses, of course, but it is clear that when firms complain to antitrust authorities about their competitors, it is highly likely that something other than consumer harm is at stake. A successful Robinson-Patman action can require sellers to charge the same price to all consumers, which of course is the same outcome desired by illegal cartels. When enforced stringently, these actions can chill normal tendencies to use price as a competitive instrument for expanding sales and at the same time expanding consumer benefits.

14. Hahn and Layburn (2003) suggested that the Congressional Office of Regulatory Analysis would be given all-encompassing oversight responsibilities for assessing the impact of regulatory activity at all regulatory agencies—executive branch and independent agencies (Robert Hahn and Erin M. Layburn, "Tracking the Value of Regulation" *Regulation* 26, no. 3 (Fall 2003): 16–21). Separation of powers suggests that two review agencies may be required, one for independent agencies and the current OIRA, which is responsible to the executive branch.

15. William Niskanen (2003) suggests making a fundamental change in the authorization of regulatory agencies, which would remove their capability to promulgate rules after notice and due process procedures. He argues that since regulations are laws, Congress should review all proposed regulations and then have an up or down vote on any rule a member recommends for action (William C. Niskanen, "More Lonely Numbers" *Regulation* 26, no. 3 (Fall 2003): 22).

When agencies bring suit against regulated firms, it is possible for agencies to arrive at settlements that actually involve more industry-wide regulation, termed "regulation by litigation." Asking the second question in such circumstances requires agencies to justify their actions in a different way. If the intended litigation outcome is regulation instead of enforcement of rules, then the agency should be required to use traditional notice-and-comment regulation instead of the courts. Traditional regulation provides due process opportunities for all interested parties to participate in the regulatory process. Litigation closes the door to comments by parties who may be affected by the regulatory outcome, which itself is not justified on the basis of benefit-cost analysis or competitiveness analysis.

When the effects of agency litigation are large enough to impose significant costs on the economy, OIRA should be authorized to require executive branch agencies to submit their plans for OIRA review, especially if the agency is engaged in regulation by litigation. Then, building on the earlier recommendation regarding new duties for the Congressional Budget Office, independent agencies engaged in significant enforcement actions should be required to submit their plans to CBO for review.

Asking the second question is as important as asking the first question when new regulatory and enforcement actions are taken. Doing so requires agencies to justify their actions on the basis of their effects on all dimensions of consumer well-being. Including independent agencies in regulatory review processes offers incentives for greater sensitivity to consumer well-being and ensures accountability and improved transparency.

C. Given the Importance of Global Trade, How Can We Ensure that Consumers Are Protected Without Protecting Competitors or Hobbling Productivity and Innovation?

Recent events involving unexpected low quality of imported consumer products in U.S. markets brings to the fore the importance of quality assurance in global trade. The discovery of lead in imported toys and pathogens in imported foods are newsworthy because these events are rare, relative to the overall volume of imported products. Nonetheless, any unfortunate harm that befalls consumers also reminds us that quality assurance can be improved. How, then, can quality assurance institutions be strengthened in ways that maintain competition while expanding global trade opportunities?

Quality-Assurance Institutions

Consumers in American supermarkets are seldom, if ever, nervous about the safety of the food on the shelf or in bins, even when food items are fresh and open for inspection to passersby. In what might be thought of as a modern miracle, millions of consumers daily purchase goods, prepare and consume them, and enjoy good health. Though government intervention plays a vitally important role in the safety of meat and dairy products, private market forces drive most quality assurance endeavors. This is also true of other consumer items, among them automobiles, clothing, furniture, toys, and appliances.

The vast network of quality assurance factors that afford remarkable consumer protection includes:

- Market competition
- Brand-name capital
- Financial-market monitoring
- Liability insurance
- Common and code law
- Private certification and inspection services
- Government regulation

Private-Market Quality Assurance

Open-market competition is the strongest force in the web of mechanisms that ensure marketplace quality. When buying and using products, consumers

make choices, become informed, and reward with patronage sellers who provide goods and services that satisfy consumer needs. Firms producing shoddy merchandise will not succeed among consumers who seek goods of predictably high quality. The greater the level of competition for consumer patronage, the more readily available is a supply of high-quality goods. When competition is limited, for whatever reason, consumers stand to suffer, since the incentive to earn patronage by providing reliably high-quality goods and services is not as strong as it is when competition for patronage is fierce.

However, the presence of brand names in the marketplace provides quality assurance, even when competition is less active. Firms (and individuals) invest in brands through advertising and other selling expenditures. Thus, the delivery of faulty products can reduce or even destroy the value of the brand investment; firms go to great lengths to ensure that quality protects the value of the brand—a major asset in the marketplace.

In addition to product and service brands, strongly preferred seller brands are also invaluable and can replace product brands when it is difficult for consumers to monitor or identify producer reputations. Big-box retailers such as Lowe's, Home Depot, Wal-Mart, J.C. Penney, and Sears bring hundreds of thousands of items under their roofs and offer guarantees of quality. Once the seller's brand name is put at risk for one item, it is at risk for every item. Such retailers stand in a consumer's stead when insisting on quality assurance from suppliers, regardless of whether the supplier is local, national, or international.

Similar quality assurance forces affect upstream suppliers. Food manufacturers buy ingredients from both domestic and international suppliers. Unlike the FDA, which inspects food plants at most once a year, upstream suppliers (and insurance companies) inspect some food plants once a week, often on a random basis, and inspection standards usually far exceed those set by the government. Thus, private-market contracts and inspections are the primary drivers of food safety and quality.

The quality assurance effects that competition and brand name protection foster are reinforced by credit-card issuers and financial-markets' monitoring. Credit companies provide consumer guarantees by permitting consumers, who find a purchased item unsatisfactory, the right to refuse payment. The credit card company then brings its pressure to bear on the seller. Similarly, financial markets put indirect, but heavy, pressure on firms that produce faulty goods and services. Stock-exchange-listed producers and sellers are put at risk by the market, because investors are risk averse and dislike bad news, whether it is about earnings, law suits, or product recalls. When bad news about a producer surfaces, investors tend to sell shares in the firm first and ask questions later. The selling of shares reduces equity values, raises the cost of capital, and makes it more difficult for the punished firm to expand.

Of course, firms can and do purchase insurance to reduce exposure to the unfunded risks of poor performance. When they do purchase protection, the insurance company adds yet another element to the web by requiring quality-assuring behavior.

Though competition, brand-name capital, credit-card companies, financial-markets monitoring, and insurance requirements bring quality assurance to the marketplace, still other mechanisms protect consumers. Common law provides one of the oldest protections to U.S. consumers. When a seller fails to deliver the quality promised or expected, consumers may have a cause of action against the seller. Of course, bringing suit is expensive, but the threat is real—especially when many consumers have been harmed by one seller's failure to provide goods and services as promised. Where the scope and magnitude of harm is large, lawyers who specialize in mass-tort cases can organize and fund action on a contingency-fee basis. Public defenders may also bring action on behalf of harmed consumers.

There is yet another category of private activities to consider. Credentialing organizations like Underwriters Laboratory, Good Housekeeping, the Better Business Bureau, chambers of commerce, and other organizations make an additional brand avail-

able to consumer product providers who meet such organizations' quality standards. To these are added international organizations like the International Organization for Standardization, a non-governmental organization headquartered in Geneva that coordinates and harmonizes standards for goods traded in global markets.[16] ISO is a network of the national standards institutes of 157 countries and certifies firms that meet its standards. Inspection services firms also work to ensure quality. These for-profit businesses inspect, certify, and guarantee products, processes, and construction.[17]

Government-Assisted Quality Assurance

Government-assisted quality assurance comes in several forms. For example, the U.S. Consumer Products Safety Commission (CPSC) provides technical guidance to firms by (1) developing technical standards and regulations for consumer goods as varied as dart boards, baby beds, bicycles, toys, electrical appliances, household cleaning compounds, and beyond; and (2) giving guidance for voluntary standards developed by standards organizations such as the American National Standards Institute (ANSI) (www.ansi.org). The ANSI holds membership in the International Organization for Standardization. As this example demonstrates, then, CPSC affects standards for products produced and sold in the United States and also indirectly influences product standards that may be adopted by international producers in the global marketplace. Together with its other regulatory powers, CPSC has authority to force product recalls, impose fines, and ban the sale of products the agency determines are high risk.

The development of voluntary technical standards leaves room for some cartel effects when larger firms dominate the process, but it softens the possibility by allowing for innovation across firms that opt for an alternate approach. Singapore, for example, encourages quality assurance in consumer markets by licensing firms that meet the state standard to display a prominent seal of approval on their products. Firms that do not choose to have their products certified can compete head-on with government-approved products. The government regulators expect products with government seals to command a higher price. When that does not happen, the regulators assume that their seal has not added value and may therefore be encouraging product attributes not valuable in consumers' eyes. Feedback from the market leads to review of government standards.

U.S. regulatory agencies that coordinate development of voluntary standards should provide a licensed seal for display on consumer products that satisfy the standard. Such a seal both signals enhanced value to consumers and places the agency's brand name at risk.

U.S. regulatory agencies' participation in international standard-setting activities provides an important opportunity for executive branch oversight agencies such as OIRA to push for more flexible approaches. As noted earlier, performance standards provide the greatest incentive for firms to engage in the quest for low-cost ways to meet outcome-based consumer protection goals. Performance standards also reinforce competition and completely avoid the possibility of generating regulatory cartels. However, use of this instrument comes with an administrative cost. The enforcement of performance standards means that the regulator must observe performance data and impose fines when performance is not forthcoming. Moreover, the expected value of the fines must cause firms to choose performance instead of avoidance. Of course, technical standards must also be enforced, but where cartel effects exist, there is an incentive internal to industries to cooperate with the regulator's enforcement efforts.

16. Their web address is www.iso.org.

17. SGS, which is also located in Geneva, Switzerland, (www.sgs.org) is one of the largest and most globally extensive of these firms. It should be noted that there are a host of product-specific and general consumer product magazines and publications that test, review, and rate consumer products. *Consumer Reports* is perhaps the best-known example of this.

As globalization expands to the limits of markets' capabilities to produce and ship goods across world markets, the work of organizations such as the World Health Organization, the Food and Agriculture Organization of the United Nations, and the World Trade Organization to avoid cartels generated by quality standards becomes critically important.[18] Congress should explicitly encourage this global quality assurance web when it writes any form of consumer protection legislation. Each U.S. regulatory agency should be required to have an office that participates in cooperative efforts to reduce the regulatory burden affecting goods and services exchanged in world markets and, in the process, each office should work toward harmonizing standards where doing so reduces consumer costs. In every case, such offices must explicitly consider what effects actions taken will have on competition and should be required to report on these activities to a regulatory review group—whether OIRA or a review group that oversees independent regulatory agencies.

FINAL THOUGHTS

This paper reviewed public and private regulatory procedures developed to ensure that markets will deliver higher quality, lower-cost goods and services to consumers. The scope of these activities is as vast and varied as the participants that operate in global markets. Central to the discussion is the idea that efforts to improve human well-being through regulation can weaken competitive forces to the point that consumers may actually be harmed rather than protected. The analysis focused first on incentives included in the various regulatory approaches that government might develop for accomplishing a given regulatory goal. The incentive-based analysis recommended that government always attempt to avoid specifying technology-based standards and favor instead goal-oriented rules that focus on outcomes and not on regulatory inputs.

The discussion of regulatory processes noted that independent regulatory agencies operate outside the important regulatory review process required of executive branch agencies. Development of a regulatory review process within the Congressional Budget Office or as a separate congressional unit would close the regulatory review circle and raise the accountability of independent agencies to the public they seek to serve. When agencies decide to act, whether in issuing new rules or enforcing old ones, the analysis recommends that regulators ask a "second question" before taking action. The question would require them to assess the costs and benefits of the action, taking into account the effects of the action on competition in the marketplace.

Finally, the discussion of how to improve quality assurance in the global marketplace reviewed the complex web of quality assurance mechanisms that now operates across markets, regions, and countries. This review highlighted the importance of clearing houses, conferences, and nongovernmental agencies that together improve consumer protection.

Competition among firms, governments, and government agencies can improve human well-being, but regulatory actions taken to address important problems consumers face either can strengthen or weaken vital competitive forces. When agencies consider regulation, regulators should give critical attention to whether the benefits of regulation will be large enough to offset any anti-competitive effects such regulations may generate.

18. See Edward Groth II, "Assuring Food Quality and Safety: Back to the Basics—Quality Control Throughout the Food Chain—The Role of Consumers" for the Conference on International Food Trade Beyond 2000: Science-Based Decisions, Harmonization, Equivalence and Mutual Recognition (Melbourne, Australia: October 11–15, 1999), http://www.fao.org/docrep/meeting/X2602E.htm.

LESSONS FOR NEW TECHNOLOGIES

Gary E. Marchant

Emerging technologies often offer substantial economic, environmental, and health benefits to society. Yet, existing regulatory systems impede the development of many new beneficial technologies by subjecting them to discriminatory regulatory burdens and pressures. This paper describes the discriminatory regulatory approach affecting many emerging technologies and suggests approaches for leveling the regulatory playing field.

THE PROBLEM: DISCRIMINATORY REGULATORY BURDENS ON EMERGING TECHNOLOGIES

There is a growing consensus that current regulatory systems are systematically biased against new technologies. Twenty-five years ago, Peter Huber described how regulatory programs tend to target new technologies, products, and facilities disproportionately, even though these innovations often would replace riskier and older technologies, products, and facilities.[1] Experts from the World Resources Institute have observed that "[i]n an arena not noted for consensus, the worldwide community concerned with environmental policy is in remarkable agreement about the need for a new generation of technology," and bemoaned the "pervasive, implicit bias against new technology."[2] This bias suppresses beneficial new technologies to the detriment of the economy, public welfare, the environment, and public health.

Since Huber first described the problem of regulatory discrimination, it has only gotten worse. Regulatory discrimination is currently wreaking havoc on beneficial emerging technologies that have enormous potential to address many of the 21st century's most pressing problems. These new technologies include:

1. *Genetically Modified Foods:* Genetically modified (GM) foods created by modern biotechnology methods (which are used in medicine and other arenas as well) have begun to demonstrate an almost unlimited potential to increase the availability, quality, sustainability, and safety of foods. The first generation of GM crops have not only reduced costs and increased yield, but they have also produced demonstrated environmental benefits. Farmers have reduced pesticide use and shifted to using less environmentally harmful herbicides. Less destructive soil-tilling techniques have led to decreased soil erosion and run-off, improving water quality. Less plowing and herbicide applications have also reduced greenhouse gas emissions and increasing the yield of existing cultivated lands has prevented the destruction of natural habitats.[3] One recent study calculated that between 1996 and 2005, the cultivation of GM crops reduced pesticide sprayings worldwide by 493 million pounds (7 percent overall reduction), decreased the adverse environmental impacts of pesticides by 15 percent, and reduced global warming (carbon) emissions by an amount equivalent to removing 4 million cars from the road for one year.[4]

The second generation of GM crops promises even more significant benefits. GM fruits and vegetables should have improved shelf life and higher quality. Crops will have improved nutritional properties, such as more healthy oils and nutritious proteins. GM technology has the potential to reduce or eliminate allergens and toxins in some foods and add vitamins or pharmaceuticals in others. It is also creating

1. Peter Huber, "The Old-New Division in Risk Regulation," *Virginia Law Review* 69 (1983): 1025–1106.
2. George R. Heaton, Jr. and R. Darryl Banks, "Toward a New Generation of Environmental Technology: The Need for Legislative Reform," *Journal of Industrial Ecology* 1, no. 2 (1997): 23–32.
3. Jorge Fernandez-Cornejo and Margriet Caswell, *The First Decade of Genetically Engineered Crops in the United States*, Economic Information Bulletin 11 (April 2006), United States Department of Agriculture Economic Research Service, http://www.ers.usda.gov/publications/eib11/eib11.pdf.
4. Graham Brookes and Peter Barfoot, "Global Impact of Biotech Crops: Socio-Economic and Environmental Effects in the First Ten Years of Commercial Use," *AgbioForum* 9 (2006): 139–151.

drought-resistant and salt-tolerant crops and non-food sources of biofuels.

At the same time this technology is delivering substantial economic and environmental benefits, no known environmental or health harms have resulted from GM crops or foods. Expert scientific organizations generally agree that GM foods present no unique risks. For example, the National Research Council, research arm of the U.S. National Academy of Sciences, has concluded that "the transgenic process presents no new categories of risk compared to conventional methods of crop development."[5]

2. *Nanotechnology:* Perhaps the most important and promising emerging technology is nanotechnology, the science of the very small. Hundreds of nanotechnology products are already on the market and thousands more are in the development pipeline. Many of these products will provide substantial health and environmental benefits, including more effective anti-cancer agents, better hazardous-waste remediation technologies, and clean technologies such as improved solar cells, fuel cells, and emission controls.

The U.S. Environmental Protection Agency (EPA) recognizes the substantial potential environmental upside of nanotechnology: "Using nanomaterials in applications that advance green chemistry and engineering and lead to the development of new environmental sensors and remediation technologies may provide us with new tools for preventing, identifying, and solving environmental problems."[6] While no technology, including nanotechnology, is risk free, the scientific data available to date do not suggest that nanotechnology products and processes as a category is inherently more risky than non-nanotechnology applications. However, as with any novel technology, there is a great deal of uncertainty in estimating both exposure and the potency of various nanotech products. Nevertheless, in some cases, they may present even lower risks than existing technologies. One recent review of the toxicity of nanomaterials concluded, "Although it is possible that engineered NM [nanomaterials] may create toxic effects, there are currently no conclusive data or scenarios that indicate that these effects will become a major problem or that they cannot be addressed by a rational scientific approach."[7]

3. *Food Irradiation:* Food irradiation uses ionizing radiation on raw or processed foods to kill bacteria and other parasites that can cause food poisoning. According to a U.S. government fact sheet, "[i]rradiation is a safe and effective technology that can prevent many foodborne diseases. . . . An overwhelming body of scientific evidence demonstrates that irradiation does not harm the nutritional value of food, nor does it make the food unsafe to eat."[8] Not only have several federal U.S. agencies endorsed the safety of food irradiation, but so have the United Nations Food and Agricultural Organization (FAO), the World Health Organization (WHO), the American Medical Association (AMA), and many other expert organizations.

Notwithstanding the health benefits of the technology and absence of any adverse effects on food or health, the government requires irradiated foods to carry a label that indicates they have been "irradiated." Given the public's general fear of "radiation," the mandatory label and associated scare campaigns by a few activist organizations and sensationalist journalists have historically deterred use and consumer acceptance of the technology, despite its potential to address growing concerns about food contamination. As one dismayed, high-ranking U.S. health official remarked

5. National Research Council, *Environmental Effects of Transgenic Plants* (Washington, DC: National Academy Press, 2002).
6. U.S. Environmental Protection Agency, *Nanotechnology White Paper* (Washington, DC: Science Policy Council, 2007).
7. Andrew Nel, et al, "Toxic Potential of Materials at the Nanolevel," *Science* 311 (2006): 622–627.
8. Centers for Disease Control and Prevention, "Food Irradiation" 2005, http://www.cdc.gov/ncidod/dbmd/diseaseinfo/foodirradiation.htm.

some years ago, "a few highly vocal opponents have cited discredited reports and repeated outlandish fears often enough to make some consumers think twice."[9] Although public misperception of the safety of irradiation was not mentioned in the preamble to the rule, the Food and Drug Administration (FDA) was moved to propose recently that many irradiated foods should be labeled as "cold pasteurized" rather than "irradiated."[10]

Besides these three examples, many other emerging technologies have enormous potential and benefits, including synthetic biology, animal cloning, artificial intelligence, radio frequency identification (RFID), neurotechnologies, robotics, new telecommunication technologies, and the next generation of safer nuclear reactors. Notwithstanding the enormous potential benefits—as well as the significant positive environmental and health attributes—of many of these emerging technologies, existing or proposed regulatory programs have targeted them for selective and unjustified regulatory requirements. This regulatory scrutiny is *not* based on any evidence of increased risk (in fact the available evidence suggests the contrary), but rather on perceived public concern fueled by campaigns by activist organizations, sensational media coverage, and, in at least some cases, the risk-adverse nature of some agencies. As a result, in some cases, agencies do not base regulations or proposed regulations on the products and their risks, but rather on the way products are made, even if the process is no more risky (and possibly less risky) than competing or existing technologies.

A prime example of this discriminatory dynamic is GM foods. Although no known harms to human health or the environment have resulted from the widespread use of GM crops and foods, and notwithstanding the consensus of scientific authorities that GM foods as a category present no greater risks than conventional foods, the United States has singled out GM foods for unique and burdensome regulatory requirements. The United States claims to regulate biotechnology products based on the risks of the individual product rather than the process by which they were made, but the reality is quite different. The United States Department of Agriculture (USDA) regulates all plants that are considered to be plant pests and maintans a comprehensive list of such organisms. This comprehensive list covers organisms that are used in virtually all genetic plant engineering. Additionally, USDA takes the liberty of regulating GM plants that were not created with an organism on this list but have reason to be regarded as plant pests.[11] This means GM crops require separate regulatory authorizations before they can be field-tested and grown commercially. Non-GM foods (except for those few that are actually plant pests) are subject to no such requirement. The EPA also regulates GM plants that include a pest-control trait.

The FDA comes closest to adhering to the stated U.S. policy of regulating the product rather than the process when in 1992 it determined that there was no reason to treat GM foods as a category any different than non-GM foods.[12] Nevertheless, the FDA does request that all GM-food manufacturers engage in a voluntary consultation with the agency before releasing any GM food into the market.[13] During this consultation, the FDA expects the manufacturer to produce data from a series of safety tests. The FDA does not request such "voluntary" consultations for non-GM foods.

The European Union goes further. It expressly regulates GM foods differently and much more stringently than other foods. All foods containing GM ingredients above a 0.9% threshold are subject to strict

9. J.O. Mason, "Food Irradiation—Promising Technology for Public Health," *Public Health Reports* 107 (1992): 489–490.
10. Food and Drug Administration, "Proposed Rule: Irradiation in the Production, Processing, and Handling of Food," *Federal Register* 72 (2007): 16291–16306.
11. Keith Atherton, *Genetically Modified Crops: Assessing Safety* (Boca Raton: CRC Press, 2002).
12. Food and Drug Administration, "Statement of Policy: Foods Derived from New Plant Varieties," *Federal Register* 57 (1992): 22984–23005.
13. In 1993, the FDA proposed to make the voluntary consultation for GM foods a mandatory regulatory requirement, but this proposal has not been finalized.

labeling and traceability requirements.[14] Moreover, the EU enforced a de facto moratorium on any new approvals of GM crops or foods from 1998 through 2004, a practice that a WTO dispute panel found violated international trade laws.[15] While the WTO also found European bans on GM foods and crops to be unlawful, and many countries have since lifted their restrictions, France recently prohibited the cultivation of a strain of GM corn. The moratorium, which began in February 2008, was invoked under an EU safeguard clause after a watchdog group raised questions about the crop's safety.[16]

The EU concedes it does not apply this burdensome regulatory approach to GM products because they may be more risky than non-GM products (more recently, the EU appears to be backing away from the precautionary approach). Indeed, the EU's own scientific advisors found that "[t]he use of more precise technology and the greater regulatory scrutiny probably make (biotech crops) even safer than conventional plants and foods."[17] Rather, the purported justification for this more stringent regulation is public opinion and the precautionary principle, which promotes caution in implementing new technologies with unknown effects. While there is no agreed-upon definition of this doctrine, a 2000 European Commission communication on the matter said the precautionary principle "covers those specific circumstances where scientific evidence is insufficient, inconclusive, or uncertain and there are indications through preliminary objective scientific evaluation that there are reasonable grounds for concern that the potentially dangerous effects on the environment, human, animal, or plant health may be inconsistent with the chosen level of protection."[18]

As mentioned earlier, the U.S. federal government requires foods treated with irradiation to be labeled as such even though the available evidence suggests no increased risk from such products. This regulatory labeling requirement, along with skewed public perception of this technology, has suppressed the use of food irradiation significantly, to the detriment of public health.

Although few jurisdictions have yet to enact binding regulations for nanotechnology, public interest organizations are ramping up calls for such regulation, and in some cases, prohibitions. For example, in July 2007, a coalition of forty-five public interest groups issued a position statement calling for a ban on the commercialization of any "untested or unsafe uses of nanomaterials and requiring product manufacturers and distributors to bear the burden of proof."[19] Other activist organizations and scholars are likewise calling for moratoria on nanotechnology based on the precautionary principle, just as they did for GM foods a decade earlier.[20]

14. European Commission, "Regulation (EC) No. 1829/2003 of the European Parliament and of the Council of 22 September 2003 on Genetically Modified Food and Feed," *Official Journal of the European Union* (October 10, 2003), 22, http://europa.eu/eur-lex/pri/en/oj/dat/2003/l_268/l_26820031018en00010023.pdf.
15. World Trade Organization, *European Communities—Measures Affecting the Approval and Marketing of Biotech Products: Reports of the Panel*, WT/DS291/R, WT/DS292/R, WT/DS293/R (2006).
16. Agence France Presse, "French Farmers Lose Bid to Overturn GM Corn Ban," March 19, 2008, http://afp.google.com/article/ALeqM5jV1gpOmhdx71ykX6tKPSOazy0Kug.
17. European Commission, *A Review of Results: EC-sponsored Research on Safety of Genetically Modified Organisms*, eds, Charles Kessler and Ioannis Economidis (Luxembourg: Office for Official Publications of the European Commission, 2001), http://europa.eu.int/comm.research/quality-of-life/gmo.
18. European Commission, *Communication on the Precautionary Principle* (Brussels: 2000).
19. International Center for Technology Assessment, et al., "Principles for the Oversight of Nanotechnologies and Nanomaterials," 2007, http://www.icta.org/doc/Principles%20for%20the%20Oversight%20of%20Nanotechnologies%20and%20Nanomaterials_final.pdf.
20. Ronald Bailey, "The Smaller the Better: The Limitless Promise of Nanotechnology—And the Growing Peril of a Moratorium," *Reason*, December 2003, http://www.reason.com/news/show/28969.html.

If these new emerging technologies promise not only economic but also environmental and health benefits, why are they being subjected to unfair and burdensome regulatory discrimination? Part of the response may be the exotic, unfamiliar nature of many new emerging technologies. Research on public risk perception suggests that the public is frightened by less familiar and complex technologies such as nuclear, nano, and genetic technologies. These technologies are also subject to media sensationalism, as evidenced by the media's use of derogatory and sensational terms such as "Frankenfoods" and "grey goo" to refer to GM foods and nanotechnology, respectively. Finally, some activist groups exploit these public and media tendencies to launch campaigns against new technologies that usually elicit extensive publicity. These interacting forces cause "risk cascades" which so sensationalize and amplify the risks of certain technologies to the point of stigmatization.[21]

This social dynamic puts many emerging technologies in a precarious position. One unfortunate incident or injury, which may routinely occur for many less exotic and commonly accepted technologies, could result in a massive media, public, and government backlash that may be far out of proportion to the actual problem. In fact, it could bring an entire technology to a grinding halt or result in massive economic losses. For example, traces of Starlink, a genetically modified type of pest-resistant corn approved for animal use only, appeared in taco shells in 2000. Fears over potential risks of allergic reactions led to an expensive hunt for all instances of contamination in the food supply.[22] While related to a different field, Jesse Gelsinger's 1999 death also raised concerns and hampered progress in the relatively new field of gene therapy. Gelsinger died during a genetic treatment trial at the University of Pennsylvania and brought widespread public scrutiny to this emerging field.[23] Even if government regulators are generally reluctant to impose premature or unduly burdensome regulations on a new technology, a tsunami of media and activist sensationalism can sweep aside their common sense. In all cases, it is in the interest of industry and in some cases, of government, to minimize the risk of such incidents.

Stigmatizing emerging technologies has the potential to result in regulatory double standards that are unfair to the developers of beneficial new technologies and detrimental to public health and welfare. Consider the following examples.

1. *Herbicide-Resistant GM:* Crop scientists have used genetic engineering to make herbicide-resistant crops, but they have also used non-GM methods, such as chemical or nuclear mutagenesis, to produce crops with a similar herbicide-resistant trait. Both the United States and European Union stringently regulate the GM version, but give the non-GM version expressing the equivalent trait a regulatory free pass.

There is no logical reason for this differentiation in treatment. Not only is there no reason to believe that the GM version is any more risky than the non-GM version, but the opposite in probably true. Because the genetic changes in the GM version were targeted and precise, the GM version is less likely to carry other potentially harmful mutations that the other methods may have created. Yet, in "what can only be described as a culture of irrationality," the regulatory structure penalizes the arguably safer crop.[24]

2. *Magic Nano:* In 2006, a German company released a glass and tile sealant called "Magic Nano." Within days of the product release, dozens of consumers started complaining of "inhalation injuries" and several peo-

21. Robin Gregory, James Flynn, and Paul Slovic, "Technological Stigma," *American Scientist* 83 (1995): 220–223; Jeanne X. Kasperson, et al., "*The Social Amplification of Risk: Fifteen Years of Research and Theory*," in The Social Amplification of Risk, eds. Nick Pidgeon, Roger E. Kasperson, and Paul Slovic (Cambridge: Cambridge University Press, 2003).
22. Kurt Eichenwald, "New Concerns Rise on Keeping Track of Modified Corn," *The New York Times*, October 14, 2000.
23. Eliot Marshall, "Gene Therapy on Trial," *Science* 288 (2000): 951–955, 957.
24. Shane H. Morris, "EU Biotech Crop Regulations and Environmental Risk: A Case of the Emperor's New Clothes?" *Trends in Biotech* 25 (2007): 2–6.

ple were hospitalized. This incident immediately generated worldwide front-page headlines about the dangers of nanotechnology, and some organizations called for an immediate moratorium on all nanotechnology products. A few days later the German government announced that Magic Nano in fact contained no nanotechnology. Curiously, attention and concern about the case immediately vanished. The injuries to the affected individuals were apparently only newsworthy if a nanotechnology product had caused them.[25]

PROPOSED SOLUTIONS

Legislators and regulators should address this problem of discriminatory and undue regulation of beneficial emerging technologies. They need to resist pressure to adopt premature and unwarranted regulatory requirements based on stigma and emotion and instead pursue scientifically based risk assessment and weighing of costs and benefits of regulatory options. To that end, three specific policy options should be pursued: (1) reject the precautionary principle; (2) establish the principle of non-discriminatory treatment in U.S. law; and (3) create a voluntary health and safety certification program.

1. Reject the Precautionary Principle

The first and easiest step in leveling the regulatory playing field for emerging technologies is to reject incorporation of the precautionary principle—also known as "better safe than sorry"—into local, state, national, and international regulatory programs. Though lacking a concrete definition, this principle manifests itself in governments requiring proponents of a new technology to demonstrate its safety before it can be marketed. Many of the most unreasonable regulations and proposals for restricting beneficial emerging technologies are based on the precautionary principle, which opens the door to regulation based not on objective scientific evidence of risk, but rather on subjective and arbitrary political biases. The precautionary principle has been legally adopted by the European Union; the courts and legislatures of many nations including many European countries, Canada, Australia, and India; in over sixty international treaties and agreements; and most recently by several U.S. local governments such as San Francisco and Seattle.

The key problem with the precautionary principle is that it is inherently arbitrary in its application. Because there is no standard definition, and no version addresses what level of risk is acceptable or what amount of evidence is necessary to trigger its application, the precautionary principle is prone to being applied based on a political, protectionist, and arbitrary basis. Although the European Commission has asserted that the precautionary principle should be based on scientific risk assessment,[26] in reality its application by the EU and others has been anything but principled and grounded in science. Examples of this include Norway's ban on a corn flakes cereal because the added essential vitamins could conceivably harm susceptible individuals, Denmark's ban on marketing cranberry juice drinks because the added vitamin C could harm people with rare iron disorders, and France's ban on certain caffeinated energy drinks because the caffeine could harm pregnant women.[27] Although these applications of the precautionary principle were eventually overturned by courts because they lacked scientific legitimacy, they demonstrate the extremes to which the precautionary principle can be extended. More tragically, during a recent famine in his country, Zambia's president invoked the precautionary principle and refused U.S. food aid that contained some genetically-engineered corn. These examples show how easily the precautionary principle can be manipulated into unreasonable, counterproductive, and sometimes tragic results.

25. Robin Fretwell Wilson, "Nanotechnology: The Challenge of Regulating Known Unknowns," *Journal of Law, Medicine, and Ethics* 34 (2006): 704–713.

26. European Commission, *Communication on the Precautionary Principle*.

27. Gary E. Marchant and Kenneth L. Mossman, *Arbitrary and Capricious: The Precautionary Principle in the European Union Courts* (Washington, DC: AEI Press, 2004).

Meanwhile, the organic food industry has argued with some success that the precautionary principle should be used to restrict GM foods even though GM food has never caused any known harmful effect. Alternatively, there are several documented examples of organic foods causing death or illness.[28] Moreover, all GM foods are extensively safety tested while organic foods are generally not subjected to such tests. Disregarding the many problems with the precautionary principle, there is no logical reason to apply more stringent standards, such as those derived from the precautionary principle, to genetically modified foods over untested organic foods. Yet, in practice, the opposite is true. Because the precautionary principle is used to advance the political and social agendas of its proponents, not protect public health, it is frequently applied to GM foods but not to organic foods or other "natural" risks such as herbal remedies.

The arbitrary application of the precautionary principle is particularly troubling in light of a recent study showing that invoking it for a particular technology exacerbates, rather than ameliorates, public concern and anxiety about that technology. The 2005 German experiment found that precautionary measures applied to mobile phones actually exacerbate public concerns about electromagnetic radiation rather than allay them.[29]

Unfortunately, the precautionary principle is widely supported among lawmakers and lobbyists. The EU has been pursuing an active campaign to make the precautionary principle recognized by international law by including the principle throughout international legal documents and agreements. For example, the EU was the primary proponent of the 2000 Cartagena Protocol on Biological Diversity, which is an international agreement that formally adopts the precautionary principle for the movement and use of "living modified organisms."[30] Additionally, the 2006 Strategic Approach to International Chemicals Management incorporated the doctrine in its text; this UN-organized pact was largely supported by the EU and hailed as a "clear commitment to the precautionary principle" by the union.[31] In the United States, organized interest groups have been campaigning for the domestic adoption of the principle at the local, state, and national levels. A key first step for fair and rational regulation of emerging technologies should therefore be to reject adoption of the precautionary principle in domestic and international regulatory programs.

2. Establish a Principle of Non-Discrimination

A second step would be to enshrine a principle of non-discrimination in U.S. regulatory law. This principle prohibits regulatory discrimination against a product based on its production process unless there is clear evidence that the manufacturing method significantly increases the likelihood that the product will be dangerous. Under this principle, regulation would be based on a product's individual risk, not the technology used to make the product. It would therefore establish a level playing field for similar products made by different processes or technologies.

A principle of non-discrimination would prevent the type of absurdity described above in which an herbicide-resistant crop made with GM technology is subject to intensive regulation whereas a crop with the same trait caused by mutagenesis or other technologies is given a regulatory free pass. Similarly, the wide variety of products made using or incorporating nanotechnology, which likely represent a broad

28. Anthony Trewavas, "Urban Myths of Organic Farming," *Nature* 410 (2001): 409–410; Gary E. Marchant, "From General Policy to Legal Rule: The Aspirations and Limitations of the Precautionary Principle," *Environmental Health Perspectives* 111 (2003) 1799–1803.
29. Peter M. Wiedemann and Holger Schutz, "The Precautionary Principle and Risk Perception: Experimental Studies in the EMF Area," *Environmental Health Perspectives* 113 (2005): 402–405.
30. Convention on Biological Diversity, *Cartagena Protocol on Biosafety to the Convention on Biological Diversity*, 2000, http://www.cbd.int/doc/legal/cartagena-protocol-en.pdf.
31. European Commission, "Europe Welcomes Dubai Declaration as the First Global Agreement to Achieve Sound Management of Chemicals," EUROPA Press Releases, 2006, http://europa.eu/rapid/pressReleasesAction.do?reference=IP/06/129&format=HTML&aged=0&language=EN&guiLanguage=en.

range of risk profiles, would be evaluated on a product-by-product basis under the same criteria that non-nanotechnology products are evaluated. Unjustified regulatory discrimination based on manufacturing processes unfairly burdens some technologies against others. This, in turn, forces companies to substitute non-targeted technologies for these stigmatized—and often superior—technologies, resulting in economic inefficiencies and reduced consumer welfare.

The non-discriminatory principle has legal foundations in both domestic and international law. Courts generally prohibit arbitrary discrimination by agencies—as the D.C. Circuit has held, "reasoned decision making requires treating like cases alike."[32] This principle would presumably prohibit an agency from regulating one product more stringently than another because of differences in their manufacture. Moreover, courts have held that agencies cannot require product labeling simply to satisfy consumer preferences and beliefs, thus rejecting a labeling requirement for milk made from cows treated with bST (bovine somatotropin) in the absence of evidence that such products create a greater risk.[33] These precedents could easily be extended to prohibit discrimination against particular production methods based on consumer fiat and political pressure.

In international law, the World Trade Organization does not permit nations to discriminate against a country's products based on their process and production methods (PPMs).[34] Moreover, the EU's own "communication" on the precautionary principle states that it should be applied "to achieve an equivalent level of protection without invoking . . . the nature of the production process to apply different treatments in an arbitrary manner."[35]

The non-discriminatory principle could be reinforced in U.S. law in several ways. First, Congress could enact legislation requiring non-discrimination for manufacturing methods. This can take the form of free-standing legislation similar to other recent generic regulatory provisions such as the Information Quality Act (also known as the Data Quality Act)[36], or it can be part of the reauthorization of or amendment to individual regulatory statutes. Second, the White House could direct regulatory agencies to act in a non-discriminatory manner in the form of amendments to an existing or adoption of a new executive order or guidance (e.g., Executive Order 12866, which requires economic analysis of significant regulatory action). Third, courts could more explicitly adopt the non-discriminatory principle in applying the "arbitrary and capricious" standard of judicial review of agency action under the Administrative Procedure Act. In the past, federal courts have adopted similar principles in fleshing out the arbitrary and capricious standard.[37] However enacted, consistent application and enforcement of the non-discrimination principle will go a long way towards leveling the regulatory playing field and ensuring a fairer, more reasonable regulatory system.

32. *Hall v. McLaughlin*, 864 F.2d 868, 872 (DC Cir. 1989).
33. See *International Dairy Foods Association v. Amestoy*, 92 F.3d 67 (2nd Cir. 1996).
34. General Agreement on Tariffs and Trade, General Exceptions, art. XX (Geneva: GATT Secretariat, 1947); R. Read, "Like Products, Health, and Environmental Exceptions: The Interpretation of PPMs in Recent WTO Trade Dispute Cases," *Estey Centre Journal of International Law and Trade Policy* 5 (2004): 123–146.
35. European Commission, *Communication on the Precautionary Principle*.
36. The Data Quality Act or Information Quality Act was part of a spending bill that directs the Office of Management and Budget to issue guidelines to ensure that agencies maximize the quality, objectivity, utility, and integrity of the information they disseminate. Office of Management and Budget, "Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies: Republication," *Federal Register* 67 no. 36 (2002): 8452–8460.
37. E.W. Warren and Gary E. Marchant, "More Good than Harm: A First Principle for Environmental Agencies and Reviewing Courts," *Ecology Law Quarterly* 20 (1993): 379–440.

3. Create a Voluntary Health- and Safety-Testing Certification Program

Even if regulators were to apply a level playing field to emerging and existing technologies, the stigmatization of some new technologies by the combination of sensational media coverage, targeted campaigns by activist groups, and public opinion heuristics against new technologies may still create overwhelming pressure for some form of government oversight. Public opinion polls, many independent experts, and even some industry representatives suggest that some type of meaningful government oversight is needed to build public confidence and trust in new emerging technologies.[38] If government oversight is required to provide the public confidence needed to enable beneficial new technologies to succeed, how can this be done without unfairly burdening these emerging technologies with regulations and further stigmatizing them?

A solution would be for the federal government to offer a voluntary health- and safety-testing certification program. Under this proposal, a product manufacturer could voluntarily undertake certain product safety testing procedures in return for a government certification that its product had been appropriately safety tested. The requirements might include: (1) conducting a specified battery of toxicity tests that would screen the product for safety without undue cost or delay; (2) implementing specified work practices and other industrial hygiene recommendations to promote safe manufacturing; and (3) conducting post-marketing surveillance for indications of health or environmental problems after the product is commercialized.

The certification would indicate that the product has been subject to a reasonable set of government-supervised safety precautions and thus has some assurance of safety. Of course, such a set of obligations would not guarantee that the product is absolutely safe since no reasonable set of toxicity tests could ever prove complete safety. The government certification would allow the manufacturer to promote confidence in its product by its customers, employees, stockholders, and the public and defend its product against unwarranted attacks by activist groups, journalists, or business competitors. For example, if an organic food interest attacked a GM food product as potentially unsafe, the GM food manufacturer could point to its safety-testing certification and challenge the organic food industry to undertake a similar obligation. While the safety certification could conceivably be administered by an independent private entity (and there would likely be some arguments in favor of this approach), a federal government certification program would probably be preferable because of the public and media's demand for government oversight. Moreover, the government could utilize the regulatory resources and expertise existing in regulatory agencies rather than have to recreate such attributes in a new entity.

This voluntary safety-testing certification program would be a more formalized and potentially beneficial extension of existing voluntary programs. For example, the EPA has launched a voluntary Nanoscale Materials Stewardship Program for nanotechnology, in which nanotechnology manufacturers can choose to report data to the EPA and implement basic risk-management provisions. The FDA encourages GM-food producers to consult with the agency prior to commercializing GM foods so that the agency can review safety data generated by the companies. The EPA also operates a technology-verification program that certifies the environmental benefits of new technologies.[39] These types of programs can serve as prototypes for the voluntary safety-testing certification program, which could be implemented either by Congress or by individual agencies.

The certification testing would need to provide meaningful hazard-identification data while at the same time not unduly burdening or delaying the commercial launch of the product to be certified. Two recent

38. Jane Macoubrie, *Informed Public Perceptions of Nanotechnology and Trust in Government* (Washington, DC: Woodrow Wilson International Center for Scholars, 2005).

39. U.S. Environmental Protection Agency, *EPA's Environmental Technology Verification Program*, EPA/600/F-07/005 (May 2007), http://www.epa.gov/nrmrl/std/etv/pubs/600f07005.pdf.

National Research Council reports[40] have identified significant promise for new toxicogenomic and other molecular assays to provide quick, inexpensive screening toxicity tests within the next few years. In the interim, regulatory agencies would need to define appropriate test batteries that would likely consist of in vitro assays, short-term animal studies, and computational toxicity methods such as structure-activity relationships. The specific tests required would likely need to be defined based on product category and could be consistent, whenever possible, with existing voluntary-screening programs. For example, food manufacturers could submit to the same safety testing new GM foods currently undergo, providing the results to the FDA prior to commercialization. The Organisation for Economic Co-operation and Development's (OECD) Screening Information Data Set (SIDS) protocol could be applied to chemical products. Nanotechnology products could be screened under the "in-depth" arm of EPA's voluntary Nanoscale Materials Stewardship Program. More customized screening batteries may need to be defined for products without an existing program with a defined test battery. Whatever the specific test requirements, participation must be voluntary, and the tests must be carefully selected to provide useful safety information while minimizing burdens and delays for the commercialization of the product.

FUTURE RESEARCH

All three of the policy proposals listed above would benefit from additional research, including: (1) additional empirical research on how the precautionary principle has fared in the jurisdictions in which it has been adopted; (2) buttressing the legal support and precedents for the principle of non-discriminatory treatment of production methods in national and international law; and (3) further development of a certification scheme taking into account evidence on how analogous certification schemes have worked in the past. In addition, some additional useful research areas include: (1) the role of state and local governments in the governance of emerging technologies; (2) international mechanisms of harmonization of regulation of emerging technologies; and (3) designing mechanisms for the sensible incorporation of social and ethical concerns into the regulation of emerging technologies.

40. National Research Council, *Toxicity Testing in the 21st Century: A Vision and Strategy* (Washington, DC: National Academy Press, 2007); National Research Council, *Applications of Toxicogenomic Technologies to Predictive Toxicology and Risk Assessment* (Washington, DC: National Academy Press, 2007).

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Structuring U.S. Innovation Policy: Creating a White House Office of Innovation Policy

BY STUART MINOR BENJAMIN AND ARTI K. RAI | JUNE 2009

We propose that President Obama create an Office of Innovation Policy and provide it with authority to be able to have a significant positive impact on innovation policy.

U.S. policymakers are understandably focused on prodding the economy out of the current recession. There is a robust debate about how to achieve this goal, but a fairly broad consensus about the longer term: both theory and empirical evidence support the primacy of technological innovation in advancing long-term economic growth and, ultimately, human welfare. Innovation is also central to addressing the environmental and other challenges that can accompany economic growth. Thus questions of how to foster technological innovation are, quite properly, at the forefront of both scholarly analysis and policy debate.

Commentators have discussed at length a variety of substantive innovation inputs and incentives—for example, patents, trade secrecy, government funding and procurement, availability of venture capital, ownership of innovation "platforms" and "infrastructure," science and engineering education, university technology transfer, competition, concentration, innovation prizes, and open and/or collaborative strategies. Identifying these substantive policies is important, but so too is analyzing how to design U.S. government institutions that have the best chance of successfully spurring innovation. And notwithstanding the growing attention to U.S. innovation policy, the issue of how to structure U.S. innovation policy is a relatively under-examined area.[1] Discussions of specific legal/regulatory systems that have a significant impact on innovation (e.g., patents or antitrust) tend to focus rather narrowly on the particular tools that might be available to agencies and courts that operate within that system.

This report conducts a broad examination of the relationship between federal regulatory institutions and U.S. innovation policy. We propose improving U.S. innovation policy by creating a White House Office of Innovation Policy (OIP) to review federal agencies' actions that affect innovation.

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We begin with a discussion of innovation's importance to the future well-being of American society. We then discuss limitations of the current federal framework for making innovation policy. Specifically, the relative absence of innovation from the agenda of Congress and many relevant federal agencies—as well as interagency processes such as the centralized cost-benefit review performed by the Office of Information and Regulatory Affairs (OIRA) within the Office of Management and Budget (OMB)—manifests the confluence of two regulatory challenges: first, the tendency of political actors to focus on short-term goals and consequences; and second, political actors' reluctance to threaten powerful incumbent actors. Courts, meanwhile, lack sufficient expertise and the ability to conduct the type of forward-looking policy planning that should be a hallmark of innovation policy.

Ultimately, our analysis leads us to propose that President Obama (or Congress, if Congress is willing) create a White House OIP that would have the specific mission of being the "innovation champion" within these processes. We envision OIP as an entity that would be independent of existing federal agencies and that would have more than mere hortatory influence. It would have some authority to push agencies to act in a manner that either affirmatively promoted innovation or achieved a particular regulatory objective in a manner least damaging to innovation. We also envision OIP as an entity that would operate efficiently by drawing upon, and feeding into, existing interagency processes within OIRA and other relevant White House offices (e.g., the Office of Science and Technology Policy). It is important to note that OIP would not be designed to thwart federal regulation; as a matter of fact, in some cases, the existence of OIP might lead to increased federal regulation (e.g., more Environmental Protection Agency regulations might pass muster under cost-benefit analysis if innovation-related effects were calculated).

WHY INNOVATION POLICY SHOULD BE A PRIORITY FOR THE U.S. GOVERNMENT

A. Why Innovation Is Important

In the long run, productivity is the key to economic growth. There is no natural limit on growth in productivity, and in fact, productivity growth has swung wildly among different countries. Many factors affect productivity growth, but innovation is particularly important. By "innovation," we mean the development and deployment of technological improvements. This definition of innovation is not only tractable but it also comports with the most recent data on drivers of U.S. productivity growth. Specifically, the United States experienced average annual productivity increases of less than 1½ percent between 1980 and 1995, but it has averaged increases of more than 2½ percent since 1995.[2] The best explanation for the more recent U.S. productivity increases is the widespread diffusion of advances in information and communications technology.[3]

Innovation is highly cumulative—building on earlier discoveries and developments—and small changes in conditions at a particular time can have large future impacts on the course of innovation. Any current event can have an impact on later events, of course. But the failure to, say, tax a complex transaction at time T1 can be ameliorated by taxing it at time T2. If the government nets the same amount of constant dollars, then the difference of timing is small. By contrast, the failure to sufficiently encourage an innovation at time T1 may mean that innovators at time T2 lack a crucial building block and hence that the course of innovation is significantly retarded.

Notably, although our discussion equates innovation with technological change, "innovation policy" is in our view quite distinct from what might be called "technology policy" (over which the Office of Science and Technology Policy has jurisdiction). Innovation policy is both narrower and broader than technology policy. It is narrower in that it focuses on how to promote the creation and diffusion of technology, whereas technology policy encompasses a wider range of substantive policy goals (for example, non-instrumental concerns about civil rights and civil liberties). At the same time, innovation policy is broader in its range of regulatory components, in that innovation policy ranges beyond a focus on technology per se to encompass, for example, antitrust and education policy.

B. Why the U.S. Government Needs to Play a Role in Innovation

In light of innovation's enormous importance to the future well-being of American society, a key question is what, if anything, the U.S. government should do to foster innovation. The answer cannot be "nothing." At a minimum, the government needs to establish the legal institutions that allow for efficiency in both market

transactions and the formation of firms. Furthermore, optimal levels of innovation will sometimes—perhaps often—require government action beyond that involved in ordinary competitive markets.

Economists have long advanced good theoretical and empirical arguments for why markets will not allow innovators to capture a sufficient percentage of the welfare benefits they produce.[4] With early-stage or large-scale research, the benefits may be too uncertain, long term, and diffuse to monetize, let alone control. Problems of uncertainty and lack of appropriability are less acute for more directed innovation, but even then controlling inexpensive copying is likely to be difficult. Consequently, government incentives for innovation—whether they take the form of patents, allocation to private parties of spectrum rights, prizes, research funding, tax incentives, or other mechanisms—are important.

More generally, in the last several decades the weight of economic authority has decisively turned against Robert Solow's view that technical change is an exogenous variable that cannot be influenced by policy.[5] Leading growth theorists like Paul Romer have demonstrated that innovation is endogenously determined and emerges as a consequence of knowledge externalities and spillovers; such externalities and spillovers, in turn, represent variables that many forms of government policy, including but not limited to subsidies, can affect.[6]

WHAT CURRENT U.S. GOVERNMENT POLICY GETS WRONG

A. Why Government Institutions Slight Innovation Policy

Absent measures designed to foster careful thinking about innovation, it will likely be systematically ignored and/or misunderstood by government actors. In the discussion that follows, we give examples of counterproductive U.S. regulatory behavior with respect to innovation.

A skeptic might note that counterproductive regulatory behavior is likely to be a pervasive phenomenon no matter what the substantive policy goal, but there are several reasons to believe that it will be even more pervasive in the context of innovation than in the context of other goals. First, almost by definition, innovation involves thinking about long-term outcomes, many difficult to conceive. U.S. political actors have very little incentive to force themselves to think about long-term outcomes because they are unlikely to be around to reap credit (or blame). Relatedly, the political pressures of dealing with day-to-day exigencies lead many political actors to give short shrift to long-term outcomes and the role of innovation.

Absent measures designed to foster careful thinking about innovation, it will likely be systematically ignored and/or misunderstood by government actors.

Second, the theoretical and empirical literature indicates that start-up firms are particularly likely to be the sources of breakthrough or disruptive innovation. On the theoretical side, economists from Joseph Schumpeter onwards have noted that such entrepreneurial firms may be more likely than incumbents with vested interests in existing products to be able to move outside routine tasks into "untried technological possibilit[ies]."[7] As an empirical matter, the data indicate that significant innovations, particularly in fields like biotechnology and information technology, have been driven by new entrants.[8] Unfortunately, incumbent firms are generally better organized and have more lobbying clout than upstarts.[9]

Even U.S. government institutions such as courts that are not constrained by political considerations are likely to systematically neglect innovation policy. The reason is that courts must act ex post, in the context of the limited information put forward in the particular dispute that is brought before them. In fact, even the U.S. Court of Appeals for the Federal Circuit, which is tasked with managing a system (the U.S. patent system) that has innovation as its sole reason for existence, has tended explicitly to disavow policy analysis. As a consequence of this disavowal, the patent system has embraced software patents of broad and often unclear scope without considering the patent thickets that such allowance would create for the highly cumulative process of software development.[10] In contrast, patent scope with respect to genes has been relatively narrow even though a broader scope would arguably be more aligned with innovation goals, at least with respect to genes that cover therapeutic proteins.

B. Piecemeal Approaches to Innovation by U.S. Government Entities

Even when U.S. government entities like federal agencies and courts actually focus on innovation, they generally act without having much awareness of what other institutions faced with similar problems have done—much less coordinating with those institutions. Improving the awareness and coordination of innovation-related activities among federal agencies and courts could be tremendously helpful.

Consider as one example the recurrent debate among legal scholars and economic analysts over how best to regulate technology platforms—that is, basic or infrastructural innovation that is difficult to invent around and can serve as the basis for much future innovation. Embedded within this inquiry are several important subsidiary inquiries. First, a government regulator must make a threshold assessment of the degree to which the innovation in question is in fact a platform technology. Second, assuming that the regulator has determined that a given innovation is in fact a platform, it must determine whether the owner of the technology is likely to exploit it in a manner that is detrimental to innovation. Third, assuming that the regulator is worried that a monopolist will not optimally deploy its platform, the regulator will have to determine whether to act *ex ante*, before concrete problems have arisen, or *ex post*.

These economic questions arise with any platform-based innovation, no matter the science behind the platform or the specific applications to which it is put. When, for example, the U.S. Patent and Trademark Office (PTO) or the Federal Circuit makes a decision regarding the treatment of extremely broad claims in a patent on embryonic stem cells (a trio of such broad patents was granted and subsequently challenged), it might consider lessons learned by Federal Communications Commission (FCC) regulators that have considered the issue of property rights over (or compelled access to) platforms. The debates about the viability and contours of an essential facilities doctrine could help to inform a decisionmaker at the National Institutes of Health faced with the question of whether to declare that no patent rights should be sought on a particular genome sequencing project.

Platform technologies do not represent the only area in which multiple federal agencies are likely to have important arguments that other agencies should be listening to. The 2003 Federal Trade Commission (FTC) report suggesting mechanisms for improvement of the patent system, for example, was motivated by the proposition that issues of competition policy and innovation policy overlap.[11] More fundamentally, every new area of technology represents another venue for deciding whether competition or quasi-monopoly rights is the best mechanism for promoting innovation. Yet in issue area after issue area, these policy challenges are addressed on an *ad hoc*, agency-specific basis.

The lack of coordination among agencies is particularly challenging for innovations that represent technological convergence and have wide-ranging applications. For example, the so-called "minimal genome" that synthetic biologists seek to develop (and on which Craig Venter has recently sought a patent) could be used in a wide variety of industries, ranging from clean energy to pharmaceuticals. Currently, innovation in energy and pharmaceuticals is regulated in the United States by a large number of different federal agencies—ranging from the National Institutes of Health and the Food and Drug Administration (pharmaceuticals) to the Department of Energy and the Environmental Protection Agency (energy).

With the abolition of the congressional Office of Technology Assessment in the mid-1990s, the ability of Congress to secure unbiased advice on questions of innovation policy is also quite limited. Moreover, even with unbiased advice, it is not clear that Congress would be capable of acting in a systematic manner with respect to innovation. Although the passage of the America COMPETES (Creating Opportunities to Meaningfully Promote Excellence in Technology, Education, and Science) Act is a positive sign, Congress's failure to fund the act at authorized levels in the first year mitigates this success.

Federal agencies' failure to coordinate innovation policy often leads to inconsistency and incoherence in federal policies. As an example, the PTO has insinuated itself into middle of the complex questions involving the regulation of "Voice over Internet Protocol" (VoIP) telephony by granting broad and possibly invalid patents over key elements of such telephony to a number of large incumbent providers, including Verizon, Sprint, and AT&T. The PTO almost assuredly had no particular intention to regulate the battle over VoIP. To the contrary, thinking about VoIP has been the province of the FCC, which views VoIP as a valuable alternative to local landline telephony.[12] Nevertheless, the

PTO's issuance of broad patents has allowed Verizon, Sprint, and AT&T to pursue via government-granted property rights what they have been unable to achieve via FCC regulation. These large incumbents filed suits based on broad patents that seriously damaged a much smaller start-up, Vonage, that has implemented VoIP successfully.[13] If the large incumbent firms' patents are in fact valid, then some payment to Verizon, Sprint, and AT&T is appropriate. But the threatened remedy of injunctive relief—in the shadow of which Vonage settled the various lawsuits for large sums of money—conflicts with the FCC policy of promoting more competition in telephony markets.[14]

The PTO's intervention with respect to VoIP was largely inadvertent, but in some situations the failure to coordinate some aspect of innovation policy flows from federal agencies' conflicting agendas. This problem has arisen in U.S. spectrum policy. Although innovation in wireless services depends on the availability of radio frequencies, the management of these frequencies has been characterized by difficulties arising from the involvement of different agencies with competing goals. One might imagine that conflicts in spectrum policy would arise between the FCC (which manages the allocation of commercial spectrum) and the National Telecommunications and Information Administration (NTIA) (which manages the spectrum assigned to the government), and these agencies have indeed differed on spectrum policy. But the conflicts between these two agencies and the Department of Defense (the largest government user of spectrum) have been more notable and pitched.[15] The Department of Defense resisted spectrum liberalization proposals put forward in the late 1990s and 2000, and it successfully thwarted attempts at revamping its spectrum allocations. Top spectrum officials agree that "the FCC, NTIA, and Congress have created a bureaucratic morass of [spectrum] regulations and oversight that impedes progress."[16]

Given that different federal agencies have different missions, it is not surprising that there are both regulatory overlaps and regulatory lacunae. Both phenomena can lead to lack of coordination and inefficiency, as federal agencies often take actions in tension with those of another agency (in the case of overlaps) or take actions that are outside their core area of expertise and in the process do a poor job. An example of regulatory overlaps is the jurisdiction of multiple federal agencies over U.S. telecommunications mergers. Such mergers are reviewed by the FCC, as well as by the Department of Justice's Antitrust Division and the FTC. Those agencies often apply different standards and often reach differing results (for purposes of innovation and otherwise), leading to much wasted effort for regulators and the regulated parties.

An example of a regulatory lacuna is the FCC's attempt at protecting television producers' copyrights via copy control mechanisms known as "broadcast flags." Content owners expressed fears about unauthorized sharing of their programming once such programming became digital, and they lobbied the FCC to require devices capable of receiving digital television signals to recognize the broadcast flag created by content producers. The FCC had little background or expertise in matters of copyright and copy control, and indeed it had no obvious jurisdiction: Congress never saw fit to give the FCC authority over consumers' use of television receivers after the completion of a broadcast transmission.[17] But content producers correctly thought the FCC would be sympathetic to their concerns, and as a result, the FCC mandated the broadcast flag, resting not on any explicit grant of jurisdiction over copying or copyright but instead on its "ancillary jurisdiction."[18] The U.S. Court of Appeals for the D.C. Circuit vacated the FCC's order as beyond its jurisdiction. Beyond the jurisdictional problem, however, there was good reason to doubt the wisdom of the FCC's approach. The broadcast flag responded to a problem that had not yet arisen by imposing significant restrictions on the architecture of consumer equipment and thereby making legal copying and use more difficult. The FCC had regulated outside its area of core expertise at the behest of a politically powerful constituency that feared that otherwise their concerns would go unheeded, and the result was a regulatory venture that diverted government attention from more appropriate means of limiting piracy.

In other cases, the organic statutes enacted by Congress explicitly create tensions between federal agencies. As matters currently stand, for example, patents are interpreted not simply by the PTO and the courts that review the PTO but also by the International Trade Commission (ITC). The PTO interprets patent applications and patents under the Patent Act, but the ITC interprets patents in the context of its own organic statute, the Tariff Act. Under section 1337 of the Tariff

Act, the ITC can block imported articles that infringe U.S. patents held by domestic industries. Moreover, according to the ITC, because it has a different source of statutory authority, it is not always bound by the patent interpretations that the PTO and the courts develop when they interpret the Patent Act. To the contrary, the ITC claims it should receive deference to its legal interpretations even when its interpretations diverge from those that might be rendered under the Patent Act. The ITC's argument has been accepted by the very court, the Federal Circuit, that reviews the PTO.[19]

C. Limitations of Current Federal Mechanisms for Centralized Review of U.S. Regulatory Actions

To the many scholars who have studied the last 25 years of presidential efforts to exercise greater centralized control of federal agency actions, some of the problems discussed in the prior section will have a familiar ring. In the past, there have been some efforts to exert greater centralized control over regulatory actions. One question that arises, therefore, is the extent to which current mechanisms of centralized review of federal agencies' actions could support the development of a coordinated set of innovation-friendly policies—at least in those cases where the inconsistency is not created by Congress, and courts do not act at cross-purposes with such coordination.

Presidential efforts to exert greater centralized control have typically been promoted as attempts to counter the parochialism of federal agencies and to harmonize conflicts between such agencies, particularly in the area of risk regulation. The most systematic mechanism through which greater presidential control has been pursued is a series of executive orders imposing the somewhat controversial requirement that federal agencies conduct cost-benefit analyses of major regulations. Centralized review of these analyses is then conducted by OIRA, an office within OMB. OIRA's reviews of agencies' cost-benefit analyses began with the Reagan administration and have continued in some form through succeeding administrations.

The details of OIRA's review have varied somewhat depending on the administration—for example, the Clinton administration introduced greater transparency into the OIRA review process by requiring, inter alia, public disclosure of all communications between OIRA personnel and individuals not employed by the executive branch. But the basic principles have remained the same. To the extent that OIRA finds a "significant" federal regulation inconsistent with its cost-benefit analysis, it can return the regulation to the promulgating agency (which can then revise or withdraw it). Although OIRA's analysis does not always trump that of the agency, it does dominate. Lower-level disputes between OIRA staff and staff at the rulemaking agency are resolved by the OIRA administrator. Only if an agency head disagrees with the OIRA administrator is there a real fight—in that case, the OMB director or the agency head brings the dispute to the attention of the President, who is responsible for its resolution. OIRA is staffed by career policy analysts with various types of social science expertise. Its only political appointee is the OIRA administrator; in the Obama administration, the OIRA administrator is legal scholar Cass Sunstein.

The reason OIRA has not maximized net regulatory benefits is because it has failed to think proactively about government-wide priorities, including innovation.

Proponents of OIRA review might argue that innovation-related benefits and costs can, and should, be addressed as part of the more general cost-benefit review done by OIRA. In support of this argument, they might note that although existing executive orders require federal agencies to engage in a variety of specialized analyses (addressing, inter alia, the impact of their regulations on the environment and on small businesses), agencies often fail to perform those analyses.[20] They might also contend that putting innovation into the global cost-benefit analysis is not only more parsimonious but also quite possibly preferable as a normative matter: specifically, because innovation is not the only value that federal regulation may seek to promote, putting innovation into the larger context of an overall cost-benefit analysis is affirmatively desirable.

We agree that innovation-related impacts of federal agency actions can, and should, ultimately be folded into a larger cost-benefit analysis. But that does not necessarily mean that analysts within OIRA itself are best suited for providing guidance about, or reviewing, the "innovation module" of the larger cost-benefit analysis. In fact, even proponents of OIRA do not claim OIRA has fully achieved a system in which net regu-

latory benefits are maximized. In significant part, the reason OIRA has not maximized net regulatory benefits is because it has failed to think proactively about government-wide priorities, including innovation.[21]

Perhaps in response to the widespread criticisms of OIRA's current regulatory review process, the Obama administration recently announced plans for, and invited comments on, a new executive order for regulatory review.[22] Several of the comments submitted mention the importance of using dynamic analyses that emphasize technological innovation.[23] Unfortunately, current OIRA staff may be particularly ill equipped to look at dynamic innovation impacts.

The executive order creating the CTO position does not give it power to coordinate, rationalize, and spur agency action. We believe an explicit grant of such power is necessary for an innovation policymaker to have real impact.

Circular A-4 (OIRA's most recent guidance to administrative agencies on how to perform cost-benefit analysis) does mention estimating regulatory benefits and costs "based on credible changes in technology over time,"[24] but its discussion of this issue is very sparse. Circular A-4 does not give any sense, for example, of how "credibility" should be gauged given the existing state of the technological art. Nor does the circular discuss with any sophistication the costs and benefits of alternative regulatory mechanisms for stimulating innovation. The circular's major contribution in this regard is a statement that regulatory performance standards are generally superior to engineering or design standards because they "give regulated parties the flexibility to achieve regulatory objectives in the most cost-effective way."[25] Although this statement is correct as far as it goes, it does not make the obvious point that performance standards are also superior because they have the capacity to stimulate innovation. The failure of Circular A-4 to mention this point may reflect a larger lack of concern with, or knowledge of, long-term innovation effects. OIRA's lack of guidance is particularly striking given the substantial literature that models the economic effects of technical change, both under the assumption that it is exogenous and that it is policy-induced.

Finally, OIRA's organizational role, which is limited to cost-benefit analyses of major proposed federal regulations, is ill-suited for the more varied roles that would need to be played by our proposal for innovation-friendly policy. Many of the major government actors whose actions affect U.S. innovation act primarily through adjudication (whether internal agency adjudication or judicial adjudication) rather than rulemaking. So although OIRA could implement the centralized focus on innovation that we envision, it is by no means the only option, nor is it the best one.

Notably, the Obama administration recently created via executive order a Chief Technology Officer (CTO) position. Under the executive order, the CTO serves as both an assistant to the President and as an associate director of the Office of Science and Technology Policy. Although the executive order does not specify the duties of the CTO, President Obama's announcement of Aneesh Chopra as CTO indicated that a component of the CTO's job description would include promoting technological innovation in the private sector. This is a useful step forward. However, the executive order creating the CTO position does not give it power to coordinate, rationalize, and spur agency action. As we discuss in Section IV, we believe an explicit grant of such power is necessary for an innovation policymaker to have real impact.

IN WHICH BRANCH SHOULD AN INNOVATION POLICYMAKER BE LOCATED?

A threshold question is in which branch of the U.S. government an innovation policymaker should be located. Creating an innovation policymaker in the judicial branch does not make much sense. The most plausible version of such a policymaker would be a court (or perhaps a few courts) that had an "innovation mission" and oversaw all innovation-related cases. Even with greater centralization, however, it is difficult to imagine courts with the expertise necessary to serve as innovation policymakers. And even if that level of expertise could somehow be achieved, Article III still stands in the way of any federal court acting as the ex ante policymaker that would be desirable in at least some cases.

As a policy matter, an innovation policymaker that improved congressional decisionmaking would appear quite attractive. A congressionally controlled regulator,

however, cannot exercise any actual power. Several U.S. Supreme Court cases—specifically, Bowsher v. Synar [26] and Metropolitan Washington Airports Authority v. Citizens for the Abatement of Airport Noise, Inc.[27]—held that Congress could not delegate the power to execute laws to a person that Congress controls. The result of these cases is a flat prohibition on Congress delegating authority to modify or delay laws to entities that it controls. Congress still can and should have its own entity making recommendations about innovation (perhaps a revived Office of Technology Assessment). Input from such an entity could be valuable in persuading members of Congress as well as the general public, even if its legal impact was fairly modest. But the broader role of innovation policymaker cannot be played by an entity that Congress controls.

That leaves the executive branch as the most plausible home for an innovation policymaker. Although an executive branch entity would not be able to resolve problems created by the plain language of statutes, it could coordinate and promote a pro-innovation agenda that operated within the realm of federal agencies' delegated authority. Additionally, as we discuss further below, we would explicitly design our innovation policymaker—OIP—so as to avoid unnecessary proliferation of executive branch offices and, relatedly, agency obligations.

CREATING AN OFFICE OF INNOVATION POLICY

Having proposed that OIP should be located in the executive branch, we now turn to the specifics of OIP's operation: first, should OIP be centralized or decentralized; second, precisely how much legal authority should it have; third, what sort of analysis should it undertake; and fourth, how should it be created?

A. Degree of Centralization

The tradeoffs between centralized and decentralized regulators are well known. To oversimplify greatly, centralization allows for efficiency, coordination, and clarity, but at the possible cost of bad decisionmaking (whether due to the influence of powerful interests or otherwise). A centralized regulator might make a bad decision and adhere to it without ever squarely, or perhaps fairly, confronting alternatives. Decentralization through the placement of innovation offices in the relevant agencies allows for experimentation and hence the opportunity to see real alternatives in action. But it achieves experimentation at the cost of a lack of uniformity, lack of interorganizational learning, lack of focus on the regulatory objective, potentially significant transaction costs for regulated entities subject to a welter of different regimes, and significant government costs arising from so many regulators covering similar ground.

There is no expert entity in the United States that looks at innovation generally. The system is entirely piecemeal. Even for proponents of a decentralized approach, this is extreme.

We do not seek to rehash the debate over centralization versus decentralization here. Our point is simply one of balance: U.S. innovation policy within (and outside of) the executive branch is currently at a decentralized extreme. Even the centralized appeals court for patent cases sees only a small portion of innovation-related issues (with perhaps the predictable result that its vision of innovation has historically been one in which patents are preeminent). There is no expert entity in the United States that looks at innovation generally. The system is entirely piecemeal. Even for proponents of a decentralized approach, this is extreme. Moreover, the costs of such radical decentralization seem particularly high with respect to innovation. Simply stated, it makes little sense to continue with a haphazard regime in which congressional legislation, agency action, and court decisions look at only one particular industry or innovation incentive, and none looks more broadly at policy through the explicit lens of spurring innovation.

A striking example of the difficulties entailed by decentralization is federal agencies' response to an executive order that requires them to analyze the impact of their decisions on federalism values.[28] Agencies have largely ignored this requirement—researchers found federalism impact statements in less than 1 percent of rulemakings, despite the fact that a much higher percentage of agency rules would seem to call for federalism analyses under the guidelines set forth in the executive order.[29] This finding does not necessarily mean that federal agencies have acted in bad faith. The problem may well be that agencies are unfamiliar with

federalism analysis and deem the resources entailed in acquiring the relevant expertise prohibitive. The point is simply that asking the existing federal agencies to take on new, overarching analyses—whether pertaining to federalism or innovation—is a tall order and one that may not be filled very well by the wide range of existing agencies.

What about the other extreme—complete centralization? For example, Congress could replace federal agencies that currently regulate innovation (whether by design or by default) with a new entity that would do their jobs and focus entirely on innovation. That is, Congress could eliminate agencies with a narrow focus on a particular industry or innovation incentive and replace them with a "Department of Innovation."

Complete centralization would represent a massive, very costly change—the dislocation and transition costs would be great. In part because of those costs, complete centralization is very unlikely. It is difficult to imagine any realistic state of affairs in which Congress decided to abandon administrative agencies that have spent decades building up their own institutional knowledge, not to mention abandoning Congress's own familiarity with the agencies.

Moreover, there are considerable advantages in having federal agencies with specialized knowledge. Regulation of areas like the environment, telecommunications, and drug safety is enormously complex. Thus it is unlikely that a policymaker with expertise in innovation generally (as opposed to, say, environmental issues specifically) would ever understand the intricacies of environmental regulation with sufficient depth to make the very finely calibrated decisions that implementation of environmental statutes requires.

Most importantly, many federal agencies that currently regulate innovation also pursue other, equally important regulatory objectives. Many FCC commissioners, for example, have viewed its "public interest" mission as including redistribution and the promotion of salutary programming. Although these objectives could conceivably be pursued outside an industry-specific context (for example, we might have an agency with the mission of "promoting redistribution"), such a reorientation is difficult to imagine and seems undesirable.

We are left then with some advantages to a horizontal regulator (i.e., a regulator in charge of innovation wherever it may arise) and other advantages to vertical (or sector-specific) regulators such as the FCC (which considers innovation alongside other goals as it regulates telecommunications) or the patent system (which considers innovation—to the extent it considers innovation at all—only in the context of patents). Purely vertical regulation allows for greater expertise but also for tunnel vision and a failure to encourage innovation. In contrast, purely horizontal regulation encourages innovation but at the cost of sector-specific expertise and a focus on other goals.

Even if we reject complete centralization and complete decentralization, that still leaves a range of possibilities. Fruitful discussion of these possibilities is inextricably linked to a decision about how much authority OIP should have in the first instance. We turn next to this question.

B. What Authority Should OIP Have?

With respect to legal authority, some salient options include: authority to create and promulgate regulations; to amend regulations proposed by existing agencies (or, in the case of agencies like the PTO that act primarily via adjudication, other agency actions); to block proposed agency actions; to remand (but not permanently block) proposed actions for further consideration; to delay proposed actions for further review; and/or to review proposed actions with no authority to take any further action. OIP's authority could also be enhanced via standards of judicial review—for example, making its decisions unreviewable, placing a presumption behind its recommendations, forcing the substantive agency to justify its action if the innovation policymaker disapproved of it, or asking whether the agency took a hard look at the innovation policymaker's contrary suggestions.

Giving an innovation policymaker the authority to unilaterally block or promulgate regulations or adjudications arguably places innovation above all other goals that administrative agencies have and, for that matter, turns administrative agencies into mere recommenders to the innovation entity. Such concentration of power in one entity, and the concomitant privileging of innovation above other goals, is excessive. Innovation

is tremendously important, and fostering innovation should be made an explicit goal of regulatory policy. But a goal does not mean the goal. Federal agencies (as directed by Congress) have many important goals—for example, distributional concerns, health and safety protection, and the like. Nothing in this report is meant to suggest that innovation should replace or overwhelm such other goals, and indeed we do not adhere to such a position. The burden of demonstrating that innovation should trump all other considerations is a very great one, and we do not believe that innovation—or any other single consideration—can meet it.

At the other end of the spectrum, an innovation policymaker that made recommendations with no legal consequences whatsoever also seems unattractive because such recommendations would be too easy to ignore. There are many entities—governmental and otherwise—that can and do make recommendations to Congress and to administrative agencies. Without the backing provided by some enforcement mechanism, those recommendations often have little weight. Merely making recommendations might make sense in those situations in which the recommender is bringing forward information that was entirely unknown to the relevant decisionmaker and the decisionmaker does not have a vested interest in ignoring that information. But in a significant number of contexts, including the innovation context, the initial decisionmaker will often have chosen a particular path with some awareness of information and arguments that would lead in a different direction. The problem is that the decisionmaker may suffer from tunnel vision or capture by powerful interests, or more generally be unduly influenced by interests relevant to its mission that are not consonant with the public interest. In those situations, unenforceable recommendations will likely produce very little. If we want our governing structure to take innovation policy seriously, it needs some actual power—some ability to alter the course of proposed regulations.

We thus reject the extremes of power (ability to block agency action versus hortatory power only. Between these extremes, there are a variety of options, and it would be folly to claim that there is one perfect choice among them. But we think that two axes are of particular importance, and thinking of the proposed innovation policymaker in the context of these axes does a fair amount of work.

The first axis is the likelihood of resistance on the part of the federal decisionmakers who would respond to the innovation policymaker. The discussion so far suggests that the innovation policymaker will propose better innovation policies than other decisionmakers will. Insofar as other federal entities can be expected to resist the innovation policymaker's policies—either out of bad faith or sincere but misplaced concerns—that resistance would counsel in favor of increased power for the innovation policymaker.

In the case of major regulations that are currently subject to cost-benefit review by OIRA, we propose that OIP provide the innovation "module" of the analysis.

This is a basic concern that arises whenever a government wants to reorient existing behavior. If the White House wants to push agency officials to do something they are only marginally disinclined to do, a mere recommendation, or a recommendation backed by a very mild sanction, likely would be sufficient to overcome the officials' resistance. A request that officials wear a security badge or wash their hands after using the bathroom might fall into this category. If, instead, there is reason to expect strong resistance on the part of agency officials, a bigger club—in the form of greater power—might be necessary. Effective integration of a previously segregated environment (like the U.S. armed services before 1948), for example, might require an integration enforcer with considerable powers to overcome the strong resistance of some agency officials.

The second axis addresses the same general concern with respect to the innovation policymaker: to what extent is the policymaker likely to be overeager, pushing broader regulatory solutions than would be ideal? As with the question regarding resistance from agency officials, this is a question about the likelihood of error compared with an ideal model that will never be obtained in reality. We know that there will be deviations from an ideal path, but in some cases the danger of overzealousness—whether in seeking to add regulations or block them—will be greater than in others. Insofar as that danger increases, it serves as an argument for limiting the innovation policymaker's powers.

As we have discussed, we do not favor giving OIP the power to block federal agencies' actions. Once the possibility of OIP blocking agency action is off the table, the danger posed by an overeager regulator is greatly reduced. If, as we propose, OIP cannot permanently block agency action, interest groups will be aware of that limitation. As a consequence, interest groups will have less incentive to influence OIP than they would if it could block regulations. This obviously means that OIP cannot altogether remake government policy in a fundamental way, but it also means that it cannot deliver regulatory gains to interest groups—and that means the danger of OIP overzealousness is diminished.

OIP should be authorized both to propose new agency action and respond to existing agency action. Federal agencies would be subject to a requirement that they consider and respond to OIP's analysis.

Turning back to the first axis, we expect some resistance to OIP's ideas. Federal agencies are familiar with the interests of those they regulate. By and large, these agencies have not focused on innovation per se and have not looked at effects of their actions on the U.S. economy as whole (as opposed to their slice of it). This fact is not surprising—indeed, it is part of the design of agencies—but federal agencies' lack of familiarity with the analysis we are proposing likely will create hesitation about adopting it. That said, we do not expect utter intransigence from federal agencies, because empirical evidence does not support the extreme vision of some public choice theorists: that government officials will always do the bidding of powerful interests who supply them with money, clout, or whatever they maximize. Well-funded groups have a great deal of influence—indeed, that influence is part of the reason that we do not propose that existing entities do the innovation analysis on their own—but influence is not control.

Still, the possibility of some agency resistance—whether in good faith (e.g., tunnel vision) or bad faith (e.g., capture by powerful interests)—cannot be dismissed. That possibility leads us to propose a mechanism through which OIP's policy position would be made public, and federal agency officials would be obliged to respond to OIP's position publicly, even though such officials would not be obliged to implement it.

Specifically, in the case of major regulations that are currently subject to cost-benefit review by OIRA, we propose that OIP provide the innovation "module" of the analysis. OIP should provide this analysis ex post, as part of the OIRA review, and also ex ante, through guidelines to agencies that supplement the current, largely static analysis in OIRA's Circular A-4. In other contexts, where OIRA is not involved, OIP could also issue guidelines for thinking about impacts on innovation.

Moreover, OIP should be authorized both to propose new agency action and respond to existing agency action. Federal agencies would be subject to a requirement that they consider and respond to OIP's analysis. OIP's input could not force the agency to take any particular action. Rather, the agency would be required to consider OIP's analysis carefully, and to articulate a reasoned response that would become part of the record to which a court would look in the event of a judicial challenge.

At its core, our proposal is for a form of review that is quite common in administrative law—"hard look" review, in which a court considers whether an agency took a hard look at all the significant arguments and data, including those that did not support its position, in making its policy decisions. If a reviewing court finds that an agency failed to take such a hard look at an important argument or set of data, the court rejects the agency action and remands it to the agency for such consideration. The agency can adhere to its original position, but it must respond to the countervailing materials.

Our proposal is that OIP's input would be submitted to the agency and become part of the record before the agency. OIP's submissions would thus qualify as material at which the agency should take a hard look, and to which the agency would be required to respond. The agency could reject OIP's position, but it could not do so without demonstrating that it had considered OIP's ideas and analysis. And a reviewing court would play

the familiar role that it plays in hard-look review—determining whether the agency took a hard look at OIP's submissions to the agency and thus effectively requiring the agency to show that it considered them.

There is no guarantee, of course, that the agency will in fact sincerely consider OIP's input, rather than merely pay lip service to it. But that is always the danger of any system that does not mandate particular outcomes. And we believe the public nature of OIP's input would be helpful. The fact that an innovation policymaker was publicly questioning a federal agency's course of action would change the regulatory dynamic. The agency would have to articulate why the analysis put forward by OIP was unpersuasive, and we expect that such a requirement would have a disciplining effect and render some arguments harder to make.

OIP's mandate should be to cast the widest possible net in terms of gathering information relevant to application of its decision principles.

The prospect of hard-look review by a court should be sufficient to require federal agencies to take OIP's input seriously. But we also propose an additional backstop against agency recalcitrance in the form of remand of agency actions that ignore OIP's input. This backstop would also be the relevant "stick" in cases where OIRA was involved. In effect, OIP would be able to conduct its own hard-look review, asking whether the agency (or OIRA) responded to its arguments and remanding the action if it failed to do so. OIP would be able to remand only once, so that a truly resistant agency could ignore OIP's original submission and its remand, and then promulgate its action as it saw fit (subject, of course, to the danger of a court saying that it failed to take a hard look at OIP's input). But that seems quite unlikely, given that the agency could avoid the time, energy, and litigation risk entailed in the strategy above by demonstrating that it seriously considered and responded to OIP's analysis.[30]

In this regard, the empirical analysis we have done (discussed further below) of some recent, innovation-related FCC rulemakings is instructive. The FCC was persuaded by the expert submissions of another governmental entity that addresses telecommunications policy—the NTIA—even without a formalized role for the NTIA in the FCC's rulemaking process. Creating a formal role for OIP in agencies' decisionmaking processes, complete with a requirement that agencies take a hard look at OIP's input, will make it only more likely that agencies will take OIP's submissions very seriously.

The example of the NTIA's comments highlights another aspect of OIP's involvement. Like OIRA, OIP would participate in the rulemaking process, rather than waiting until an agency's rulemaking process was complete in order to give its input. Requiring OIP to wait (as a court must) until an agency completes its rulemaking process might entail significant delays in the already lengthy rulemaking process. And insofar as the agency was persuaded to change its rulemaking, some of the agency's earlier work would have been for naught. Having OIP give its input during the formation of the agency's rule would allow for much more efficiency, and reduce the chances of OIP's analysis adding a lengthy delay in the rulemaking process.

C. What Sort of Analysis Should OIP Undertake, and What Procedures Should It Use?

The previous discussion gives shape to the sort of analysis OIP should undertake. The primary bases upon which OIP might criticize proposed agency action would be twofold. First, OIP might find that the agency action in question was aimed at promoting innovation but did so in a manner that was flawed or at cross-purposes with the actions of other agencies. Second, OIP might find that the action in question aimed to achieve a goal other than innovation but that the agency could achieve that goal in a manner less damaging to innovation. OIP would also have the important role of providing the innovation component to OIRA's cost-benefit analysis of major regulation.

The principles that OIP would use for its analysis would be quite parsimonious, which should also help to avoid undue delay. Again, the idea would be not so much that individual federal agencies could not use the principles, but that such agencies would not necessarily have the motivation and expertise to use the principles appropriately. The most important principle (which might, in certain cases, represent the entirety of OIP's analysis) would simply be whether, on balance,

the proposed regulatory action maximized the sum of innovation incentives for all innovators, both current and future.

For example, a compulsory access regime for a particular platform technology might address blockages to optimal improvement caused by one of the many exceptions to the "one monopoly profit"/"internalizing complementary externalities" principle.[31] To that extent, the compulsory access regime could improve incentives for future innovators. On the other hand, to the extent that the compulsory scheme undercompensated the platform innovator, it might decrease incentives for future platform innovators (including innovators that might come up with alternative platforms). More immediately, if the platform was not purely a knowledge platform (e.g., if it was a physical platform such as broadband cable), compulsory access might decrease incentives to maintain or improve the platform.

OIP's mandate should be to cast the widest possible net in terms of gathering information relevant to application of its decision principles. OIP would seek input from other agencies—both regulatory and funding agencies. It could also learn from nongovernment actors, including familiar sources like think-tanks and academics, along with less familiar ones like prediction markets and other means of harnessing the wisdom of crowds.[32]

In considering the procedures OIP should use, we might ask whether administrative law requirements that are intended to secure public input—in particular, public comments—should apply to OIP. With respect to transparency, the answer is clear. At a minimum, transparency requirements similar to those imposed on OIRA during the Clinton administration should apply. And as we noted above, OIP's input would be part of the record before the agency and thus would be publicly disclosed. There is of course the question of compliance. Commentators have complained that OIRA's compliance with transparency obligations has been incomplete. OIP would presumably have a greater interest in transparency than does OIRA: unlike OIRA, OIP would not be able to block agency action, so OIP's authority would flow from the degree to which it could persuade others to accept its views. Because it would have somewhat less inherent power than OIRA, OIP would need to make greater use of the "bully pulpit."

Implicit in the discussion above are basic elements of OIP's procedures—gathering information, conducting analysis, and communicating its ideas. These are the core aspects of almost any decisionmaking process for any entity. The real question is whether OIP's processes would include the central distinctive element of the informal rulemaking process under the Administrative Procedure Act (APA): the requirement of a process pursuant to which members of the public can comment on proposed federal regulations. Neither agency decisionmaking nor judicial review of agency actions requires a comment process, so its costs and benefits in the context of innovation regulation are worth careful consideration.

Creation of an innovation policymaker via executive order is the most attractive, and feasible, path.

There is a longstanding debate among commentators about the benefits of the comment process. Kenneth Culp Davis, for instance, praised the notice-and-comment process as "one of the greatest inventions of modern government," because it allows citizens to participate in the lawmaking process.[33] David Barron and Elena Kagan have suggested that "notice and comment often functions as charade" and that "notice-and-comment rulemaking today tends to promote a conception of the regulatory process as a forum for competition among interest groups, rather than a means to further the public interest."[34]

The central cost of the comment process is straightforward: the relevant agency's time in reading, assessing, and, when appropriate, responding to the various comments. Even if comments turn out to add little, the agency has to read and assess them in order to make that determination. That alone is a substantial use of agency resources. Then there is the time and energy required to demonstrate that the agency has taken a hard look at whichever arguments and data in the comments a court may later find significant and thus require an agency response.

The more difficult issue involves evaluating the benefits of comments. We took a close look at the comment process in three recent FCC proceedings relating to innovation to see what role it played there. The rulemakings involved media ownership rules, proposals

for broadband Internet services over power lines, and the use of "white spaces" in the broadcast spectrum (frequencies used as buffers and thus not occupied by transmitters) by new services. All three of these FCC proceedings attracted significant public interest and large numbers of comments from individual citizens. We chose them on the theory that the increased amount of public comment was likely to present the strongest case of individuals' impact on the rulemaking process. For each proceeding, we examined who submitted comments to the FCC; how often those comments were inconsistent with the economic interests of the commenters; how often the comments contained arguments or information that was not contained in earlier comments; whose comments the FCC responded to in its resulting order; and whose comments the FCC agreed with in its resulting order.

Our conclusions from our review of the comment process for these three FCC proceedings are not encouraging. We found that comments were submitted disproportionately by well-organized groups. None of the comments was against the economic interests of the relevant commenters. And the vast majority of comments from private and public interest groups, and virtually all the comments from private citizens (which were mainly form letters), were duplicative of comments that had already been submitted. In contrast to the literal duplication entailed in form letters, the comments from organized interest groups used different words and different phrasing. But when we looked closely at the substance of the points that commenters made, we found a very high degree of duplication. The words differed, but the arguments did not.

The bottom line is that the comment process yielded little more than we might expect from a bare-bones lobbying process. The ideas and information that seemed important (both to us in reading the comments and to the FCC in responding to them) could be expected to be made by any given lobbyist on a particular side of the issue. All the other comments on the same side added little.

In sum, the results of the available theoretical and empirical work, including our own, strongly suggest that an APA-style public comment process is not essential, or even particularly helpful, for purposes of improving innovation regulation.[35]

D. How Should OIP Be Created?

One big advantage of our proposal over other possible mechanisms for improving U.S. innovation policy is that, while it can be implemented via legislation, it can also be implemented by executive order. The President can (and often does) create new offices via executive order, and giving a new office the authority to submit materials to agencies raises no constitutional issues.

The only constitutional concern raised by an OIP created by the President through executive order would involve the President's ability to authorize OIP to remand regulations back to independent agencies, as opposed to executive agencies. Some executive orders on federal regulation have refrained from giving entities like OIRA the ability to block regulations issued by independent agencies, authorizing such power only with respect to executive agency regulations.[36] However, there is no case law holding that giving an entity created by executive order the power to block independent agencies' regulations would be unconstitutional.[37] In any event, we are not proposing a veto (which OIRA effectively has), but instead what amounts to a delay. OIP can remand only once and cannot force the agency to do anything, so an agency that refused even to read OIP's input would be subject only to a delay in promulgating its regulation. The weight of commentary indicates that such a procedure would not violate the separation of powers. So although Congress could eliminate any question by passing legislation giving this power to OIP, we do not believe that would be necessary.

The advantage of having an OIP that can be created by executive order is quite significant. Indeed, creating OIP by executive order makes it much more likely that an effective OIP will in fact be created. There are several reasons. One is the simple fact that it is easier to persuade the President to promulgate a policy than to persuade veto-proof majorities in the House and Senate. Another reason is that there is widespread agreement that the President is more politically accountable to the national public than Congress. As a result, the President has greater reason to be concerned about the overall health of the national economy. And the innovation with which we are concerned may well negatively affect some regions of the country even as it helps others (the costs and benefits of innovation are sometimes geographically lumpy). Simply stated,

the President's broader electoral constituency makes him more responsive to majoritarian preferences than Congress. As a result, creation of an innovation policymaker via executive order is the most attractive, and feasible, path.

It also bears noting both that the proposed OIP should face less danger of capture by powerful interests than other institutions do and that the absolute danger of such capture would be reasonably low. We have already noted two reasons for this: OIP will not be able to block regulations, and it will have both an obligation and an incentive to operate transparently. But another reason is significant as well: OIP's broad scope will make capture more difficult, and therefore less likely. The classic case of capture arises when an agency (or congressional committee) covers one or two industries. The major incumbents from those industries (or from advocacy groups with an interest in these industries) can band together and exert a huge amount of influence. That is the story, for instance, with respect to broadcasters' decades-long influence at the FCC. An entity that takes a cross-cutting approach to all regulation is less subject to the power of a few major stakeholders precisely because there will not be a few major stakeholders. Some of the entities affected by OIP will of course be powerful, but they will also be diffuse and they will not necessarily be repeat players, making it less likely that they will find it worth their time and energy to organize themselves much better than citizens groups are organized. Thus the logic of collective action should not produce the results that we see with more narrowly focused agencies.

CONCLUSION

Promoting innovation is a critical goal of U.S. public policy, and it can take many forms: direct investment, tax incentives, procurement, etc. One crucial element of U.S. innovation policy that has been given short shrift, however, is structuring federal regulatory policy so that it promotes—or at least does not retard—innovation. Currently, there is no formal process within the executive branch to ensure that this happens.

There is no perfect mechanism for improving U.S. innovation policy, but we conclude that the best approach would be to establish an Office of Innovation Policy that could serve as an innovation policymaker within the U.S. government. Thus we propose that President Obama create OIP by executive order and provide it with enough authority to be able to have a significant positive impact on innovation policy, but without giving it so much power that it can run roughshod over the other agencies.

We believe OIP should have sufficient power to have the experiment be meaningful, and that OIP should be able to continue indefinitely if the experiment works out well.[38] Some might question the significance of our proposal. Isn't creating OIP a fairly small change to the system? Certainly adding OIP to the existing mix is a smaller change than jettisoning the existing substantive agencies in favor of a new agency with authority to regulate, and increase, innovation in all fields. But we believe that implementing this proposal will significantly change the regulatory environment. First, an entity focused on innovation would add an important new voice to the regulatory conversation. There would now be an entity speaking clearly and forthrightly on the centrality of innovation. Second, and more important, OIP would not merely have a voice: it would be able to remand agency actions that harm innovation. It would also have as part of its mission proposing regulation that benefits innovation. This is no small matter. Indeed, it would change the regulatory playing field overnight.

To those who might oppose an OIP on the grounds that making predictions about the future is very difficult—and experts are often wrong when they make such predictions—our response is straightforward: Agencies are already making predictions about the future (whether consciously or not) when they make laws that affect innovation. They are simply doing so in a manner that is unsystematic, haphazard, and subject to undue influence by well-funded incumbents. We can do better.

ENDNOTES

1. For one exception, see Robert D. Atkinson and Howard Wial, *Boosting Productivity, Innovation, and Growth Through a National Innovation Foundation* (Washington, D.C.: Information Technology and Innovation Foundation and Metropolitan Policy Program at Brookings, April 22, 2008) <www.itif.org/files/NIF.pdf>.

2. Dean Baker and David Rosnick, *"Usable Productivity" Growth in the United States: An International Comparison, 1980–2005* (Washington, D.C.: Center for Economic and Policy Research, June 2007):7, 11.

3. Harald Edquist and Magnus Henrekson, "Technological Breakthroughs and Productivity Growth," in *Research in Economic History*, Vol. 24, ed. Alexander J. Field, Gregory Clark, and William A. Sundstrom (United Kingdom: Emerald Group Publishing, 2007); William Nordhaus, *The Sources of the Productivity Rebound and the Manufacturing Employment Puzzle*, NBER Working Paper No. 11354 (Cambridge, Mass.: National Bureau of Economic Research, 2005); Dale W. Jorgenson, Mun S. Ho, and Kevin S. Stiroh, *Productivity: Vol. 3—Information Technology and the American Growth Resurgence* (London; Cambridge, Mass.: MIT Press, 2005); Erik Brynjolfsson and Lorin M. Hitt, "Beyond the Productivity Paradox," *Communications of the Association for Computing Machinery* 41(8) (1998): 49, 50. For a summary of this and other literature on the effect of IT and productivity, see Robert D. Atkinson and Andrew S. McKay, *Digital Prosperity: Understanding the Economic Benefits of the Information Technology Revolution* (Washington, D.C.: Information Technology and Innovation Foundation, March 2007) <www.itif.org/files/digital_prosperity.pdf>.

4. Gregory Tassy, *The Technology Imperative* (Cheltenham: Edward Elgar, 2007).

5. Robert D. Atkinson and David B. Audretsch, *Economic Doctrines and Policy Differences: Has the Washington Policy Debate Been Asking the Wrong Questions?* (Washington, D.C.: Information Technology and Innovation Foundation, September 2008) <www.itif.org/files/EconomicDoctrine.pdf>.

6. Paul Romer, "The Origins of Endogenous Growth," *Journal of Economic Perspectives*, 8(1) (1994): 3, 20–21. For example, geographically based industry clusters may be particularly important for producing, and taking advantage of, externalities and spillovers. Government policy can play a role in encouraging such clusters. Atkinson and Wial, *op. cit.*, 2008:13–14. Atkinson and Wial also cite economic research on market failures that may cause entire industries (e.g., the healthcare sector) to lag behind in the adoption of new technologies. *Id.* at 12–13.

7. Joseph Schumpeter, *Capitalism, Socialism and Democracy* (New York: Harper and Row, 1942): 13. See also William J. Baumol, *The Free-Market Innovation Machine: Analyzing the Growth Miracle of Capitalism* (Princeton: Princeton University Press, 2002): 57-59 (describing the significance of the entrepreneur in facilitating innovation); and Michael Carrier, *Innovation for the 21st Century: Harnessing the Power of Intellectual Property and Antitrust Law* (Oxford: Oxford University Press, 2009) (discussing recent work by Clayton Christensen and others on why established firms are unlikely to pursue disruptive innovation). Carrier and many others have also discussed the manner in which disruptive technologies can threaten the business models not only of incumbent technologists but also of adjunct industries, such as purveyors of copyrighted material. Like incumbent technologists, well-financed copyright holders are likely to have disproportionate influence over regulatory processes.

8. Zoltan J. Acs and David B. Audretsch, *Innovation and Small Firms* (Cambridge, Mass.: MIT Press, 1990): 12–23; and David B. Audretsch, *Innovation and Industry Evolution* (Cambridge, Mass.: MIT Press, 1995): 35–38. And to the extent citations to firm patents are a measure of an invention's significance, it is noteworthy that, in recent years, small-firm patents have been more likely than large-firm patents to be in the top 1% of frequently cited patents. CHI Research Inc. (Hadden Heights, New Jersey), *Small Serial Innovators: The Small Firm Contribution to Technical Change*, prepared for Office of Advocacy, U.S. Small Business Administration, Washington, D.C., Feb. 27, 2003: 10 <sba.gov/advo/research/rs225tot.pdf>.

9. Robert D. Atkinson, *The Revenge of the Disintermediated: How the Middleman Is Fighting E-Commerce and Hurting*

American Consumers (Washington, D.C.: Progressive Policy Institute, January 2001) <www.ppionline.org/documents/disintermediated.pdf>.

10. Mark A. Lemley and David McGowan, "Legal Implications of Network Economic Effects," *California Law Review* 86 (1998): 479, 524; and James Bessen and Michael J. Meurer, *Patent Failure: How Judges, Bureaucrats, and Lawyers Put Innovators at Risk* (Princeton, New Jersey: Princeton University Press, March 2008): 187–214.

11. Federal Trade Commission, *To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy* (Washington, D.C.: October 2003).

12. See Federal Communications Commission, *In the Matter of IP-Enabled Services, Notice of Proposed Rulemaking*, WC Docket No. 04-36, 19 F.C.C.R. 4863, 4864–68 (March 10, 2004) <askcalea.net/pet/docs/20040310.fcc.04-28.pdf>: "[T]he changes wrought by the rise of IP-enabled communications [including VoIP] promise to be revolutionary . . . to reduce the cost of communication and to spur innovation and individualization."

13. "Despite a widespread belief among industry observers that the carriers' patents were invalid or not infringed, Vonage ultimately settled all three cases for around $200 million, about a quarter of its annual revenue. Since settling the lawsuits, Vonage's marketing expenditures have decreased and its subscriber growth has slowed, though the company has staved off bankruptcy for the time being."(internal quotation omitted): Stuart J.H. Graham and Ted Sichelman, "Why Do Start-Ups Patent?" *Berkeley Technology Law Journal* 23(1) (2008):1063, 1080-81.

14. A vast amount of economic literature documents how the potential for hold-up created by injunctive relief allows patent holders to extract more in licensing fees and/or settlements than the actual contribution made by their patents.

15. Lynnette Luna, "Spectrum Quandary Puts 3G at Risk," *Telephony.Online* (July 23, 2001):10 <telephonyonline.com/mag/telecom_spectrum_quandary_puts/> (discussing tensions among the FCC, NTIA, and Department of Defense on spectrum policy).

16. Bob Brewin, "Cellular Carriers, DOD Debate Spectrum Needs," *Computerworld*, (April 8, 2002): 61.

17. *American Library Association v. Federal Communications Commission and United States of America*, 406 F.3d 689, 691–92 (United States Court of Appeals, District of Columbia Circuit, 2005).

18. Federal Communications Commission, *In the Matter of Digital Broadcast Content Protection: Report and Order and Further Notice of Proposed Rulemaking*, MB Docket No. 02-230, 18 F.C.C.R. 23550, 23563–64 (Nov. 4, 2003), vacated in part, reviewed in part sub nom. American Library Association, 406 F.3d at 708.

19. *Kinik Co. v. International Trade Commission*, 362 F.3d 1359, 1361, 1363 (Federal Circuit, 2004) (noting the ITC's belief that recently enacted defenses to infringement in the Patent Act do not apply to infringement actions before the ITC, and finding that the ITC is entitled to Chevron deference in its belief that certain defenses provided by the Patent Act are not available in infringement actions before the ITC).

20. Nina A. Mendelson, "Chevron and Preemption," *Michigan Law Review* 102 (2004): 737, 782–86 (discussing agencies' failure to engage in the analysis of their rules' impact on federalism as required by executive order).

21. Robert W. Hahn and Cass R. Sunstein, "A New Executive Order for Improving Federal Regulation?: Deeper and Wider Cost-Benefit Analysis," *University of Pennsylvania Law Review* 150(2002):1489, 1522: "One of our primary concerns is that no institution in government has yet vindicated the hopes of those who believed that cost-benefit analysis could be used to help promote better priority-setting, block senseless rules, and spur agency action when justified."

22. Office of Management and Budget, *Federal Regulatory Review: Request for Comments*, 74 *Fed. Reg.* 8819 (Feb. 26, 2009) <edocket.access.gpo.gov/2009/pdf/E9-4080.pdf>.

23. Jonathan B. Wiener, "Ten Ideas to Improve Regulatory Oversight," slide presentation at the annual meeting of

the Society for Risk Analysis, Boston, Mass., December 10, 2009 <www.reginfo.gov/public/jsp/EO/fedRegReview/publicComments.jsp> (noting need to improve "future ex ante impact assessment methods" by looking at technological innovation and dynamic analyses more generally).

24. Office of Management and Budget, *Circular A-4* (Regulatory Analysis) (Washington, D.C., 2003): 37 <www.whitehouse.gov/omb/circulars/a004/a-4.pdf>.

25. Ibid., 8. See also ibid., 16: "Within a command-and-control regulatory program, performance-based standards generally offer advantages over standards specifying design, behavior, or manner of compliance."

26. *Bowsher v. Synar*, 478 U.S. 714 (1986).

27. *Airport Auth. v. Citizens for Noise Abatement*, 501 U.S. 252 (1991).

28. Executive Order No. 13132 (Federalism), 64 *Fed. Reg.* 43255, 43255–56 (Aug. 4, 1999) <edocket.access.gpo.gov/2009/pdf/E9-4080.pdf>. For earlier executive orders similarly requiring agencies to perform federalism impact analyses, *see* Executive Order No. 12612, 52 *Fed. Reg.* 41685 (Oct. 26, 1987) and Executive Order No. 12372, 47 *Fed. Reg.* 30959 (July 14, 1982).

29. U.S. General Accounting Office, "Federalism: Implementation of Executive Order 12612 in the Rulemaking Process," testimony before the Committee on Governmental Affairs, U.S. Senate, Washington, D.C., May 5, 1999: 4 <www.gao.gov/archive/1999/gg99093t.pdf > (finding that only five federalism impact assessments had been prepared for the over 11,000 final rules agencies issued between April 1996 and December 1998); Mendelson, *supra* note 20, at 783 (finding five published federalism impact statements among 600 proposed and final rules during one quarter of 2003).

30. Indeed, we suspect that OIP would rarely have to invoke its authority to remand a regulation for consideration of its arguments: the risk created by judicial hard-look review, combined with the additional risk created by the prospect of OIP remand, should be more than sufficient to persuade an agency that the costs of compliance are smaller than the costs of noncompliance.

31. Joseph Farrell and Philip J. Weiser, "Modularity, Vertical Integration, and Open Access Policies: Towards a Convergence of Antitrust and Regulation in the Internet Age," *Harvard Journal on Law and Technology* 17 (2003): 85, 105-119 (discussing the idea of internalizing complementary efficiencies and the exceptions to it).

32. Michael Abramowicz, *Predictocracy: Market Mechanisms for Public and Private Decisionmaking* (New Haven: Yale University Press, January 2008); and James Surowiecki, *The Wisdom of Crowds* (New York: Random House, 2004).

33. Kenneth Culp Davis, Administrative Law Treatise § 6.15, at 283 (1st ed. Supp. 1970).

34. David Barron and Elena Kagan, "Chevron's Nondelegation Doctrine," *2001 Supreme Court Review* 201, 231–32 (2001).

35. Some have argued that the value of comments in the rulemaking process could be increased via various changes to the process. Proposed changes might allow for collaboration among commenters perhaps like Wikipedia and/or ratings of comments perhaps like Slashdot, in which users rate the quality of others' submissions, and the raters themselves are rated for the quality of their ratings. One of us focused on these questions in a different article and came to the conclusion that such an increase in the value of comments is unlikely, for several reasons—perhaps most notably that collaboration and ratings systems do not work well in contexts where policy preferences loom large. *See* Stuart Minor Benjamin, "Evaluating E-Rulemaking: Public Participation and Political Institutions," *Duke Law Journal* 55 (2006): 893, 924-32. The other of us believes that these "open source"–type approaches to improving notice and comment may have value, but that it would be premature to impose even potentially improved notice and comment procedures on an OIP before their value had been proved in other, more conventional rulemaking contexts.

36. Michele Estrin Gilman, "If at First You Don't Succeed, Sign an Executive Order: President Bush and the Expansion

of Charitable Choice," *William & Mary Bill of Rights Journal* 15(4) (2007):1103, 1154 (noting that Reagan's regulatory-review executive order did not apply to independent agencies, whereas Clinton's executive order applied the procedural, but not the substantive, review requirements to independent agencies).

37. Harold H. Bruff, *Balance of Forces: Separation of Powers Law in the Administrative State* (Durham, North Carolina: Carolina Academic Press, 2006): 167–97.

38. If our confidence in OIP was lower, we would propose a time limit, with a sunset provision to shut down OIP after a given number of years (unless it was renewed).

ABOUT THE AUTHORS

Stuart Minor Benjamin and Arti K. Rai are Professors of Law, Duke Law School. This report draws from a longer article written by the authors, Stuart Minor Benjamin and Arti K. Rai, "Fixing Innovation Policy: A Structural Perspective," 77 *The George Washington Law Review* 1 (2008).

ABOUT THE INFORMATION TECHNOLOGY AND INNOVATION FOUNDATION

The Information Technology and Innovation Foundation (ITIF) is a nonprofit, non-partisan public policy think tank committed to articulating and advancing a pro-productivity, pro-innovation and pro-technology public policy agenda internationally, in Washington and in the states. Through its research, policy proposals, and commentary, ITIF is working to advance and support public policies that boost innovation, e-transformation and productivity.

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The Next Generation of (Safety) Regulation for HRO's

Federal Aviation Administration

Presentation to: HSS Visiting Speakers Program

Name: Christopher A. Hart

Date: July 24, 2009

Aviation Safety Experience

- Conventional Wisdom:

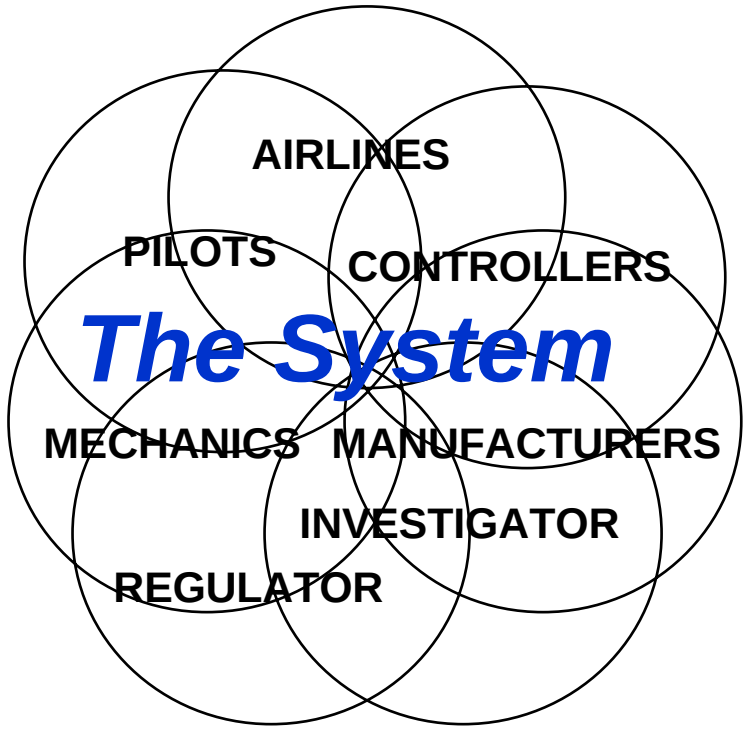
More vigorous regulation and enforcement
will result in improved safety

- Lesson Learned from Experience:

There is a mishap rate plateau beyond which
further improvement necessitates
a more collaborative approach

The Context: Increasing Complexity

- **More System *Interdependencies***
  - Large, complex, interactive system
  - Often tightly coupled
  - Hi-tech components
  - Continuous innovation
  - Ongoing evolution
- **Safety Issues Are More Likely to Involve *Interactions Between Parts of the System***

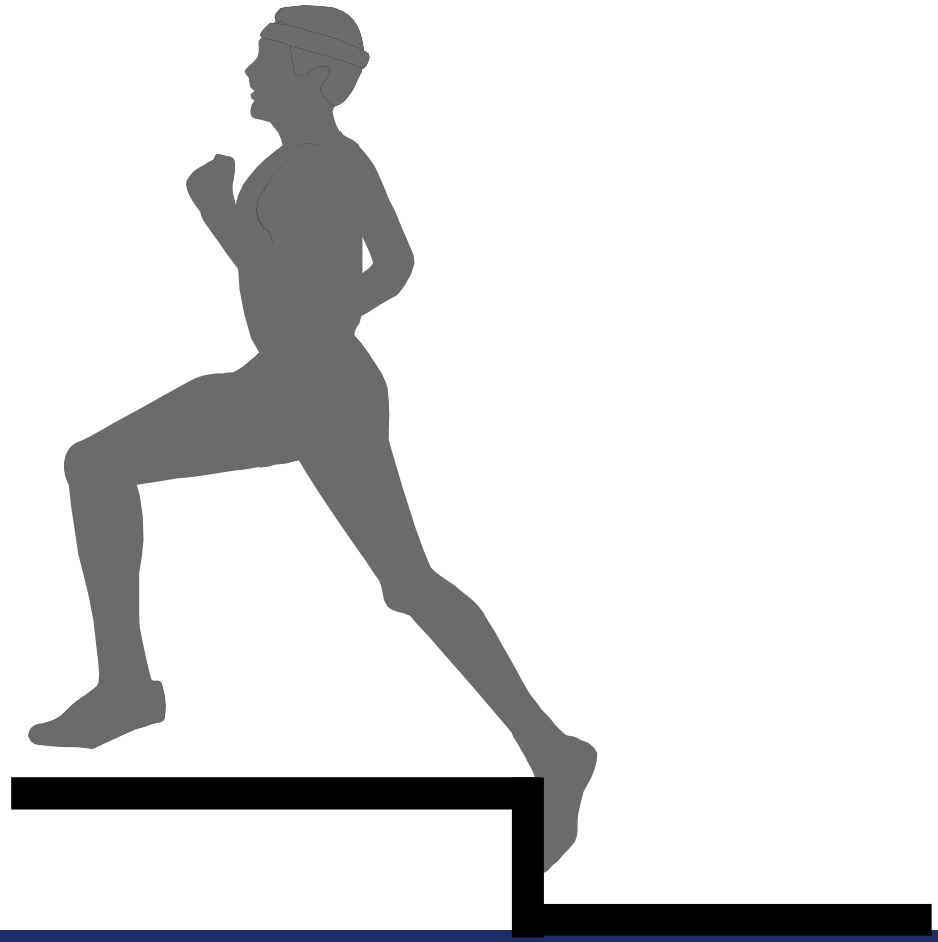


When Things Go Wrong . . .

Is the Person *clumsy?*

Or is the problem . . .

The *Step???*



Response to Human Error

The Good Ol' Days . . .

You are highly trained

and

If you did as trained, you wouldn't make mistakes

so

You weren't careful enough

so

You should be PUNISHED!

(Swat Mosquitoes)

Where It's Going . . .

You are human

and

Humans make mistakes

so

Let's *also* explore why the system allowed, or failed to accommodate, your mistake

and

Let's IMPROVE THE SYSTEM!

(Drain the Swamp)

Enhance Understanding of Person/System Interactions By:

- Collecting,

- Analyzing, and

- Sharing

Information

Major Source of Information: "Front-Line" Employees

"We Knew About That Problem"

(and we also knew it might hurt someone sooner or later)

Two Objectives:

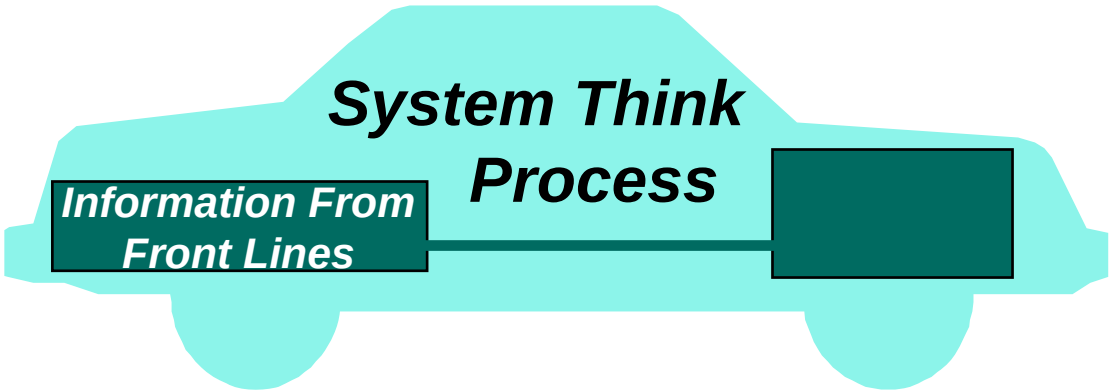
Make the System

(a) Less Error Prone

and

(b) More Error Tolerant

Collaboration Can Facilitate:



Improved
Safety

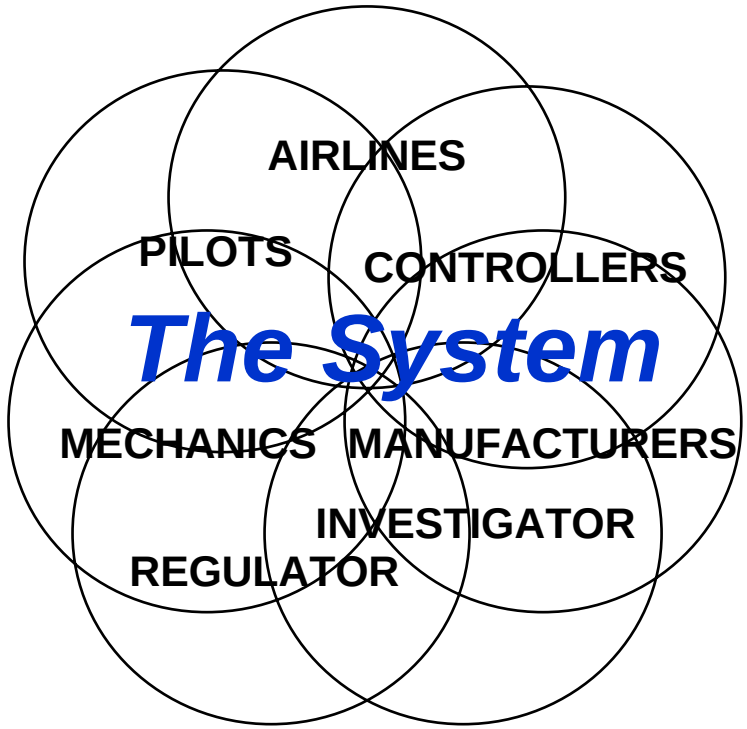
- AND -

Improved
Productivity

Aviation "System Think"

Engage ***All*** Participants In Identifying Problems and Developing and Evaluating Remedies

- Airlines
- Manufacturers
  - *With the systemwide effort*
  - *With their own end users*
- Air Traffic Organizations
- Labor
  - *Pilots*
  - *Mechanics*
  - *Air traffic controllers*
- Regulator(s) [Query: Investigator(s)?]



How The Regulator Can Help

- **Emphasize Importance of System Issues In Addition to Operator Issues**
- **Encourage and Participate in Industry-Wide "System Think"**
- **Facilitate Collection and Analysis of Information**
  - ***Clarify and announce policies for protecting information and those who provide it***
  - ***Encourage other industry participants to do the same***

Aviation Success Story

65% Decrease in Fatal Accident Rate, 1997 - 2007

largely because of

Proactive Safety Information Programs

plus

System Think

P.S. Aviation was already considered *VERY SAFE* in 1997!!

United States Government Accountability Office

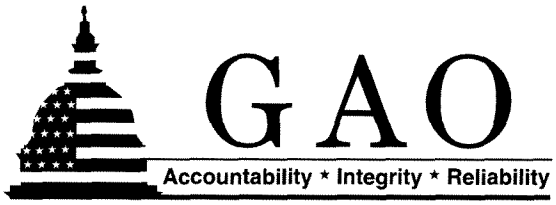
GAO

Report to Congressional Committees

June 2009

TECHNOLOGY TRANSFER

Clearer Priorities and Greater Use of Innovative Approaches Could Increase the Effectiveness of Technology Transfer at Department of Energy Laboratories



GAO-09-548

June 2009

GAO
Accountability · Integrity · Reliability

Highlights

Highlights of GAO-09-548, a report to congressional committees

TECHNOLOGY TRANSFER

Clearer Priorities and Greater Use of Innovative Approaches Could Increase the Effectiveness of Technology Transfer at Department of Energy Laboratories

Why GAO Did This Study

The Department of Energy (DOE) spends billions of dollars each year at its national laboratories on advanced science, energy, and other research. To maximize the public's investment and to foster economic growth, federal laws and policies have encouraged the transfer of federally developed technologies to private firms, universities, and others to use or commercialize. The American Recovery and Reinvestment Act of 2009 further emphasized the role of such technologies for addressing the nation's energy, economic, and other challenges.

Congress requested GAO to examine (1) the nature and extent of technology transfer at DOE's laboratories; (2) the extent to which DOE can measure the effectiveness of its technology transfer efforts; and (3) factors affecting, and approaches for improving, DOE's efforts. GAO analyzed documents and data and spoke with officials at DOE headquarters and all 17 DOE national laboratories.

What GAO Recommends

GAO is recommending a number of actions, including that DOE articulate departmental priorities and a definition for technology transfer, improve its performance data, and ensure that laboratories have sufficient expertise and a systematic approach for identifying their commercially promising technologies. In commenting on a draft of this report, DOE generally agreed with the findings but did not comment on the recommendations.

View GAO-09-548 or key components.
For more information, contact Gene Aloise at (202) 512-3841 or aloisee@gao.gov.

What GAO Found

Although DOE's laboratories routinely share their technologies, capabilities, and knowledge with outside entities, it is difficult to assess the full extent of technology transfer efforts because policies defining technology transfer are unclear and headquarters and laboratory officials do not always agree on which activities should be included. Certain activities performed for or with private companies, universities, and state or local governments are widely regarded as technology transfer, including (1) performing research on behalf of or in collaboration with these entities; (2) licensing the laboratories' existing technologies for such entities to use or commercialize; and (3) allowing these entities access to the laboratories' unique facilities and equipment for their own research. Successful technology transfer efforts have focused on a variety of areas ranging from cancer treatment to biofuels. DOE and laboratory officials do not agree, however, on whether research sponsored by other federal agencies should be considered technology transfer, and DOE's policies are unclear on this. Although work for other federal agencies—worth about $1.8 billion in 2008—may result in technologies that are eventually transferred to the marketplace, in the short run, the work entails sharing federal research and technologies with other federal agencies for noncommercial aims.

DOE cannot determine its laboratories' effectiveness in transferring technologies outside DOE because it has not yet established departmentwide goals for technology transfer and lacks reliable performance data. The Energy Policy Act of 2005 required DOE to establish goals for technology transfer and provide Congress its implementation plan no later than February 2006; DOE has not yet done so. While some DOE laboratories and program offices have begun articulating their own technology transfer goals, these vary widely. In addition, DOE performance data on technology transfer activities are problematic because data accuracy and completeness are questionable.

A number of factors can constrain the extent to which DOE laboratories transfer their technologies, although some are using approaches to help increase the likelihood that promising technologies will be commercialized. Officials at the 17 laboratories identified three primary challenges: (1) competing staff priorities or gaps in expertise needed to consistently identify promising technologies or potential markets; (2) lack of funding to sufficiently develop or test some promising technologies to attract potential partners; and (3) lack of flexibility to negotiate certain terms of technology transfer agreements. Some laboratories have used innovative approaches, such as inviting entrepreneurs to evaluate their research and commercialize a technology or tapping into outside funding for the additional development needed to attract commercial interest. Approaches used by other federal laboratories may offer additional ways for DOE to improve its technology transfer. These efforts are especially important given the goals of American Recovery and Reinvestment Act of 2009 and the additional funding provided to DOE to meet those goals.

Contents

Figures

Abbreviations

CRADA	Cooperative Research and Development Agreement
DOE	Department of Energy
NNSA	National Nuclear Security Administration

GAO
Accountability * Integrity * Reliability

United States Government Accountability Office
Washington, DC 20548

June 16, 2009

The Honorable Byron Dorgan
Chairman
The Honorable Robert Bennett
Ranking Member
Subcommittee on Energy and Water Development
Committee on Appropriations
United States Senate

The Honorable Peter J. Visclosky
Chairman
The Honorable Rodney P. Frelinghuysen
Ranking Member
Subcommittee on Energy and Water Development
Committee on Appropriations
House of Representatives

Since the 1940s, the Department of Energy's (DOE) national laboratories and specialized research facilities have played a central role in pushing the research frontiers of physics and other basic sciences and applying this knowledge to developing technologies.[1] Over the years, some of the research at these laboratories has contributed to the development of technologies—ranging from wind turbines to key components of computer microchips—that have benefited daily life, while creating opportunities for the businesses and investors that bring the laboratories' technologies to the marketplace. In the face of today's challenges, Congress and the administration, among others, have stressed the importance of science and technology in improving America's economy, moving to sustainable forms of energy, and protecting national and global security. Recent measures, including the American Recovery and Reinvestment Act of 2009, have underscored the federal role—DOE's in particular—in funding the scientific research to develop the technologies for meeting these challenges and bringing them into widespread use.

As one of the largest research agencies in the federal government, DOE spends billions of dollars each year on publicly funded research to support

[1]The Department of Energy, whose predecessors include the Atomic Energy Commission, was created in 1977 from diverse agencies.

its diverse missions, including energy development, energy efficiency, and nuclear security. Most of this research is carried out under DOE's direction and oversight by scientists, engineers, and others employed at DOE's 17 national laboratories, including its 16 contractor-managed and operated laboratories and 1 DOE-managed and operated laboratory. The results of this research may further science and, at the same time, hold commercial potential for addressing needs of businesses, governments, organizations, or individuals.

To maximize the return on the public's investment in research and to foster economic growth, federal policies have encouraged the transfer of federally developed technologies to private firms, universities, local governments, and others capable of benefiting themselves from the technologies or further expanding the technologies' benefits by bringing them into the marketplace. Laws such as the Stevenson-Wydler Technology Innovation Act of 1980 and the Bayh-Dole Act of 1980 have enabled federal laboratories to transfer their technologies and scientific capabilities by, for example, licensing the laboratories' technologies to outside entities or partnering with those entities on research and development projects. Subsequent laws have aimed to further expand technology transfer or to improve the technology transfer efforts of individual agencies. For instance, the Energy Policy Act of 2005 sought to improve the process for transferring technologies by requiring the Secretary of Energy to, among other things, appoint a technology transfer coordinator for the department and to develop technology transfer goals and a plan for implementing them.

While DOE is responsible for establishing technology transfer policies and overseeing performance, carrying out technology transfer activities is a responsibility of the laboratory staff operating DOE's laboratories. To accomplish technology transfer, these laboratory operators need to promote their laboratories' technologies and scientific capabilities to outside entities, identify potential partners, and negotiate technology transfer agreements.

In response to congressional direction in the explanatory statement accompanying the Consolidated Appropriations Act of 2008, this report examines (1) the nature and extent of technology transfer at DOE laboratories; (2) the extent to which DOE can measure the effectiveness of technology transfer efforts at its laboratories; and (3) factors affecting technology transfer and approaches that may have potential for improving technology transfer.

To conduct our work, we analyzed DOE's data on the extent of its technology transfer activities and contacted all 17 DOE national laboratories. To understand the nature, extent, and overall effectiveness of DOE's technology transfer efforts, we interviewed the officials responsible for coordinating the 17 laboratories' technology transfer activities, including visits to Lawrence Berkeley and Lawrence Livermore national laboratories in California and the Pacific Northwest National Laboratory in Washington state. Although we determined that DOE's technology transfer data were sufficiently reliable for selecting laboratories to contact or reporting aggregate numbers of technology transfer agreements, for verification purposes, we asked responsible laboratory and DOE officials about their efforts to ensure the data's reliability and obtained additional data from the laboratories on the nature and extent of their technology transfer efforts in fiscal years 2006 through 2008. We also obtained copies of technology transfer agreements, performance measurement plans, or other documentation of DOE and laboratory efforts to transfer technologies and measure technology transfer performance. And, we interviewed DOE headquarters officials in the Office of Laboratory Policy and Evaluation and the Office of the General Counsel, as well as members of DOE's Technology Transfer Policy Board and Technology Transfer Working Group, about the nature and effectiveness of DOE's technology transfer. In addition, to learn more about technology transfer from the nonfederal perspective, we interviewed representatives from industry and universities knowledgeable about technology transfer. Finally, to better understand how other federal agencies transfer technology, we interviewed Department of Defense officials who oversee technology transfer for that department's laboratories. A more detailed description of our scope and methodology appears in appendix I.

We conducted this work as a performance audit from July 2008 through June 2009, in accordance with general accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Background

DOE is responsible for a diverse set of missions, including nuclear security, environmental cleanup, and energy research. These missions are managed by DOE program offices, the largest of which include:

- National Nuclear Security Administration,[2] responsible for maintaining the nation's nuclear weapons stockpile and preventing nuclear proliferation;
- Office of Environmental Management, responsible for cleaning up wastes left from decades of nuclear weapons research and production;
- Office of Science, responsible for advancing fundamental research in physics and other sciences; and
- Offices of Energy Efficiency and Renewable Energy, of Fossil Energy, and of Nuclear Energy, responsible for energy research and energy technology development and deployment.

Overseen by these program offices, contractors carry out the day-to-day work of these missions at most of the 17 national laboratories and other facilities nationwide.[3] The contractors that manage and operate national laboratories include universities, private companies, nonprofit organizations, or consortia thereof. In addition to carrying out DOE-funded research, some of these contractors also manage DOE's national user facilities, located at the national laboratories, in which advanced scientific equipment or expertise are made available to researchers from outside DOE's laboratories.

Since the early 1980s, Congress has passed several laws related to technology transfer across the federal government. One of the foundational technology transfer laws, the Stevenson-Wydler Technology Innovation Act of 1980,[4] articulated technology transfer as a federal priority, requiring federal laboratories to establish an office of research and technology applications and devote budget and personnel resources to promoting technology cooperation and the transfer of federal technologies. Another key law, the Bayh-Dole Act of 1980, sought to promote the use and commercialization of federal technologies by

[2]Although the National Nuclear Security Administration is a separately organized agency under DOE, unless otherwise specified, for purposes of this report, references to DOE or its program offices include the National Nuclear Security Administration.

[3]Unlike DOE's 16 contractor-managed-and-operated national laboratories, the National Energy Technology Laboratory in Oregon, Pennsylvania, and West Virginia, one of the 17 DOE national laboratories, is managed and operated by DOE itself. As a result, DOE employees—rather than employees of one of DOE's contractors—carry out this laboratory's technology transfer and other activities.

[4]Pub. L. No. 96-480, 94 Stat. 2311.

requiring federal agencies to assure small businesses, universities, and nonprofits the right to elect title to new inventions made under their federal funding agreements.[5] Other laws also authorize contractor- or federally operated government laboratories to perform collaborative research with universities, state or local governments, nonprofit organizations, or private industry. The National Competitiveness Technology Transfer Act of 1989[6] directed federal agencies to include provisions in their contracts that establish technology transfer as a mission of contractor-operated federal laboratories. In addition, some technology transfer laws pertain solely to DOE. For example, under the Atomic Energy Act of 1954[7] and the Federal Nonnuclear Energy Research and Development Act of 1974,[8] DOE may waive its claim to title to inventions that are made under a DOE contract. This authorizes DOE to allow the contractors that operate its laboratories to elect to retain title to inventions at their laboratories, obtain patents or other legal protections, and then license the inventions to others.[9]

Federal regulations and DOE's policies and guidance, including federal and DOE acquisition regulations, govern the implementation of activities authorized under the various technology transfer laws. These policies outline DOE's and contractors' responsibilities with respect to these activities and describe the general processes and guidelines under which DOE or its contractors may take ownership of discoveries made at the laboratories, license their intellectual property, or work with outside entities seeking to benefit from the laboratories' capabilities. DOE's technology transfer coordinator, most recently the Under Secretary for Science, is the principal advisor to the Secretary of Energy on all matters related to technology transfer and commercialization. DOE's Assistant General Counsel for Technology Transfer and Intellectual Property helps formulate DOE's intellectual property and technology transfer policies,

[5]Pub. L. No. 96-517, 94 Stat. 3015. Bayh-Dole also currently requires that the right to elect title to an invention was to be included in contracts with small business, universities, and nonprofits for the operation of federal laboratories. Prior to the enactment of Bayh-Dole, however, DOE's enabling legislation authorized the department to elect title and license its technologies to others.

[6]Pub. L. No. 101-189, 103 Stat. 1352.

[7]42 U.S.C. § 2182.

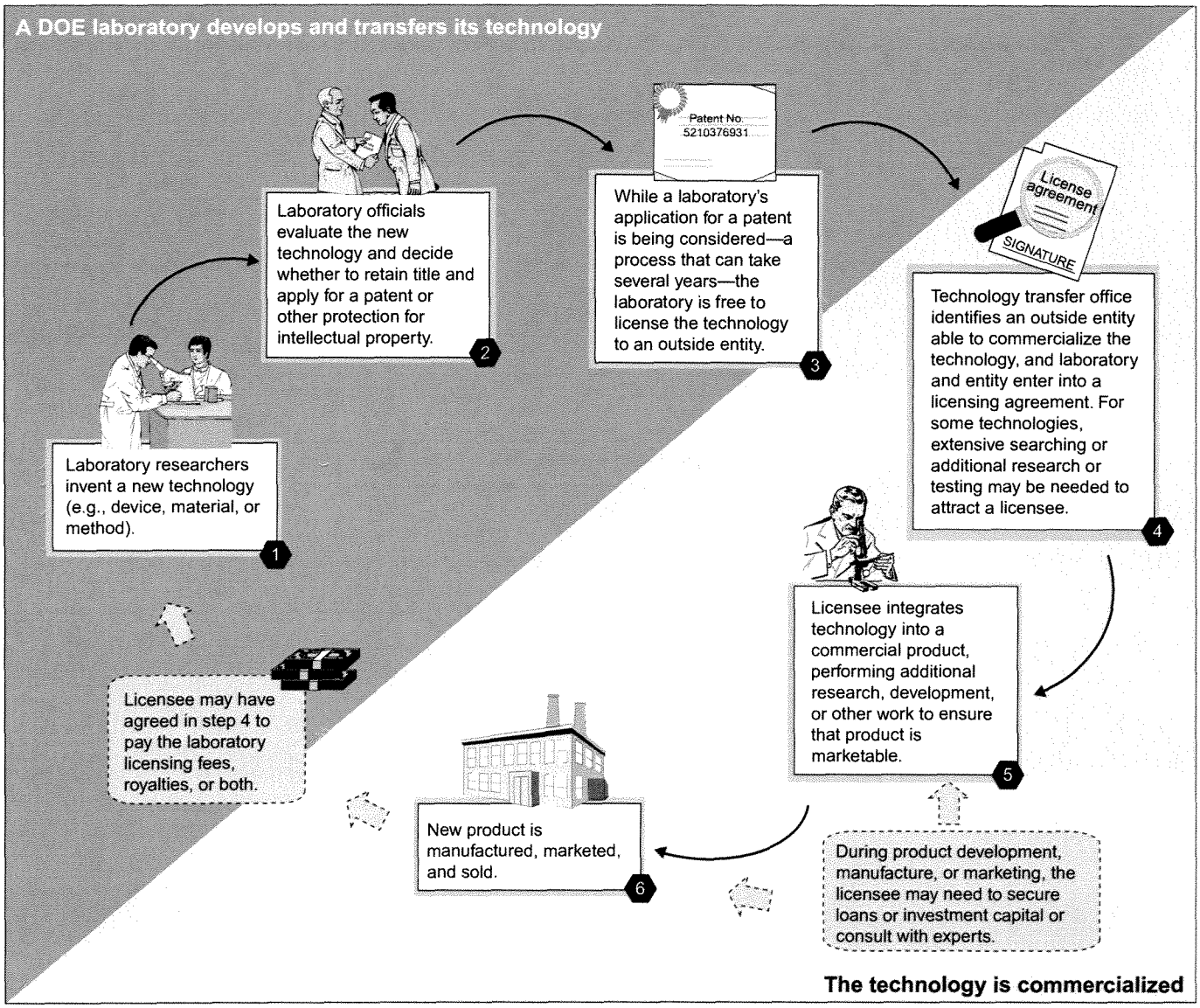
[8]42 U.S.C. § 5908.

[9]A similar provision in the Bayh-Dole Act (35 U.S.C. § 202) applies throughout the federal government; however, it pertains only to small business and nonprofit contractors.

along with others in the department, and represents DOE's interests in matters involving intellectual property and technology transfer. The Technology Transfer Policy Board—comprising representatives from various DOE program and staff offices—supports the coordinator by recommending technology transfer policies and helping oversee technology transfer activities. Field-based officials, under the guidance of DOE program officials and the Office of the General Counsel, are responsible for directly overseeing laboratory contractors' technology transfer efforts to ensure that they comply with applicable laws, regulations, and DOE policies. In addition, DOE's Technology Transfer Working Group—comprising both federal and laboratory contractor employees—is responsible for supporting and advising the Technology Transfer Policy Board and sharing information on technology transfer opportunities and best practices.

The process of commercializing federal technologies generally begins with research and development efforts at federal laboratories, which result in new technologies that may have commercial potential. At each of DOE's laboratories, the office of research and technology applications (which, for our purposes, we refer to as the technology transfer office) is generally responsible for coordinating laboratories' efforts to identify technologies and obtain patents or other legal protections for those technologies. The office may also be responsible for promoting the laboratory's technologies to potential licensees, negotiating licensing or other agreements, or managing the laboratory's existing licenses and patents. Licensees are typically responsible for commercializing the licensed technologies by integrating the technologies into commercial products and overseeing the development, manufacture, and marketing of those products. Because technology commercialization can require significant financial resources or specialized skills, licensees, particularly small businesses or startup companies, may obtain help from venture capitalists or other outside experts. And, because the pathway from laboratory bench to commercial product is complex, involving numerous and sometimes difficult steps, the process can derail at any point and products may not always reach, or find success in, the marketplace (see fig. 1).

Figure 1: Process to Commercialize DOE Laboratory Technologies



Sources: GAO analysis of DOE and other information; Art Explosion (clip art).

DOE Laboratories Share Technologies and Capabilities, but Only Certain Activities Are Widely Regarded as Technology Transfer

DOE and Laboratory Officials Agreed That Four Key Types of Technology-Sharing Activities and Their Associated Agreements Are Technology Transfer

In addition to conducting research on behalf of DOE's missions, DOE's national laboratories routinely share their technologies, capabilities, and knowledge with outside entities by performing research, licensing the laboratories' technologies, and making their facilities and personnel available to others. Before carrying out many of these activities, the parties must first enter into agreements that spell out the terms and conditions for sharing the laboratories' technologies and capabilities. While DOE's laboratories may enter into agreements with a variety of outside entities working in areas ranging from health care to biofuels, only some of the laboratories' technology- and knowledge-sharing activities are widely considered to be technology transfer. Specifically, the technology transfer officials we spoke with at DOE's headquarters and the 17 national laboratories generally agreed that the following activities at DOE's laboratories and their associated agreements—if conducted in partnership with, or on behalf of, businesses, universities, state or local governments, or other nonfederal entities—constitute technology transfer:

- **Cooperative research and development agreements (CRADA):** Under these agreements, laboratory employees collaborate with nonfederal partners to carry out research projects that will directly benefit DOE program missions and the partners' research and development goals. Under a CRADA, a laboratory may contribute personnel, equipment, or other in-kind resources to a project, while its CRADA partners must contribute funds, in-kind resources, or both.[10] For example, the National Renewable Energy Laboratory in Colorado collaborated with

[10]DOE is not required to contribute in-kind resources toward a CRADA, nor may DOE funds flow to a CRADA partner. The partner, however, must contribute in-kind resources and—if DOE decides not to contribute any of its own resources—must fund any work performed by the DOE laboratory.

Sacramento's utility district on the design and construction of demonstration homes incorporating the laboratory's research on energy-efficient buildings. The work, which occurred under a CRADA, allowed the laboratory to field-test its research and helped the utility develop design specifications for energy-efficient homes, assisting builders and helping to meet statewide goals for improving buildings' efficiency. In fiscal years 2006 through 2008, all 17 of DOE's national laboratories entered into CRADAs with private firms, universities, state or local governments, nonprofit organizations, or other nonfederal partners. In fiscal year 2008, over 90 percent of the 689 CRADAs at the 17 laboratories were with private industry partners.[11]

- **Nonfederal work-for-others agreements:** Under a nonfederal work-for-others agreement, a DOE laboratory agrees to conduct research on behalf of a nonfederal sponsor. Although this research must be consistent with the laboratory's and DOE's missions and draw on the laboratory's unique capabilities, these agreements differ from CRADAs in that the research need not directly benefit DOE's programs. Consequently, the sponsor must pay the entire cost of a project done under these agreements. In turn, however, the sponsors typically may elect to receive ownership of any new intellectual property, including new inventions by laboratory employees, resulting from the research.[12] For example, Los Alamos National Laboratory in New Mexico, under a nonfederal work-for-others agreement with the University of California, Los Angeles, is developing key components of a detection and response system for avian flu, which will enable rapid DNA analysis of a large number of biological samples at multiple locations worldwide. Drawing on the laboratory's expertise in computer modeling and simulation, and using its patented biological

[11]Unless otherwise noted, data presented throughout this report on the number of the 17 laboratories' technology agreements, or the dollar amounts associated with those agreements, came from the data we collected from those laboratories in November 2008. See appendix I for additional details.

[12]If the work-for-others sponsor elects to receive ownership of any resulting laboratory inventions—effectively giving the sponsor exclusive authority to determine whether and for what purpose others can use the inventions—the sponsor must also grant the government a license to use the invention on behalf of the government. In contrast, ownership over laboratory inventions, made in whole or in part by laboratory employees, resulting from a CRADA is determined through negotiation between the laboratory and the CRADA partner. Regardless of any negotiated outcome, by law the CRADA partner always has the option to choose an exclusive license in a predetermined field of use for reasonable compensation. And, the federal government always retains full rights to use the inventions on behalf of the government, even if the invention was made solely by the nonfederal partner's employees.

analysis technologies, the laboratory will develop computer software and hardware, as well as analysis tools and protocols for detecting and responding to infectious disease outbreaks. All 17 of DOE's national laboratories had work-for-others agreements with nonfederal partners in fiscal years 2006 through 2008. In fiscal year 2008 alone, the laboratories participated in over 2,600 work-for-others agreements with nonfederal sponsors—65 percent of which were sponsored by private industry and 35 percent by universities, state or local governments, or other nonfederal sponsors.

- **Licensing agreements:** In addition to performing research, laboratories share their technologies by licensing their patented discoveries, copyrighted software programs, or other intellectual property to nonfederal entities seeking to use or commercialize those technologies. In some cases, the licensee agrees to pay fees or royalties to the laboratory in exchange for the laboratory's permission to use or commercialize a technology. For example, Ames Laboratory in Iowa and Sandia National Laboratories in California and New Mexico developed and patented a lead-free solder, which became popular after concerns emerged about potential risks posed by lead solder in electronics. As of July 2007, Ames laboratory was licensing or sublicensing the technology to 55 companies around the world, generating in fiscal year 2007 about $5 million in licensing income. In fiscal years 2006 through 2008, 16 of the 17 national laboratories had licensed their patented technologies to others, generating in 2008 about $44 million in fees and royalties.[13]

- **User-facility agreements:** Under a user-facility agreement, scientists from outside organizations can use DOE's unique scientific equipment for their own research, sometimes in collaboration with laboratory staff. Several of DOE's national laboratories are home to the department's user facilities. For example, the Center for Nanoscale Materials—an 88,000-square-foot user facility completed in September 2007 at Argonne National Laboratory in Illinois—makes customized laboratory space and specialized equipment available for research on materials and structures at the atomic, or nano, scale, with applications ranging from medicine to microchips. Some of the center's users are also allowed to access the Advanced Photon Source, another of Argonne's user facilities, for

[13]This $44 million includes only patent licenses with private industry. Although DOE's laboratories may have licensed their patented technologies to other nonfederal entities, such as universities, to reduce respondent burden, we limited the licensing data that we collected from the laboratories to focus exclusively on patented technologies licensed to private industry in fiscal year 2008. See appendix I for additional details.

nanoscience research using the photon source's ultrabright x-ray beams. Users may conduct their research at DOE's facilities for free or a negotiated cost, if the results of their research will be made public. The users who wish to keep their results private, however, must reimburse DOE for the full cost of using the facilities. According to DOE data for fiscal year 2008, DOE had more than 2,800 user-facility agreements for user facilities at 8 of the 17 laboratories.[14]

Successful examples of technology transfer cited by laboratory officials, often involving the use of multiple agreements, reflected research and development or technology commercialization efforts that led to or show promise for advancements in important areas ranging from medicine to fuel-efficient vehicles. For example:

- Lawrence Livermore National Laboratory in California transferred technology to a small medical manufacturing company seeking to develop and commercialize a medical device that could dramatically improve the effectiveness and reduce the costs of treating certain types of cancer. The new device, slated for use in a cancer treatment known as proton therapy—which doctors consider superior to other types of cancer therapy because cancerous cells can be more precisely targeted—is based on a miniaturized version of an atomic particle accelerator, which the laboratory had developed for testing nuclear weapons. According to Lawrence Livermore officials, if the development and commercialization efforts are successful, the device will shrink the size and cost of current proton therapy technology—from a basketball-court-sized machine weighing several hundred tons to a much smaller device 2 meters long and costing millions of dollars less—making the therapy more widely available. After performing initial research to verify that the weapons-testing technology could be adapted for cancer treatment, in 2007, the laboratory licensed the technology to the medical manufacturer and agreed to collaborate on additional research, resulting in a licensing agreement and a CRADA. Under the licensing agreement, the laboratory gave the company exclusive rights to make, use, or sell the laboratory's patented technology—limited, however, to the field of cancer therapy—and the company agreed to pay licensing fees and royalties to the laboratory. Under the CRADA, the laboratory and the company agreed to perform additional research and develop a full-scale prototype of the proton therapy device.

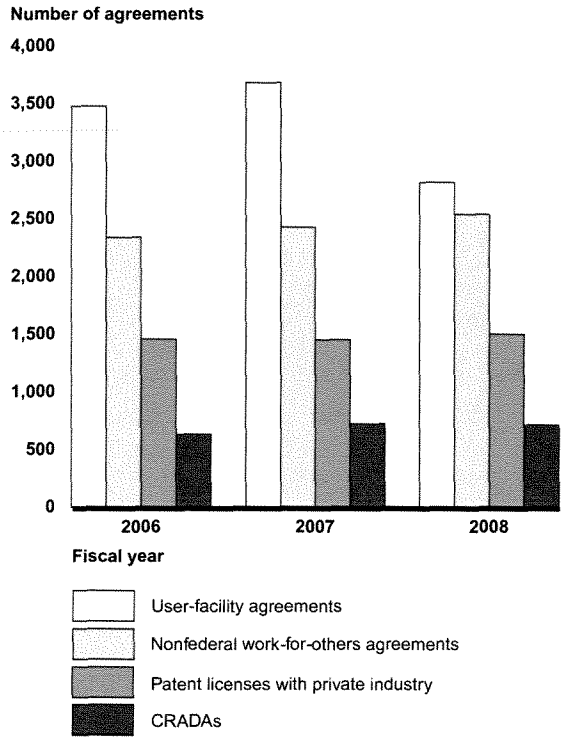
[14]Data on the number of user-facility agreements came from data collected annually by DOE headquarters.

- Pacific Northwest National Laboratory in Washington state entered into a patent license and multiple CRADAs with a major agricultural products company to develop and pilot-test technologies and processes for converting corn fibers or other corn materials into fuel (ethanol) or various industrial chemicals. If successful, the project will lay the groundwork for improving biorefineries' efficiency, enabling refineries to use a wider variety of corn materials—for instance, corn silk and husks rather than just kernels—and produce a wider variety of products more cost-effectively. The Pacific Northwest laboratory granted the company exclusive and nonexclusive royalty-bearing licenses to the laboratory's patented technologies and processes for isolating and converting sugars, such as those in corn materials, into other chemicals. Under a CRADA, funding from the company and DOE's Office of Energy Efficiency and Renewable Energy's Biomass Program are offsetting the laboratory's costs for conducting research on the sugar conversion process and other technical challenges.

- Lawrence Berkeley and Livermore national laboratories in California and Sandia National Laboratories have long-standing partnerships, resulting in multiple technology transfer agreements, with a consortium of major computer- and microchip-manufacturing companies, universities, and other organizations, working collaboratively on industrywide problems and managing risks and costs associated with the research and development and production of semiconductors. Because the industry's ability to increase computer speed and memory using current semiconductor technologies and production methods is reaching its limits, one of the consortium's efforts is to develop the next generation of mass-produced semiconductor, which, if successful, could result in computer chips that are 100 times faster and hold 1,000 times more memory than current chips, according to the industry consortium. Berkeley laboratory scientists are using the Advanced Light Source—a user facility at the Berkeley laboratory housing a powerful ultraviolet and x-ray source 1 billion times brighter than the sun—to develop and test a more precise method for etching paths into microchips that house the circuitry and other components. The technology transfer agreements involved include multiple nonfederal work-for-others agreements and an earlier CRADA.

The number of agreements associated with the four types of activities widely recognized as technology transfer—cooperative research and development, nonfederal work for others, licensing, and user-facility agreements—remained relatively stable from fiscal years 2006 through 2008 (see fig. 2). See appendix II for additional data on DOE's agreements.

Figure 2: DOE Laboratories' Technology Transfer Agreements, Fiscal Years 2006 through 2008



Source: GAO analysis of DOE data.

Note: Numbers of user-facility agreements come from data collected annually at DOE headquarters. All other numbers come from the 17 national laboratories, as part of our November 2008 data collection effort. See appendix I for additional details.

Lack of Clear Policies on What Constitutes Technology Transfer Complicates Assessment of Full Nature and Extent of Activities

Although DOE and laboratory officials generally agreed that CRADAs, nonfederal work for others, licensing, and user-facility agreements, constitute technology transfer, they did not agree on whether other routine activities—similarly aimed at sharing the laboratories' technologies, capabilities, or knowledge—also constitute technology transfer, and DOE policies do not provide a clear definition. In particular, DOE carries out a large body of work funded by other federal agencies under a type of agreement known as a federal work-for-others agreement. For example, the Department of Homeland Security has funded work at the Pacific Northwest National Laboratory that has drawn on the

laboratory's expertise in areas such as radiation detection to develop passenger- and cargo-screening technologies for ports of entry.

In fiscal years 2006 through 2008, 16 of the 17 national laboratories conducted work under these agreements. DOE's laboratories had about 4,900 federal work-for-others agreements in fiscal year 2008, including about 600 funded by the Department of Homeland Security under an arrangement granting that agency priority access to staff and facilities at DOE's laboratories.[15]

Although technology transfer officials from 10 of the 17 laboratories said they consider federal work-for-others agreements to be technology transfer, the officials at several of the other laboratories—as well as representatives from DOE's Office of the Assistant General Counsel for Technology Transfer and the Technology Transfer Policy Board—told us that they do not, in part because the transfer involves another federal agency rather than private industry. This difference may stem from the fact that DOE's policies do not clearly define in all cases what activities and types of agreements constitute technology transfer, or the policies provide conflicting views. Specifically, the definitions of activities and agreements, such as CRADAs and technology licenses, which are considered to be technology transfer in DOE's acquisition regulations and a January 2008 policy statement on technology transfer by the Secretary of Energy[16] are broad enough to allow federal work-for-others agreements to fall under the department's definition of technology transfer. The January 2008 policy statement—which defines technology transfer as the process by which knowledge, intellectual property, or capabilities developed at DOE national laboratories are transferred to "any other entity, including private industry, academia, state, and local governments, or other government entities"—does not explicitly include or exclude work for other federal agencies. Likewise, DOE's acquisition regulations provide a broad definition that does not explicitly state whether federal work-for-

[15]The Homeland Security Act of 2002 (6 U.S.C. § 189) authorizes the Department of Homeland Security to access the capabilities of DOE's laboratories to further its own mission objectives. Under a memorandum of agreement between the two departments, DOE laboratories give research funded by the Department of Homeland Security equal priority for laboratory staff and facilities as DOE-funded research. Under DOE policy, work for all other federal agencies must not interfere with work for DOE or the Department of Homeland Security.

[16]*Secretarial Policy Statement on Technology Transfer at Department of Energy Facilities* (Jan. 31, 2008).

others is to be considered technology transfer.[17] In contrast, a DOE policy directive reissued in 2003, which aimed to improve various aspects of DOE's "technology partnering" activities, identified work for nonfederal entities as one of the activities covered by the directive, but the covered activities did not include federal work-for-others.[18] We did not identify any law or policy specifically stating that DOE may not consider work for other federal agencies to be technology transfer. Nevertheless, laws and policies emphasize the federal government's role in transferring technology to nonfederal entities. For example, the Stevenson-Wydler Act states that its purpose is "stimulating improved utilization of federally funded technology developments...by State and local governments and the private sector," and Executive Order 12591 requires all agencies to "assist in the transfer of technology to the marketplace."

Although nonfederal entities may ultimately commercialize the results of federal work-for-others projects, in the short run these projects involve making federal capabilities available to other federal agencies for noncommercial aims. Under a federal work-for-others agreement with the U.S. Department of Transportation, researchers at Argonne National Laboratory, for example, developed a system for detecting and responding to chemical attacks in confined, populated spaces, such as buildings and subway tunnels. Developed by the laboratory's Decision and Information Sciences Division in the wake of the 1995 sarin gas attack on the Tokyo subway, the technology integrates chemical detectors, closed-circuit televisions, advanced computer modeling of chemical dispersion, and other components to provide early warning of likely chemical attacks and recommend an appropriate response. According to Argonne laboratory officials, the system was demonstrated and is currently operating in the

[17]Department of Energy Acquisition Regulation section 970.5227-3, "Technology Transfer Mission," defines technology transfer activities as "including but not limited to: identifying and protecting intellectual property made, created, or acquired at or by the laboratory...negotiating all aspects of and entering into CRADAs; providing technical consulting and personnel exchanges; conducting science education activities and reimbursable work for others; providing information exchanges; and making available laboratory or weapon production user facilities."

[18]The directive, DOE Order 482.1, "DOE Facilities Technology Partnering Programs" aimed to ensure that DOE's technology partnering activities are carried out efficiently, are consistent with applicable laws, and receive proper review and oversight. The activities and agreements covered under the directive include CRADAs; nonfederal work-for-others, technology licensing, and user-facility agreements; activities to identify and protect intellectual property; technical consulting; and personnel exchanges.

Washington, D.C., and Boston subways, among other places, and it has been licensed to a large company for commercialization.

Laboratory and DOE officials identified still other activities as technology transfer, although again there was little agreement. For example, officials at 11 of the laboratories said that they consider publishing or presenting research findings to be technology transfer. Technology transfer officials from the Fermi National Accelerator Facility in Illinois said that while publications and presentations are not formally tracked as part of the laboratory's technology transfer efforts, these activities are commonplace at the laboratory—in fiscal year 2007 alone, the laboratory had 285 journal publications and 450 presentations at conferences—and involve sharing the laboratory's knowledge with others. Officials at the other laboratories, in contrast, did not specifically identify publishing or presenting research to be technology transfer. Officials at the Pacific Northwest and Sandia national laboratories told us they considered their laboratories' economic development programs, in which laboratory personnel provide technical advice to local small businesses, to be technology transfer. Technology transfer officials at 5 other laboratories agreed that these or similar types of programs constitute technology transfer, while officials at the 10 remaining laboratories did not. In addition, DOE and laboratory officials we spoke with said that applied research programs can involve extensive knowledge- or technology-sharing activities with private industry that do not, however, take place under a CRADA or another type of agreement widely viewed as technology transfer. In response to a solicitation from the National Energy Technology Laboratory, for example, a private company was awarded DOE funding and an opportunity to work with the laboratory to develop and test a more energy-efficient method for drying the coal used in many power plants.

Nevertheless, without a clear definition, it is impossible to accurately quantify the overall extent of technology transfer at DOE's laboratories because the decision to include or exclude certain agreements and activities can materially alter any measure of technology transfer. For example, in fiscal year 2008, the 17 laboratories had nearly 7,500 work-for-others agreements in total—about 4,900 with other federal agencies and 2,600 with nonfederal entities. The total revenue from these work-for-others agreements was about $2.1 billion—$1.9 billion from work for other federal agencies and $232 million from work for nonfederal entities. Because the number of agreements and associated revenue for work for other federal agencies is a large portion of the total, whether or not this work is considered technology transfer will significantly affect any

characterization of the extent of technology transfer activities at the laboratories.

DOE Cannot Determine the Effectiveness of Technology Transfer at Its Laboratories because It Has No Overarching Goals or Reliable Performance Data

DOE Has Not Established Overarching Goals for Technology Transfer

DOE cannot determine the overall effectiveness of its laboratories' technology transfer efforts because it has not yet defined its overarching strategic goals for technology transfer. The Energy Policy Act of 2005 required that DOE establish goals for technology transfer and provide Congress its plan for implementing those goals no later than February 8, 2006. As of March 2009, more than 3 years after the deadline, DOE headquarters had not yet established departmentwide goals for technology transfer or submitted its plan to Congress. DOE's efforts to develop departmentwide goals and an implementation plan began about 18 months after the deadline imposed by the act. In a June 2007 memo by the Secretary of Energy appointing the Under Secretary for Science as the department's technology transfer coordinator, the secretary directed the coordinator to establish a Technology Transfer Policy Board and made that board responsible for developing the implementation plan, including departmentwide technology transfer goals. In March 2009, members of the policy board told us that they do not currently know when the plan will reach Congress. Although a plan has been drafted, officials said that no further progress will be made until a new technology transfer coordinator is appointed and the plan can be reviewed and modified as needed to reflect the priorities of the new Secretary of Energy and other key officials.

Absent departmentwide strategic goals, some DOE programs have articulated their own goals for technology transfer. The National Nuclear

Security Administration (NNSA)—which oversees the Lawrence Livermore, Los Alamos, and Sandia national laboratories—is considering ways to expand its laboratories' technology partnerships with other federal agencies and nonfederal entities, as part of its ongoing effort to transform the nuclear weapons complex, so that it may more effectively respond to a broader range of national security threats.[19] A February 2008 white paper described strategies by NNSA's Office of Institutional and Joint Programs for increasing NNSA laboratories' outreach efforts and ability to partner with others, including steps for streamlining NNSA and laboratory business rules and processes for executing CRADAs, work-for-others agreements, and other agreements. Similarly, a goal of "effective and coordinated" commercialization of technologies was included in the planning of DOE's new bioenergy research centers, based at the Oak Ridge National Laboratory in Tennessee and the Lawrence Berkeley National Laboratory.[20] Funded by the Office of Science, the centers bring together personnel and resources from DOE laboratories, universities, private companies, and nonprofit organizations to collaborate on research and development of new and more efficient methods of transforming plant materials—potential energy crops beyond corn, such as switchgrass, poplar, and rice—into ethanol or other fuels as a substitute for gasoline. At the Oak Ridge center, the collaborating institutions created a management plan for how inventions developed through the center's research would be disclosed and revenues from technology licenses shared. To increase the likelihood that technologies will be commercialized, a council, comprising technology transfer specialists from the collaborating institutions, was formed to evaluate the commercial potential of all new inventions arising from the center's research. According to a laboratory official, since the center began operating in early 2008, the commercialization council has evaluated a number of technologies, including some that have been licensed. A similar approach is being used at the Berkeley center, although that laboratory will play a more central role in managing the intellectual property created by the center's collaborating institutions.

In addition, the contractors operating many of DOE's laboratories and the DOE program offices overseeing the laboratories have also been developing and negotiating annual performance goals for technology

[19]See GAO, *Nuclear Weapons: Views on NNSA's Proposal to Transform the Nuclear Weapons Complex*, GAO-08-1032T (Washington, D.C.: July 17, 2008).

[20]At the same time, DOE also funded a third bioenergy research center at the University of Wisconsin.

transfer, which are incorporated into the laboratories' contracts. For fiscal year 2008, contracts for 12 of the 17 laboratories included performance goals related to technology transfer—up from 10 laboratories in 2007. The goals varied widely across the laboratories, however, ranging from specific numerical targets to more process-oriented goals. For example, Lawrence Livermore National Laboratory set a target of doubling its new technology-licensing agreements from 20 to 40, from 2008 to 2012. In contrast, a fiscal year 2008 goal at Brookhaven National Laboratory in New York focused on improving administrative processes, in order to help put technology transfer agreements in place more quickly. Furthermore, laboratories' goals can change from year to year to focus on different priorities, which can make it more difficult to evaluate the laboratories' performance over time. In fiscal year 2009, for example, Oak Ridge National Laboratory set a new goal of increasing its technology transfer office's interaction with that laboratory's new technology park, which houses private companies collaborating with the laboratory's scientists.

Data Used to Measure Technology Transfer Efforts Are of Questionable Reliability

In addition to lacking departmentwide goals and an implementation strategy for technology transfer, DOE uses data of questionable reliability to evaluate its laboratories' overall effectiveness in transferring their technologies. Under the Technology Transfer Commercialization Act of 2000,[21] Congress required all federal agencies that operate or direct laboratories to prepare annual reports on the agency's technology transfer activities for the Office of Management and Budget, which are summarized in an annual report to Congress and the President. As part of this effort, DOE has been collecting data annually from its 17 laboratories on the number of technology transfer agreements—CRADAs, work-for-others agreements, technology licenses, and user-facility agreements—and dollar amounts associated with these agreements. The department also issued annual technology transfer reports on its activities for fiscal years 2001 through 2006 and continues to collect these data from its laboratories.

We found that the completeness and accuracy of DOE's technology transfer data are questionable. In some cases, laboratories failed to provide data on certain types of technology transfer agreements and DOE failed to ensure that the laboratories were reporting the data as requested. For example, 3 of the 17 laboratories did not provide complete information on their federal or nonfederal work-for-others agreements,

[21]Pub. L. No. 106-404, 114 Stat. 1742, 15 U.S.C. § 3710(f).

even though this information was requested in DOE's reporting guidelines. One laboratory failed to report complete information on its federal work-for-others agreements for fiscal years 2004 through 2008. This laboratory's officials told us that their laboratory does not consider all federal work-for-others agreements to be technology transfer, and, unlike nonfederal work-for-others agreements, federal work-for-others is not handled through the laboratory's technology transfer office. In other cases, laboratories used inconsistent reporting methods or failed to report their data accurately. Officials at one laboratory told us they excluded from their annual reporting any work-for-others agreements for which no funding was received during the year, whereas officials at another laboratory said they reported on all open agreements, regardless of whether there was funding activity. Also, as the result of our review, three laboratories made corrections to technology transfer data they had previously submitted to DOE, including data on the number of technology licenses in fiscal years 2004 through 2007, and funds associated with CRADAs and work-for-others agreements. Moreover, to help us verify the reliability of DOE's technology transfer data and obtain addition information on its laboratories' technology transfer activities, in November 2008 we collected data from the 17 laboratories on their activities during fiscal years 2006 through 2008 and found discrepancies between DOE's data and our own. For example, one laboratory had reported to DOE that it had 158 nonfederal work-for-others agreements in fiscal year 2008 but reported to us that it had 114 such agreements that year—a 39 percent difference. Likewise, there were similar discrepancies in the data reported by other laboratories, including differences as large as 55 percent in the number of nonfederal work-for-others agreements in fiscal year 2008. Overall, however, the difference in the total number of these agreements for all 17 laboratories was smaller—only 6.2 percent.

Officials from DOE's Technology Transfer Policy Board also said they recognize that the current performance measures have some limitations in providing a clear picture of the effect of technology transfer activities. They said they are currently working to develop improved measures of technology transfer performance. At least one measure—the data element capturing the number of startup companies established to commercialize the DOE laboratories' technologies—however, may go beyond simply tallying agreements and associated revenues.

Some DOE, laboratory, and non-DOE officials we interviewed said that broader results, such as the economic benefits of technology transfer, while informative, are difficult to measure, in part because tracking technologies once they have left the laboratories can be difficult. While

some technology licenses provide that laboratories shall receive some information about the extent to which licensed technologies are commercialized—if licensees agree to pay royalties to the laboratory once the technologies have been integrated into commercial products and sold, for example—laboratories may not be able to assess the outcomes of other technology transfer agreements as easily. In some cases, laboratories may not be privy to the results of technology transfer agreements. For example, companies that perform research at DOE's user facilities under a proprietary user-facility agreement are not required to make public the results of their work. And, while these facility users may have to disclose to the government any patentable technologies resulting from this research, they are not required to report on the commercial success of those technologies. In other cases, the results of technology transfer agreements might never be commercialized, or it could take years before the results are used in commercial products or applications—particularly if the technology transfer agreement took place at an early stage of research and development.

Nonetheless, a few organizations within DOE are attempting to measure the economic and environmental impacts of their research, development, and technology deployment efforts, including technology transfer. For example, as part of an effort by several DOE program offices to measure the overall benefits of the department's research, development, and technology deployment programs, DOE's Office of Energy Efficiency and Renewable Energy has forecast various economic and environmental outcomes of the activities it funds at the National Renewable Energy Laboratory, other DOE laboratories, and non-DOE institutions. Specifically, in March 2007, the office estimated that as a result of these efforts, in 2010, U.S. consumers would begin saving approximately $2.1 billion to $4.3 billion[22] in annual energy costs and avoid the annual emission of up to 9 million metric tons of greenhouse gases. According to the office's estimates, these energy-cost and carbon-emissions savings could accelerate substantially over time, depending on such factors as future energy prices or public policy. Similarly, DOE's Office of Fossil Energy—which funds fossil energy research both internally, at the National Energy Technology Laboratory, and at outside institutions—estimated that its pollution-control research, development, and technology

[22]These consumer savings, as described in *Projected Benefits of Federal Energy Efficiency and Renewable Energy Programs, FY 2008 Budget Request*, March 2007 (NREL/TP-640-41347), are expressed in 2004 dollars.

deployment efforts since the 1970s are responsible for a 93 percent drop in the costs of removing nitrous oxide pollutants from power plant emissions. Although such accomplishments may depend, in part, on successfully transferring laboratory technologies, these offices' performance measures reflect the results of a broader array of programmatic activities.

Challenges Can Constrain Commercialization of DOE Laboratory Research, but Innovative Approaches Show Promise

Challenges throughout the Technology Transfer Process Can Constrain DOE Laboratories' Efforts to Identify and Transfer Technologies for Others to Commercialize

Throughout the technology transfer process—which generally includes identifying promising technologies created at DOE's laboratories, attracting potential partners to commercialize the laboratories' technologies or tap into the laboratories' capabilities, and negotiating technology transfer agreements—the laboratories face a number of challenges. Technology transfer officials at the 17 laboratories identified three main challenges that constrain the number of promising technologies transferred out of the laboratories or limit laboratories' ability to share their capabilities: competing priorities within a laboratory or a lack of staff with the expertise to identify and promote technologies having commercial promise; lack of funding to develop and demonstrate promising technologies in order to attract partners willing to commercialize them; and DOE-required terms and conditions of technology transfer agreements, which sometimes complicate negotiations with potential partners.

Competing priorities, insufficient numbers of technology transfer staff, or gaps in staff expertise have sometimes constrained laboratories' ability to recognize and promote technologies with commercial promise. DOE has acknowledged that although laboratory staff, particularly scientists, excel at innovation and invention, not all of them look beyond their research to possible applications in the marketplace. Some laboratory officials

attributed this situation to a lack of interest in the processes involved in transferring technologies, while other laboratory officials said that their scientists are more focused on research and publication of their results than on collaborating with private companies. The Federal Technology Transfer Act of 1986,[23] however, makes technology transfer a responsibility of all federal laboratory scientists and engineers. Sometimes the commercial potential of certain research may not be evident until late into or after the research effort. As a result, laboratories may overlook or fail to promote promising technologies. In addition, technology transfer officials at 9 of the 17 laboratories said their laboratories may lack sufficient numbers of technology transfer staff or that skill gaps among the staff may constrain their laboratories' ability to identify and promote promising technologies. For example, technology transfer officials at one laboratory said that the number of staff devoted to technology transfer had declined from previous levels due to budget cuts, constraining the laboratory's ability to promote its technologies and identify and negotiate with potential partners. Officials at another laboratory said that while technology transfer staff have the technical expertise to understand the laboratory's technologies, the laboratory lacks sufficient staff with the entrepreneurial or business development background needed to assess the commercial potential for all their technologies and match them with market needs. As a result, potential partners may be unaware of some commercially promising technologies at the laboratory. In addition, private sector representatives who have worked with DOE laboratories said that laboratory officials sometimes do not fully understand the marketplace or commercialization process beyond the laboratory's involvement.

After DOE's federally funded research effort has ended and promising technologies have been identified, additional development or testing may be needed before the laboratory can attract entities to license and commercialize those technologies. Known as the "valley of death," the situation can result in a failure to transfer promising technologies because, on the one hand, DOE has limited funding to continue research beyond its initial mission scope and, on the other, potential industry partners are often reluctant to assume the risks of investing in technologies whose potential has not been demonstrated with a prototype, performance data, or similar evidence. Technology transfer officials at 14 of the 17 laboratories told us that the lack of funding for additional development or

[23]Pub. L. No. 99-502, § 4, 100 Stat. 1785, 1790 (1986).

testing was a significant constraint to transferring their promising technologies to the marketplace.[24] Examples of promising technologies currently languishing in the "valley of death" include the following:

- Scientists at Oak Ridge National Laboratory developed a technology that detects toxic agents in water supplies, such as reservoirs, rivers, and lakes, by analyzing the effects of such agents on algae occurring naturally in the water. Although the technology, which gives results faster than present methods for testing water safety, has been licensed, and municipalities have shown interest in it, according to laboratory officials, adoption by municipalities has been stalled by lack of funding to develop a prototype, which is needed before the Environmental Protection Agency can certify the technology for monitoring drinking water.

- Officials at Idaho National Laboratory identified 14 technologies that showed promise but had not been successfully transferred out of the laboratory, including a process for creating synthetic fuels from carbon dioxide, electricity, and steam. The same technology can also create hydrogen, which can itself be turned into electricity. Thus the technology could help in a transition away from fossil fuels. According to laboratory officials, the technology has garnered "a high degree of interest" from industry but lacks funding for further research and development, which will be needed to attract private investment.

- Similarly, a device, known as a carbon-ion pump, shows promise as a technology for removing carbon dioxide from industrial emissions. According to the technology transfer office at Lawrence Livermore National Laboratory, where the device was developed, the pump involves a simple process for removing carbon dioxide from the air and other gases, is appropriate for small industrial plants, and can produce clean water as a by-product. The director of the laboratory's technology transfer office identified the pump as 1 of 20 technologies at the laboratory that

[24]Although DOE laboratories have sometimes used CRADAs to develop and help commercialize promising technologies, the use of CRADAs peaked in the mid-1990s, when DOE, in response to congressional direction, phased out a program whose specific purpose was to provide DOE resources for CRADAs. Although DOE may use its program funding to offset the costs of DOE laboratory work performed under CRADAs, programs may be less likely to do so if the CRADA does not meet the specific goals of a particular DOE research program. For additional information, see GAO, *Technology Transfer: Several Factors Have Led to a Decline in Partnerships at DOE's Laboratories*, GAO-02-465 (Washington, D.C.: Apr. 19, 2002).

had significant potential but needed funding for additional research and development before they could increase opportunities for commercial partnerships.

Even when outside entities are interested in partnering with a laboratory, negotiating technology transfer agreements can sometimes be problematic. Although laboratory contactor officials generally negotiate the agreements with their potential partners, the agreements must be approved by DOE and include certain terms and conditions required by federal law or DOE policy. While these terms and conditions may reflect legal requirements and address legitimate policy concerns, officials at each of the 17 laboratories said that they can also present difficulties for partnering entities, sometimes slowing the negotiating process or discouraging potential partners. For example, outside entities entering into a work-for-others agreement with a DOE laboratory must agree to pay in advance, most typically, for 90 days of the work. Officials at several of the laboratories said that this requirement can be especially problematic for small businesses because they may not have enough capital to pay in advance. Also, the requirement does not reflect standard commercial practices and can therefore prolong negotiations even with businesses that can afford to fund the work up front. DOE headquarters officials representing the Technology Transfer Policy Board and the Office of the General Counsel told us, however, they are concerned that without the requirement DOE could be violating federal appropriations laws, because budgetary resources would have to be used to cover any costs that a sponsor failed to pay. Other terms and conditions require the laboratories' CRADA partners and licensees to laboratory inventions to "substantially manufacture" in the United States any commercial products that include technologies licensed from DOE laboratories.[25] Officials from several DOE laboratories and a number of private-sector representatives we interviewed said that the requirement can present difficulties, in particular for companies that typically manufacture their products overseas. According to DOE headquarters officials, the requirement reflects federal and DOE policies of supporting U.S. industrial competitiveness. Nevertheless, private-sector representatives we contacted emphasized the importance of reaching an acceptable agreement with the laboratories within a reasonable time frame, in light of competition in the marketplace.

[25]Alternatively, the licensee or CRADA partner may make a legally binding commitment to provide an "alternate net benefit to the U.S. economy."

Some DOE Laboratories and Programs Have Developed Their Own Approaches to Increase Technology Transfer

To bridge the gap between the laboratories' research focus and the need to transfer technologies beyond the laboratories, technology transfer officials have taken a number of steps, such as the following:

- At Lawrence Livermore National Laboratory, technology transfer officials regularly evaluate their laboratories' pending research publications for evidence of inventions or technologies that have not been disclosed for commercial opportunities that may have been overlooked.
- Technology transfer officials at some DOE laboratories that are managed and operated by universities—such as Ames Laboratory, which is managed by Iowa State University, and the SLAC National Accelerator Laboratory, managed by Stanford University[26]—work with the universities' technology transfer offices to help the laboratories patent technologies and manage intellectual property.
- Technology transfer officials at Brookhaven National Laboratory expanded their office's reach by working with their laboratory's public relations office to promote selected technologies, which proved successful in attracting licensees for those technologies.
- Four laboratories have brought in entrepreneurs-in-residence, representing venture capital firms, with strong backgrounds in business and science to help identify and commercialize promising technologies. DOE's Office of Energy Efficiency and Renewable Energy funded entrepreneurs at three of these laboratories—the National Renewable Energy Laboratory and Oak Ridge and Sandia national laboratories.[27] These entrepreneurs had 1 year to identify at least one energy-efficiency or renewable-energy technology and develop a plan for commercializing it. The Sandia-based entrepreneur told us that, after months of reviewing the laboratory's technologies, he estimated that 80 percent of the more than 100 technologies he assessed were promising and could be ready for commercialization in about 1 year, after additional development or testing. DOE plans to fund entrepreneurs at four additional laboratories in 2009.

To reduce the number of technologies stalled in the "valley of death," a DOE program office and the laboratories have sought ways to fill the funding gap:

[26]In 2008, the Stanford University-managed and operated laboratory changed its name from Stanford Linear Accelerator Center to SLAC National Accelerator Laboratory.

[27]Los Alamos National Laboratory also funded an entrepreneur there from 2005 to 2008.

- The Office of Energy Efficiency and Renewable Energy in 2007 and 2008 awarded over $14 million to eight DOE laboratories to help those laboratories fund additional research and development on their promising clean-energy technologies. For example, the National Renewable Energy Laboratory used $250,000 of grant money for additional research on advanced cooling fan technology, which came out of the laboratory's geothermal energy research from the 1990s, that could also be used to cool industrial plants more efficiently than current technologies. An industrial partner approached the laboratory willing to match the laboratory's $250,000 investment, as required by the grant program, and then commercialize the technology. According to laboratory officials, the laboratory used the money and industry partner matching funds to develop a prototype of the technology for the industrial setting, which the partner is currently commercializing and expects to bring to market in 2009.

- Officials at several laboratories said they invest a portion of the laboratories' licensing income in other technologies in need of further research and development to help make them more attractive to outside investors. For example, technology transfer officials at the Idaho National Laboratory said this laboratory invests approximately $300,000 to $400,000 of its annual licensing income for this purpose. An internal committee reviews the laboratory's technologies and selects those to be developed and, it is anticipated, eventually licensed and commercialized. In one case, the laboratory spent licensing income to develop a method of producing nanotechnologies that are useful in solar energy and other applications, which attracted a startup company interested in commercialization. According to laboratory officials, such investments have been highly successful, not only for bridging the "valley of death," but also for generating new funding to develop the technology and licensing income for the laboratory.

Finally, the laboratories have taken steps to simplify the negotiation of technology transfer agreements:[28]

[28]One laboratory, the Pacific Northwest National Laboratory, has a unique arrangement, called a "use permit," which allows the nonprofit research organization contracted to operate the laboratory to use the laboratory facilities and staff for its own research and technology-sharing activities. This arrangement also provides the contractor enhanced flexibility to negotiate agreements with potential partners for activities falling under its use permit. The use permit will end in 2012. See appendix III for more information.

- Some laboratories have worked with local DOE officials to develop standard technology transfer agreements with terms and conditions that DOE has preapproved, allowing the laboratories to avoid seeking DOE approval for agreements being negotiated with potential partners. Officials at Brookhaven National Laboratory told us that, as a result of using preapproved agreements, they have been able to reduce the time it takes to put technology transfer agreements in place—down to 1 day in some cases.

- At least one laboratory has taken this approach a step further by creating standardized agreements that apply to specific entities with which the laboratories expect to have a longer-term partnership. Savannah River National Laboratory in South Carolina, for example, has developed a "model" CRADA for its cooperative research projects with universities in South Carolina.

- Similarly, Sandia and Los Alamos national laboratories have set up "umbrella" CRADAs with major companies, such as Goodyear or Chevron, with which the laboratories have ongoing partnerships and enter into multiple agreements. Under these agreements, the laboratories and their partners have agreed in advance to certain terms and conditions, such as the parties' rights to review one another's draft publications or their rights of ownership of intellectual property resulting from the cooperative research. Other terms and conditions, such as the scope of work to be completed, are negotiated when new work is being considered by the parties. Officials at one of these laboratories told us that standardizing agreements has streamlined the negotiating process and resulted in more long-term partnerships with industry.

- In addition, laboratories have taken other steps to mitigate sometimes problematic terms and conditions of technology transfer agreements. The contractor operating Lawrence Berkeley National Laboratory, for example, sometimes uses its own funds to help potential partners pay in advance for 90-days' work toward their technology transfer agreement.

At headquarters, DOE officials have also taken some steps to increase the likelihood that promising technologies will be transferred out of the laboratories and commercialized. The Technology Transfer Policy Board has published in the Federal Register a request for information from private industry, DOE laboratories, and others seeking to identify problems with DOE's current technology transfer agreements, along with best practices DOE could consider. As of April 2009, DOE was consolidating responses to its request. The board has also altered some

user-facility agreements to make it easier for users to collaborate with laboratory staff.

Approaches Used Outside DOE Could Offer Additional Ways for Strengthening DOE's Own Efforts

Other federal laboratories outside DOE are using other approaches aimed at increasing technology transfer. To learn about some of these approaches, we spoke with Department of Defense (Defense) officials from the Office of Technology Transition—created to oversee and encourage technology transfer departmentwide—as well as officials who more directly oversee technology transfer for the Office of Naval Research and the Army and Air Force research laboratories. According to these officials, certain efforts by the Office of Technology Transition have helped technology transfer staff at Defense's laboratories enhance their capabilities, resulting in additional technology transfer opportunities. Specifically:

- **Training and networking opportunities:** The Office of Technology Transition sponsors annual departmentwide training and networking sessions for technology transfer staff, which sometimes include private industry representatives interested in partnering with Defense laboratories. Training topics range from general overview of technology transfer, aimed at new technology transfer staff, to more specific topics, such as negotiation techniques or legal issues. The officials we spoke with said that these sessions are well received and represent a valuable training opportunity and a means for sharing best practices.

- **Web-based information sharing:** The Office of Technology Transition also funds a searchable Web-based tool that enables all of the Defense laboratories to publicize in a single location their available technologies and partnering opportunities to potential partners within and outside the government. The site helps consolidate and organize information on licensing and partnering opportunities available at approximately 120 Defense laboratories and programs.

- **Funding for additional expertise at Defense laboratories:** The Office of Technology Transition pays for contracts with outside experts, used as needed by Defense's laboratories to supplement their technology transfer staff members' capabilities.[29] According to the Defense officials we spoke

[29]Defense's Office of Technology Transition contracts with these experts under authority provided in 15 U.S.C. § 3715, "Use of Partnership Intermediaries," according to an official in that office.

with, the laboratories have used these experts to help identify promising technologies, publicize technology partnering opportunities, identify potential partners, or assist in negotiating technology transfer agreements. Defense officials said the contracted experts have helped technology transfer offices with small numbers of staff carry out additional technology transfer activities. Laboratories have also benefited from some of the experts' connections with industry, as well as from their business development experience.

Although DOE and its laboratories have taken various steps to improve technology transfer, approaches used by Defense or suggested by others outside DOE could offer additional strategies for DOE to strengthen its own technology transfer efforts. Specifically, although DOE laboratory technology transfer staff may share best practices through the Technology Transfer Working Group or less formal means, DOE does not organize regular departmentwide training or networking opportunities for all DOE and laboratory staff involved in technology transfer. According to the department, only DOE and laboratory attorneys involved in intellectual property issues and technology transfer meet annually for networking and training. Likewise, while several of the laboratories showcase their technology transfer opportunities on their public Web sites, DOE does not have a departmentwide database, consolidating this information in a single location, and interested parties would have to compile information from multiple Web sites to obtain a more complete view of DOE's technology transfer opportunities.[30] Lastly, although outside experts—such as the entrepreneurs funded by DOE's Office of Energy Efficiency and Renewable Energy—have been made available at a few of DOE's laboratories, to date not all of the laboratories have benefited. In contrast, the outside experts under contract with the Department of Defense's Office of Technology Transition are available to all of the laboratories to carry out a wider variety of tasks than the entrepreneurs funded by DOE and are not focused on commercializing a single technology. Furthermore, unlike the entrepreneurs, who are available to the participating

[30]DOE, in fact, has a single searchable Web site showcasing current opportunities to license DOE laboratory technologies, but only technologies owned by DOE; the site does not include laboratory technologies owned and patented by the contractors operating most of the 17 laboratories. If DOE laboratory contractors do not elect title to inventions made at the laboratory within a certain time frame, DOE may decide to pursue patents (or other legal protection for intellectual property) and then license the patented technologies to interested parties. According to DOE's Office of the General Counsel, because DOE only owns 5 to 10 percent of the new inventions made at the laboratories, the Web site only includes a fraction of the technologies at the laboratories.

laboratories for a limited duration, the Department of Defense's experts are available on an ongoing basis. In addition, private industry representatives, including those responding to DOE's request in the Federal Register, offered suggestions for improving DOE's technology transfer, such as a venture capital firm's suggestion that DOE ensure adequate resources are available departmentwide for developing or testing promising technologies to attract industry.

Conclusions

DOE's national laboratories and specialized research facilities, long a source for groundbreaking research and technical innovation, routinely share their technologies and unique capabilities with others, helping pave the way for technological solutions and economic opportunities in diverse fields ranging from solar energy to health care. The unprecedented scale and urgency of the challenges currently threatening the economy, natural environment, and global security clearly signal the need for new technologies and effective collaborations among those capable of developing and commercializing them. While DOE has made invaluable contributions in this regard, more could be done to ensure that promising technologies are being transferred. Unclear priorities within DOE about the role of technology transfer are complicating the already difficult task of transferring and commercializing new technologies. DOE's lack of overarching goals—including a consensus on what activities constitute technology transfer—and reliable performance data have left DOE's laboratories and program offices to chart their own course, often with mixed results. While some laboratories have used various approaches to help address the constraints that limit their technology transfer efforts, not all the laboratories or programs have done so. Other strategies, such as those employed by the Department of Defense, could further enhance the laboratories' capacity to transfer their technologies and speed the arrival of solutions to the commercial marketplace. Given the billions spent each year on research at DOE's laboratories and the urgency of today's challenges, DOE needs to take a stronger role in ensuring that its laboratories are providing the maximum return on the public's investment in federal research.

Recommendations for Executive Action

To better measure, and improve, the effectiveness of DOE's technology transfer efforts, we recommend that the Secretary of Energy, working in concert with laboratory directors, take the following seven actions:

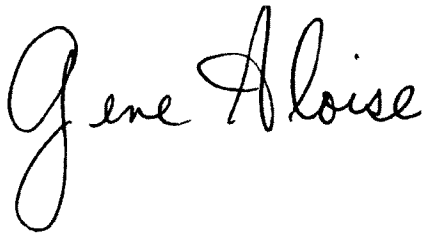
- explicitly articulate departmentwide priorities for DOE's technology transfer efforts;
- develop clear goals, objectives, and performance measures in line with these priorities;
- clarify which activities qualify as technology transfer, including whether research sponsored by other federal agencies qualifies;
- collect reliable performance data and further consider ways to use the data to monitor the progress and effectiveness of technology transfer efforts;
- ensure sufficient laboratory access to both technical and business development expertise;
- develop a systematic approach to identify technologies with commercial promise; and
- develop a comprehensive means of sharing information across laboratories and with private entities, such as a Web-based clearinghouse for technologies ready for further development or commercialization.

Agency Comments and Our Evaluation

We provided a draft of this report to the Secretary of Energy for review and comment. The Acting Director of the Office of Science responded on behalf of DOE and generally agreed with our findings. Although DOE was silent on whether it agreed or disagreed with our recommendations, DOE noted that many of the recommendations touch upon policy issues that will likely be addressed under the new administration. DOE's written comments on our draft report are included in appendix IV. DOE also provided technical comments that we incorporated as appropriate.

We are sending copies of this report to interested congressional committees, the Secretary of Energy, and other interested parties. In addition, this report will be available at no charge on the GAO Web site at http://www.gao.gov.

If you or your staffs have any questions about this report, please contact me at (202) 512-3841 or aloisee@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. GAO staff who made key contributions to this report are listed in appendix V.



Gene Aloise
Director, Natural Resources and Environment

Appendix I: Scope and Methodology

To determine the nature and extent of technology transfer at the Department of Energy's (DOE) laboratories, we reviewed the federal laws and DOE policies and guidance related to technology transfer. We also analyzed technology transfer data collected annually by DOE headquarters from the department's national laboratories and other facilities, which are responsible for carrying out DOE's technology transfer. We contacted the officials responsible for technology transfer at DOE's 17 national laboratories:

- Ames Laboratory, Iowa;
- Argonne National Laboratory, Illinois;
- Brookhaven National Laboratory, New York;
- Fermi National Accelerator Laboratory, Illinois;
- Idaho National Laboratory, Idaho;
- Lawrence Berkeley National Laboratory, California;
- Lawrence Livermore National Laboratory, California;
- Los Alamos National Laboratory, New Mexico;
- National Energy Technology Laboratory, Oregon, Pennsylvania, and West Virginia;
- National Renewable Energy Laboratory, Colorado;
- Oak Ridge National Laboratory, Tennessee;
- Pacific Northwest National Laboratory, Washington;
- Princeton Plasma Physics Laboratory, New Jersey;
- Sandia National Laboratories, California and New Mexico;
- Savannah River National Laboratory, South Carolina;

- SLAC National Accelerator Laboratory, California;[1] and
- Thomas Jefferson National Accelerator Facility, Virginia.

According to DOE's data, the 17 national laboratories were responsible for more than 92 percent of the cooperative research and development, work for others, and technology licensing agreements during fiscal years 2006 and 2007. We interviewed contractor officials responsible for technology transfer at each of these laboratories—including visits to the Lawrence Livermore, Lawrence Berkeley, and Pacific Northwest national laboratories—about the nature and extent of their technology transfer efforts. We also discussed at most laboratories the officials' efforts to ensure the accuracy or completeness of technology transfer data collected annually by DOE headquarters. Although we determined that DOE's data were sufficiently reliable for selecting the laboratories to contact during this study or reporting the total number of agreements at DOE laboratories, we were unsure about whether they could be used to report on the precise extent of technology transfer at individual laboratories. As a result, in November 2008, we collected additional data from the 17 laboratories about their technology transfer agreements in fiscal years 2006 through 2008, including selected information about the number of these laboratories' cooperative research and development, work for others, patent licensing, and user-facility agreements and revenues associated with these agreements. Because there were indications in the DOE data that its laboratories were using inconsistent methods for reporting the dollars associated with some of its agreements—work-for-others agreements, in particular—and DOE could not verify the reliability of its data, we asked the 17 laboratories to report this data using a consistent definition.[2] Also, to reduce respondent burden, we limited the data we collected on the number of the laboratories' licensing agreements to focus exclusively on patented technologies licensed to private industry. And, we limited the data we collected on revenues from user-facility agreements to focus on agreements with private industry because, according to DOE officials, most such revenues come from proprietary user-facility agreements with private industry. In addition, we collected data and other information about "use permit" agreements, which are

[1]In 2008, the Stanford University-managed and operated laboratory changed its name from Stanford Linear Accelerator Center to SLAC National Accelerator Laboratory.

[2]Specifically, we asked the laboratories to report on the dollars "costed"—or actual costs—of the work performed under these agreements in the fiscal year.

unique to 1 of the 17 laboratories. (See app. II for data on the 17 laboratories' agreements and app. III for information on "use permit" agreements.) Furthermore, we spoke with DOE headquarters officials from the Office of the General Counsel, the Office of Laboratory Policy and Evaluation in the Office of Science, and the Technology Transfer Policy Board. We also spoke with members of DOE's Technology Transfer Working Group.

To determine the extent to which DOE can measure the effectiveness of technology transfer efforts at its laboratories, we obtained and analyzed the laboratories' annual performance goals and assessments for fiscal years 2006 through 2009, as available, as well as documentation of DOE program-office efforts to establish technology transfer goals. We also discussed performance measurement issues with the 17 laboratories and DOE headquarters officials, and, to learn more about technology transfer and performance measurement from the nonfederal perspective, we spoke with associations representing university and private-sector technology managers engaged in technology transfer.

To identify the factors affecting technology transfer and approaches that may have potential for improving technology transfer, we asked the technology transfer officials at the 17 laboratories and DOE headquarters officials to discuss key factors, positive or negative, affecting DOE's ability to transfer its technologies, as well as any efforts to improve technology transfer or helpful practices. As appropriate, we obtained documentation of factors that were mentioned and results of any improvement efforts. Finally, to better understand how other federal agencies transfer technology, we interviewed Department of Defense officials who oversee technology transfer in that department's Office of Technology Transition, Army and Air Force Research Laboratories, and the Office of Naval Research about the strategies used to transfer technologies.

We conducted this work as a performance audit from July 2008 through June 2009, in accordance with general accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Appendix II: Information on the Department of Energy's Technology Transfer Agreements and Associated Revenue

DOE's laboratories share their technologies, capabilities, and knowledge with other entities through a variety of activities. Certain activities, and the agreements used to implement them, are widely regarded as technology transfer. The four primary types of technology transfer agreements are cooperative research and development, work for others, licensing, and user-facility agreements. The following tables contain information about the type and number of these agreements for fiscal years 2006 through 2008 and, when available, the associated revenue at the 17 DOE laboratories we reviewed.

Cooperative Research and Development Agreements

Under a cooperative research and development agreement (CRADA), laboratory employees collaborate with nonfederal partners to carry out research that will benefit DOE program missions and the partners' research and development goals. As shown in table 1, the majority of CRADAs are with private partners, defined as for-profit firms (domestic or foreign), industry associations, or consortia whose members include representatives from private industry. A few of the laboratories, including Los Alamos National Laboratory and the National Renewable Energy Laboratory, often partner with other entities such as universities or state and local governments.

Table 1: Number of Cooperative Research and Development Agreements, Fiscal Years 2006 through 2008

	All CRADAs			CRADAs with private partners[a]		
DOE national laboratory or facility	2006	2007	2008	2006	2007	2008
Ames	3	3	5	3	3	5
Argonne	37	42	32	37	42	32
Brookhaven	50	54	47	50	54	47
Fermi Accelerator	3	6	10	3	6	10
Idaho	64	76	67	57	68	61
Lawrence Berkeley	13	14	12	13	14	12
Lawrence Livermore	33	38	36	33	38	36
Los Alamos	55	70	89	48	61	70
National Energy Technology	38	33	28	31	26	21
National Renewable Energy	49	52	94	37	40	72
Oak Ridge	78	88	65	76	87	62
Pacific Northwest[b]	30	43	38	30	43	38
Princeton Plasma Physics	0	1	1	0	1	1
Sandia	139	149	138	139	148	137
Savannah River	8	10	11	4	5	6

DOE national laboratory or facility	All CRADAs			CRADAs with private partners[a]		
	2006	2007	2008	2006	2007	2008
SLAC Accelerator	5	11	11	5	11	11
Thomas Jefferson Accelerator	6	6	5	6	6	5
Total	**611**	**695**	**689**	**572**	**653**	**626**

Source: GAO analysis of national laboratories' data.

[a]CRADAs with private partners are a subset of all CRADAs.

[b]Figures for the Pacific Northwest National Laboratory do not include work performed under this laboratory's unique arrangement, or use permit, with DOE; see appendix III for more information.

Under a CRADA, even if laboratories contribute personnel, equipment, or other in-kind resources to a project, their CRADA partners must contribute funds (see table 2), in-kind resources, or both.

Table 2: Partner-Contributed Funds for Research under CRADAs, Fiscal Years 2006 through 2008

DOE national laboratory or facility	From all partners (dollars in thousands)			From private partners[a] (dollars in thousands)
	2006	2007	2008	2008
Ames	$90	$20	$150	$150
Argonne	215	600	236	236
Brookhaven	2,000	2,100	3,700	3,700
Fermi Accelerator	44	279	445	445
Idaho	4,316	2,941	5,910	4,399
Lawrence Berkeley	600	100	500	500
Lawrence Livermore	1,240	4,142	9,972	9,972
Los Alamos	2,700	10,700	12,500	11,400
National Energy Technology	376	608	92	84
National Renewable Energy	1,776	2,179	3,102	3,102
Oak Ridge	8,300	16,300	12,400	11,200
Pacific Northwest[b]	100	100	1,400	1,400
Princeton Plasma Physics	0	0	0	0
Sandia	23,962	21,326	20,631	20,631
Savannah River	868	664	1,372	1,332
SLAC Accelerator	144	186	319	319
Thomas Jefferson Accelerator	709	600	524	524
Total	**$47,439**	**$62,844**	**$73,252**	**$69,393**

Source: GAO analysis of national laboratories' data.

Note: Because a CRADA can span multiple years, the figures in table 2 represent the amounts "costed" by the laboratories in each of the fiscal years.

[a]We collected data on funds from private partners only for fiscal year 2008; the amounts are a subset of funds from all partners.

[b]Figures for the Pacific Northwest National Laboratory do not include work performed under this laboratory's unique arrangement, or use permit, with DOE; see appendix III.

Work-for-Others Agreements

Under a work-for-others agreement, a DOE laboratory agrees to conduct research, for a fee, on behalf of a sponsor. Although this research must be consistent with the laboratory's mission and draw on the laboratory's unique capabilities, the research is not required to benefit DOE programs, as it is under a CRADA. DOE has work-for-others agreements with both federal and nonfederal entities, but DOE headquarters and its laboratories do not all agree on whether work-for-others agreements with federal entities should be considered technology transfer. Table 3 shows the relative number of work-for-others agreements carried out with federal entities; with all nonfederal entities, including private partners; and with private partners, defined as for-profit firms (domestic or foreign), industry associations, or consortia whose members include representatives from private industry.

Table 3: Number of Work-for-Others Agreements, Fiscal Years 2006 through 2008

DOE national laboratory or facility	With federal agencies			With all nonfederal entities			With private partners[a]		
	2006	2007	2008	2006	2007	2008	2006	2007	2008
Ames	11	9	10	9	10	11	7	9	8
Argonne	135	147	137	133	145	114	86	82	63
Brookhaven	122	120	107	54	55	44	16	18	14
Fermi Accelerator	4	4	3	6	3	4	4	2	2
Idaho	436	464	502	184	233	278	147	173	216
Lawrence Berkeley	294	266	244	452	431	438	157	153	158
Lawrence Livermore	598	683	711	315	335	519	314	296	277
Los Alamos	684	812	1,006	154	162	185	75	73	87
National Energy Technology	8	13	7	15	21	9	14	20	8
National Renewable Energy	63	70	79	93	110	120	90	95	106
Oak Ridge	937	1,013	1,048	447	473	556	394	421	503
Pacific Northwest[b]	462	494	491	12	20	18	2	9	7
Princeton Plasma Physics	17	17	18	8	8	8	4	3	4
Sandia	527	528	530	275	265	262	216	203	201
Savannah River	85	82	81	19	26	31	16	21	26
SLAC Accelerator	0	0	0	1	1	4	1	1	4
Thomas Jefferson Accelerator	11	10	4	9	9	10	9	9	10
Total	**4,394**	**4,732**	**4,978**	**2,186**	**2,307**	**2,611**	**1,552**	**1,588**	**1,694**

Source: GAO analysis of national laboratories' data.

[a]Work-for-others agreements with private partners are a subset of work-for-others agreements with nonfederal entities.

[b]Figures for the Pacific Northwest National Laboratory do not include work performed under this laboratory's unique arrangement, or use permit, with DOE; see appendix III.

Under a work-for-others agreement, the sponsor must pay the entire cost of a project. Table 4 shows the funds associated with work-for-others agreements from fiscal year 2006 through 2008.

Table 4: Sponsor-Contributed Funds for Research under Work-for-Others Agreements, Fiscal Years 2006 through 2008

DOE national laboratory or facility	From federal agencies (dollars in thousands)			From all nonfederal entities (dollars in thousands)			From private partners[a] (dollars in thousands)
	2006	2007	2008	2006	2007	2008	2008
Ames	$1,490	$1,510	$1,850	$460	$430	$850	$500
Argonne	80,400	73,800	85,700	28,300	33,000	26,889	9,400
Brookhaven	40,300	39,100	41,700	16,800	3,500	4,400	2,100
Fermi Accelerator	153	66	132	301	298	3,889	3
Idaho	165,978	192,597	256,223	12,869	12,358	8,495	4,448
Lawrence Berkeley	69,400	67,300	64,200	47,000	43,200	40,700	12,300
Lawrence Livermore	277,000	215,800	236,000	34,200	33,900	43,600	27,200
Los Alamos	232,000	216,000	207,000	16,400	15,700	21,200	8,000
National Energy Technology	527	120	833	133	37	94	94
National Renewable Energy	3,758	3,426	4,126	7,220	6,898	9,780	9,363
Oak Ridge	196,000	237,000	289,000	39,000	54,000	48,000	44,100
Pacific Northwest[b]	237,500	218,900	228,700	2,600	1,300	1,200	700
Princeton Plasma Physics	1,200	1,100	900	500	400	100	100
Sandia	380,531	390,907	430,056	28,299	24,158	20,617	17,489
Savannah River	8,764	13,414	17,801	1,177	1,396	1,931	1,791
SLAC Accelerator	0	0	0	0.5	0	0.7	0.7
Thomas Jefferson Accelerator	14,526	7,761	1,800	353	455	243	243
Total	**$1,709,526**	**$1,678,802**	**$1,866,022**	**$235,612**	**$231,029**	**$231,988**	**$137,831**

Source: GAO analysis of national laboratories' data.

Note: Because work-for-others agreements can span multiple years, the figures in table 4 represent the amounts "costed" by the laboratories in each of the fiscal years.

[a]We collected data on funds from private partners only for fiscal year 2008; the amounts are a subset of dollars from all nonfederal entities.

[b]Figures for the Pacific Northwest National Laboratory do not include work performed under this laboratory's unique arrangement, or use permit, with DOE; see appendix III.

Patent Licensing Agreements

In addition to performing research, laboratories share their technologies by licensing their patented discoveries, copyrighted software programs, or

other intellectual property to nonfederal entities seeking to use or commercialize those technologies. In some cases, the licensee agrees to pay fees or royalties to the laboratory in exchange for the laboratory's permission to use or commercialize the technologies. Table 5 shows the total number of licenses with private partners. DOE may also have licensing agreements with other nonfederal entities, such as universities, which are not captured in the table.

Table 5: Number of Patent License Agreements with Private Partners, Fiscal Years 2006 through 2008, and Associated Revenue, Fiscal Year 2008

	Number of licenses			Revenue[a] (dollars in thousands)
DOE national laboratory or facility	2006	2007	2008	2008
Ames	47	45	41	$6,500
Argonne	75	89	88	3,877
Brookhaven	520	473	498	9,500
Fermi Accelerator	0	0	0	0
Idaho	70	74	79	93
Lawrence Berkeley	72	80	86	2,700
Lawrence Livermore	91	99	108	9,411
Los Alamos	148	169	187	1,500
National Energy Technology	8	10	11	67
National Renewable Energy	44	53	50	643
Oak Ridge	109	99	82	2,600
Pacific Northwest	87	81	77	3,338
Princeton Plasma Physics	2	2	3	30
Sandia	178	151	164	3,506
Savannah River	12	17	18	44
SLAC Accelerator	2	1	1	5
Thomas Jefferson Accelerator	10	10	11	40
Total	**1,475**	**1,453**	**1,504**	**$43,855**

Source: GAO analysis of national laboratories' data.

[a]We collected data on revenue from licenses to private partners for fiscal year 2008 only.

User-Facility Agreements

Under a user-facility agreement, scientists from outside organizations can use DOE's scientific equipment for their own research, sometimes in

collaboration with laboratory staff. Users may conduct their research at DOE's facilities for free or a negotiated cost, if the results of their research will be made public. The users who wish to keep their results private, however, must reimburse DOE for the full cost of using the facilities. Table 6 shows the number of user facility agreements with private partners from fiscal year 2006 through 2008, and the amount paid by the partner for fiscal year 2008.

Table 6: Number of User-Facility Agreements with Private Partners, Fiscal Years 2006 through 2008, and Associated Revenue, Fiscal Year 2008

	Total agreements			Revenue[a] (dollars in thousands)
DOE national laboratory or facility	2006	2007	2008	2008
Ames	0	0	0	0
Argonne	189	202	221	$2,200
Brookhaven	85	111	163	1,000
Fermi Accelerator	0	0	0	0
Idaho	0	0	0	0
Lawrence Berkeley	82	96	119	1,700
Lawrence Livermore	0	0	0	0
Los Alamos	33	36	36	500
National Energy Technology	0	0	0	0
National Renewable Energy	0	0	0	0
Oak Ridge	75	180	157	600
Pacific Northwest	9	9	5	0
Princeton Plasma Physics	0	0	0	0
Sandia	5	6	7	69
Savannah River	0	0	0	0
SLAC Accelerator	75	75	75	376
Thomas Jefferson Accelerator	0	0	0	0
Total	**553**	**715**	**783**	**$6,445**

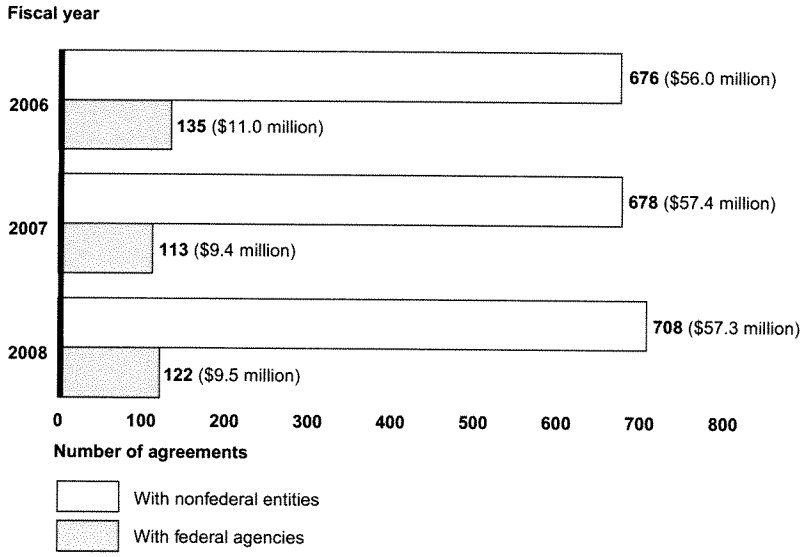
Source: GAO analysis of national laboratories' data.

[a]We collected data on revenue from user-facility agreements with private partners for fiscal year 2008 only.

Appendix III: The Use Permit at the Pacific Northwest National Laboratory

Since 1964, the contractor in charge of managing and operating the Pacific Northwest National Laboratory in southeastern Washington state has been allowed to use the laboratory's personnel and DOE-owned facilities for its own private work, subject to some restrictions, under a unique arrangement called a use permit. Due to expire in 2012, this arrangement was originally developed to stimulate economic diversity and private investment in the local community by encouraging the contractor (Battelle Memorial Institute) to pursue private research and development work and to invest in facilities and equipment at the laboratory beyond what the federal government would invest, in part to support this private research work. Pacific Northwest National Laboratory contractor officials who administer the use permit estimated that about $70 million in research and development work is performed each year under the use permit—equivalent to about 10 percent of all the work done at the laboratory. Most of this work is undertaken on behalf of outside entities—including federal agencies, private companies, universities, state or local governments, or others—that enter into agreements with the Pacific Northwest laboratory's contractor for work under the use permit. In conducting this work, however, the contractor must use its own funds to pay the full costs of using the laboratory's government-owned facilities, equipment, and personnel at the laboratory. Since fiscal year 2006, the contractor has entered into about 700 to 800 separate agreements each year under the use permit (with the same entity in some cases), the majority with nonfederal entities (see fig. 1). Laboratory contractor officials said that, because of the use permit, the laboratory does not have as many CRADAs or nonfederal work-for-others agreements as other DOE laboratories. In fiscal year 2008, for example, the Pacific Northwest National Laboratory reported having 18 nonfederal work-for-others agreements, whereas other DOE laboratories with roughly comparable budgets had, in some cases, significantly more nonfederal work-for-others agreements that year.

Figure 3: Agreements under the Use Permit at Pacific Northwest National Laboratory, Fiscal Years 2006 through 2008, and Associated Revenue



Source: GAO analysis of data from Battelle Memorial Institute.

According to contractor officials, the flexibilities afforded the contractor under the use permit—flexibilities not available at other DOE laboratories—have helped increase the extent to which the laboratory's technologies and capabilities are transferred. For example, under the use permit, the Pacific Northwest laboratory contractor may respond to competitive solicitations, such as those put out by federal agencies, and compete against private entities for research and development work to be carried out using the laboratory's facilities and staff. The contractor also has enhanced flexibility to negotiate the terms and conditions of its research agreements, enabling the parties to tailor the terms of the agreements to fit the parties' interests and making optional many of the constraints imposed by terms and conditions required under DOE's technology transfer agreements. According to laboratory contractor officials, this feature has made the use permit an attractive option for entities doing business with the laboratory and has helped bring resources into the local community, in line with the use permit's original goals. Whereas terms and conditions of DOE agreements may conflict with standard commercial practice, under the use permit the contractor can, for example, assume the risk of guarantee that it will perform the agreed-upon scope of work within the allotted budget and time frame. And, according to contractor officials, because the contractor has more flexibility to set

the price of agreements, the contractor can earn a profit from work performed under the use permit, reflecting in part the risks the laboratory contractor assumes in performing work on its own account.

DOE, in contrast, has expressed concerns about the use permit arrangement. Specifically, officials in DOE's Office of Science, which oversees the Pacific Northwest National Laboratory, and Office of the General Counsel stated that the structure of the use permit limits the extent to which DOE can perform oversight. For example, work under the use permit is not allowed to interfere with research performed for DOE at the laboratory. A DOE official told us that, while he was not aware of any instances in which use permit work interfered with DOE work, DOE has limited ability to ensure this rule was followed. Furthermore, DOE officials said the flexibilities under the use permit afforded the Pacific Northwest laboratory contractor some "unfair" advantages. In responding to competitive solicitations, for example, the contractor is able to bring work into the laboratory that would otherwise be off-limits, because DOE laboratories are restricted by federal statutes, regulations, and DOE policies from directly competing for work against private entities. Likewise, competing against these private entities for work could place the entities at a distinct disadvantage, because the Pacific Northwest laboratory contractor is able to access and use publicly-funded facilities and equipment, even though the laboratory contractor is paying the full costs of using government resources. Finally, according to DOE officials, this arrangement posed problems for DOE when it attempted to recompete the contract to manage the laboratory, which was due to expire at the end of 2008. Specifically, because some work carried out under the use permit would have remained unfinished at the time a new contract was to begin, it was unclear how the current contractor would complete the work if another entity won the contract to manage the laboratory. Following negotiations on these issues in 2008, DOE and the laboratory contractor agreed to extend the management and operating contract—including the use permit—until September 2012, by which time the contractor must have concluded all of the work under the use permit. After September 2012, the use permit will be ended. DOE officials have said that in the interim, they will examine ways to enhance technology transfer departmentwide.

Although we analyzed over 300 agreements under the use permit, we were unable to determine whether those agreements ultimately led to additional technology transfer. In general, these agreements appeared to draw on the Pacific Northwest laboratory's unique capabilities—a factor considered by DOE officials to help them evaluate proposed work-for-others agreements

and ensure that an agreement would not inadvertently place the laboratory into competition with the private sector—and they entailed work contributing to critical areas ranging from climate-change research to advanced homeland security technologies. Nevertheless, it was unclear to what extent these agreements would constitute technology transfer. For example, according to DOE and the contractor, a large portion of the 300 agreements could have been performed under a nonfederal work-for-others agreement, because they satisfied key criteria for performing work under those agreements. It is unknown, however, whether the partnering entities would have chosen to carry out the work, except under the use permit. As another example, agreements resulting from competitive solicitations—approximately one-third of the 300 agreements—may not have come to the laboratory without the use permit. Since traditional technology transfer agreements preclude a laboratory from competing for work, however, it is unclear whether those competitively awarded contracts for research actually constitute technology transfer.

Appendix IV: Comments from the Department of Energy

Department of Energy
Washington, DC 20585

May 29, 2009

Mr. Gene Aloise
Director, Natural Resources and Environment
U.S. Government Accountability Office
441 G Street, NW
Washington, DC 20584

Dear Mr. Aloise:

Thank you for the opportunity to comment on the draft Government Accountability Office (GAO) report, entitled *"TECHNOLOGY TRANSFER: Clearer Priorities and Greater Use of Innovative Approaches Could Increase the Effectiveness of Technology Transfer at Department of Energy Laboratories (GAO-09-548)"*. The Department of Energy agrees with many of the findings in this report. The DOE Technology Transfer Policy Board is already taking steps to examine ways to improve technology transfer activities within the Department.

Many of the recommendations made by the GAO, as well as those resulting from a study of recommendations gathered through DOE's Request for Information published November 26, 2008, *"Questions About DOE Laboratory Technology Transfer Seeking Input From All Parties Including Industry, Universities, Non-Profits and the General Public"*, which had a final deadline of March 26, 2009, touch upon policy issues that we anticipate will be addressed under the new administration.

Please find an attachment to this letter which provides additional general and specific comments on the draft report. Many of these comments were provided to the GAO in response to their initial Statement of Facts but may not have been reflected in the draft report.

Sincerely,

Patricia M. Dehmer
Acting Director
Office of Science

Printed with soy ink on recycled paper

Appendix V: GAO Contact and Staff Acknowledgments

GAO Contact

Gene Aloise (202) 512-3841 or aloisee@gao.gov

Staff Acknowledgments

In addition to the individual named above, Janet Frisch, Assistant Director; Nabajyoti Barkakati; Ellen W. Chu; Stanley Kostyla; Jeff Larson; Omari Norman; and Jeff Rueckhaus made important contributions to this report.

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Intellectual Property and Sustainable Development Series

New Trends in Technology Transfer

Implications for National and International Policy

By John H. Barton
George E. Osborne Professor of Law, Emeritus
Stanford Law School

ICTSD
International Centre for Trade and Sustainable Development

Issue Paper No. 18

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For more information about ICTSD's programme on intellectual property and sustainable development, visit our web site: http://www.iprsonline.org

ICTSD welcomes feedback and comments on this document.
These can be forwarded to: dvivas@ictsd.ch

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CONTENTS

ABBREVIATIONS AND ACRONYMS

BIT	Bilateral Investment Treaty
BOT	Build, Operate, Transfer
BRIC	Brazil, Russia, India and China
CGIAR	Consultative Group on International Agricultural Research
CIMMYT	International Maize and Wheat Improvement Center
CRADA	Cooperative Research and Development Agreement
DVD	Digital Video Disk
EMBRAPA	Empresa Brasiliera de Pesquisa Agropecuária
FDI	Foreign Direct Investment
GATS	WTO General Agreement on Trade in Services
GFATM	Global Fund to Fight AIDS, Tuberculosis and Malaria
IAEA	International Atomic Energy Agency
IAVI	International Aids Vaccine Initiative
ICSU	International Council for Science
IP	Intellectual Property
IPRs	Intellectual Property Rights
IRRI	International Rice Research Institute
LAN	Local Area Network
MPEG3	Moving Picture Experts Group Layer 3 (a group of audio and video coding standards)
MRC	Medical Research Council
NIH	National Institutes of Health
PEPFAR	President's Emergency Plan for AIDS Relief
PIPRA	Public Sector Intellectual Property Resource for Agriculture
PPP	Public-Private Partnership
R & D	Research and Development
S & T	Science and Technology
SME	Small and Middle-Sized Enterprises
TRIMS	WTO Agreement on Trade-Related Investment Measures
TRIPS	WTO Agreement on Trade-Related Aspects of Intellectual Property Rights
UK	United Kingdom
UNCTAD	United Nations Conference on Trade and Development
UNESCO	United Nations Educational, Scientific, and Cultural Organization
UNICEF	United Nations Children's Fund
UNDP	United Nations Development Program
U.S.	United States
WAPI	WLAN Authentication and Privacy Infrastructure
WIPO	World Intellectual Property Organization
WLAN	Wireless Local Area Network
WTO	World Trade Organization

FOREWORD

This study addresses the issue of new trends in technology transfer and their implications for national and international policy. It is one further contribution of the ICTSD Programme on Intellectual Property Rights and Sustainable Development to a better understanding of the proper role of intellectual property in a knowledge-based economy. They objective of the study is to explore how technology is transferred to developing countries and barriers that affect its transfer. To this end, it identifies policy approaches that might be of assistance in overcoming such barriers by addressing the flow of human resources, the flow of public-sector technology support, and the flow of private technology embodied in goods and services.

The premise of ICTSD's work in this field, together with its joint project with UNCTAD, is based on the understanding that Intellectual Property Rights (IPRs) have never been more economically and politically important or controversial than they are today. Patents, copyrights, trademarks, industrial designs, integrated circuits and geographical indications are frequently mentioned in discussions and debates on such diverse topics as public health, food security, education, trade, industrial policy, traditional knowledge, biodiversity, biotechnology, the Internet, and the entertainment and media industries. In a knowledge-based economy, there is no doubt that a better understanding of IPRs is indispensable to informed policy making in all areas of development.

Empirical evidence on the role of intellectual property protection in promoting innovation and growth remains inconclusive. Diverging views also persist on the impacts of IPRs to development prospects. Some point out that, in a modern economy, the minimum standards laid down in the WTO Agreement on Intellectual Property Rights (TRIPS) will bring benefits to developing countries by creating the incentive structure necessary for knowledge generation and diffusion, technology transfer and private investment flows. Others stress that intellectual property, especially some of its elements, such as the patenting regime, will adversely affect the pursuit of sustainable development strategies by: raising the prices of essential drugs to levels that are too high for the poor to afford; limiting the availability of educational materials for developing country school and university students; legitimising the piracy of traditional knowledge; and undermining the self-reliance of resource-poor farmers.

It is urgent, therefore, to ask the question: How can developing countries use Intellectual Property (IP) tools to advance their development strategy? What are the key concerns surrounding issues of IPRs for developing countries? What are the specific difficulties they face in intellectual property negotiations? Is intellectual property directly relevant to sustainable development and to the achievement of agreed international development goals? How can we facilitate technological flows among all countries? Do they have the capacity, especially the least developed among them, to formulate their negotiating positions and become well-informed negotiating partners? These are essential questions that policy makers need to address in order to design IPR laws and policies that best meet the needs of their people and negotiate effectively in future agreements.

To address some of these questions, the ICTSD Programme on Intellectual Property and Sustainable Development was launched in July 2000. One central objective has been to facilitate the emergence of a critical mass of well-informed stakeholders in developing countries — including decision makers, negotiators and also the private sector and civil society — who will be able to define their own sustainable human development objectives in the field of IPRs and effectively advance them at the national and international levels.

We hope you will find this study a useful contribution to the debate on intellectual property and sustainable development and particularly on the adequate conceptual framework for technology transfer and dissemination to countries in their various stages of development.

Ricardo Meléndez-Ortiz
Chief Executive, ICTSD

EXECUTIVE SUMMARY

This paper describes how technology is today transferred to developing countries and the barriers that affect that transfer. It then identifies policy approaches that might overcome those barriers. It covers (1) the flow of human resources, as through international education, (2) the flow of public-sector technology support, as through research and licensing by international organizations, and (3) the flow of private technology, as through the sale of consumer products (e.g. medicines) that may incorporate embodied technologies through licensing, and through foreign direct investment. After an introduction, the paper looks at these three areas in turn. It concentrates on policy approaches directly associated with technology transfer, thus avoiding issues of the overall investment, legal or political climate in specific developing nations.

During the 1970s, there was a major international debate about technology transfer. The paradigm used in that debate involved technology licensing from a multinational firm to a host-nation subsidiary or licensee manufacturing for the local market. The concerns were that the costs of the technology (many of which were hidden through transfer prices or management fees) were too high, that host nation use of the technology was often hindered by restrictive clauses, and that the licensees often failed to receive the best technology. The response was to form national technology transfer offices to review inbound technology transfers, to prohibit a number of clauses typically contained in these licenses, and to attempt to cap the price of the technology. This was done at the national level and proposed, albeit never successfully, at the global level.

Today, the world is quite different, because of two key changes. First, a number of developing nations have become much more technologically sophisticated. The comparison from 1976 say to 2006 is incredible in terms of the numbers of trained scientists and technologists, the level of science-based industry, and the magnitude of national scientific research and financing programs. This change is, of course, greater for the middle income and largest nations such as Brazil, China, and India and much weaker for the poorest nations, such as many of those of Africa. Nevertheless, there is an enormous change in the skills available to a large portion of the developing world.

Second, the world is now globalized in the sense that free trade has spread and that, in many industries, economies of scale now favor production facilities that serve more than one nation. The result has been increasing specialization and trade, both in components and in finished products that may have origins in a number of nations. Many feel that these changes are going to lead to an era of expanded growth for the more successful of these nations, as exemplified by the Goldman Sachs identification of the "BRICs" (Brazil, Russia, India, and China), which are likely to become a larger force in the global economy. Moreover, production chains are now often spread over a number of nations. Computer chips may be designed in one nation, manufactured in a second, diced and tested in a third, assembled into computers in a fourth, with software written in a fifth. Automobile component suppliers are becoming independent of automobile firms and doing a greater share of the overall R & D going into a car. A multinational, in general, now invests in a developing nation in order to obtain a basis for export to a global market or production process. China is in part an exception because its domestic market is so large — but much of the investment and production in that nation is for export as well.

These developments have changed the incentives and barriers for indigenous developing world firms, i.e. one those that are organized with primarily developing nation ownership and management (although they may enter into alliances and joint ventures with global firms). Such a firm must face global competition, not just local competition and it may have to find a place in an already elaborate international production structure. Moreover, not every nation can have firms leading in every area of technology — for many areas of technology, there can be only a few centers of excellence anywhere in the world.

The international regulatory structure is also different. Today, because of free trade rules, an indigenous firm in the developing world may be less able to begin through a protected market, as did the US industrial firms of the early 19th century. And because of intellectual property (IP) protections in WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), the firm may be less able to begin by imitating existing technologies, as did Japanese firms in the middle of the 20th century. Moreover, technological flow has become strongly political, not only because of the global move towards IP but also because of technological protectionism. As one author states:

> While policymakers regard S&T [science and technology] as a race between nations in a zero-sum game, businesses see themselves as part of a global information network … Government officials are more concerned about stemming the flow of technologies to competitors and possible rivals who might use it for military objectives … However, firms and businesses prefer a system that leads to the dissemination of knowledge, including to political rivals.[1]

The fact that free trade provides mutual benefit is widely recognized, even if politically difficult to implement. Less recognized, at least among politicians, is the parallel point that exchange of knowledge leads to an equally — if not more — beneficial cross-fertilization and acceleration of the benefits of free trade.

Whether from basic research to applied technology or from one firm to another, the transfer of technology is fundamentally a matter of the flow of human knowledge from one human being to another. This can be through education, the scientific literature, or direct human contact. At the legal level, one thinks about licenses dealing with legal rights to use the particular technologies in the particular context — but it is the human level that dominates the managerial and economic reality. And the classic view of a flow from basic to applied technology is a great oversimplification — sometimes, for example, problems or insights arising at the production level give rise to new ideas that contribute to fundamental basic advance. At least in some sectors, close links between the basic researchers and the manufacturing experts, and even marketing personnel contribute to competitiveness and advance.

HUMAN RESOURCES

Human resources are crucial both to the development and application of technology. Certainly, some inventions have been made by individuals with little education — but today the majority of inventions are made by those with substantial education in science or technology. The reduction of inventions to commercial application usually also requires skilled entrepreneurs and, depending on the particular field, skilled mechanics, lab technicians, or software writers. Many of the same skills are needed for the thoughtful adaption and application of a technology developed elsewhere. Hence, a broad range of scientific and technological skills is absolutely crucial for a nation to participate effectively in the international technological economy.

A summary of possible topics for international consideration on human resources issues includes:

- Improved support for developing-world technical education, whether through international lending and financing programs or through stronger linkages between developed and developing nation institutions.

- Possible international clinical programs to assist developing nation science and technology graduates to obtain experience in business. Both this and the previous point might be discussed at UNDP or at UNESCO.

- Arrangements to ease access to visas for students and scientists. This might appropriately be considered in follow-on discussions on the flow of professional services in the context of the WTO General Agreement on Trade in Services (GATS).

PUBLICLY-DEVELOPED TECHNOLOGY

There are two quite different sources of funding for new technologies: the public sector (including universities) and the private sector. Each funds research in its own sector as well as research in the other sector. The balance varies heavily from industry to industry, time to time, and nation to nation. In pharmaceuticals, for example, the balance is shaped by the budget of public sector establishments such as the U.S. National Institutes of Health (NIH) and by the magnitude of research and clinical testing by the pharmaceutical industry. The early development of computers was subsidized heavily by the government, while contemporary research and engineering of computers (other than for military applications) is supported primarily by the private sector.

In the United States, overall, the government, universities, and non-profit institutions fund roughly $95 billion of research and industry funds approximately $181 billion.[2] This is 34% public and 66% business. In many developing nations, the balance between public and private sector expenditures is more weighted in favor of the public sector.

The numbers almost certainly show that developing world public sector research far outweighs developing world private sector research. But it is probably also the case that the developing world public sector supplies far less technology to the developing world economy than does the international private sector. Thus, the role of public sector support is generally more one of building a capable infrastructure than of creating new developing world industries. There is an obvious exception in areas like agriculture, where much of the research is carried out in the global and national public sectors. And public sector support may *sometimes* be useful in "jump-starting" a new industry, as exemplified by nuclear power development in a number of nations.

There are many points here that might serve as the basis for negotiations. Among those particularly deserving attention are:

- Improving mechanisms for access to technology held by global agricultural biotechnology firms. This may involve opening markets to private sector products, licensing in technology, or possibly compulsory licensing. The international agricultural community is facing this issue for Africa; the issue is more complex in wealthier developing nations where the markets are of interest to the private sector.
- Increasing developed and developing nation government support for medical research of importance to developing nations and, particularly, for covering the costs of distributing the products of that research in the developing world. This is happening in the international medical community, but more is needed.
- Recognizing, in international technology support programs, such as those for energy and environmental technologies, the possible need for major public sector involvement in recipient nations and, where appropriate, organizing these programs so that developing nation firms are encouraged. This is particularly an issue for donor institutions like the World Bank.
- Organization, perhaps by the World Bank, of a global research inventory, by sector, to assist in defining areas, e.g. pharmaceuticals for the developing world or more efficient energy sources, in which increased public-sector research investment is needed.
- Clarification or modification of patent law to expand research exemptions and to minimize the negative impact of patents on research, an issue for the World Intellectual Property Organization (WIPO).
- New negotiated arrangements to minimize the impact of national security restrictions on the freedom of science and of international technological development, perhaps an issue for the World Trade Organization (WTO) services discussions.

- New mechanisms of funding research for global public goals.
- A treaty on access to knowledge and technology including reciprocal commitments in a number of the above areas. This is perhaps a WTO issue, but both it and the previous issue might best be dealt with at the political level, as at the G-8 discussions that considered the concept of advance purchase commitments for medicines.

PRIVATELY-DEVELOPED TECHNOLOGY

As noted above, outside a few specific sectors such as parts of agriculture, the primary means of technology transfer to developing nations is probably through commercial transfer from the developed world private sector through licensing or FDI. Participation in this private-sector network is the normal way for a developing nation firm to gain its first technology. Depending on the sector and the nation, the firm may go on to gain a substantial role in the international production chain, sometimes with its own technology, and may ultimately produce its own product for the domestic market for export.

The most important topics identified to be considered for further international negotiations include:

- International arrangements guaranteeing that trade secret law not infringe the rights of employees to change jobs (including changing jobs internationally) or the rights of firms to reverse-engineer products, provided that the rights of the former employer or of the original designer of the product are respected. There is an important strategy issue as to whether it is best to raise this group of issues diplomatically, or in developed-world judicial proceedings, or simply to proceed with local legislation that reflects the principles.
- Consideration of the purchasing policies of global health (and other) procurement entities to determine whether they are adequately open to developing nation supply tenders (and it is possible that these entities might provide additional assistance in helping firms meet necessary quality standards).
- Development of a mechanism to discourage bilateral agreements that modify the balance struck in TRIPS. This could be a requirement of some form of review or impact statement — the WTO Article XXIV or Trade Policy Review mechanisms might provide a starting point for designing a response.
- Negotiation of provisions like the WTO Agreement on Trade-Related Investment Measures (TRIMS) to ensure that developing-nation firms can buy developed-nation firms as well as the reverse.
- Evaluation and possible renegotiation of the technology-related provisions of the WTO antidumping codes, subsidy codes, and possibly of TRIMS and of Bilateral Investment Treaty provisions.
- Consideration of additional provisions or commitments in the services area to ensure the ability of developing nations to compete in the offshoring sector and in other forms of international delivery of services.
- Antitrust issues associated with the international flow of technology and with the international competitive structure of technology-based industries.

OVERALL IMPLICATIONS

A rational subsidy criterion must be the basis for all national technology policy. In the developed world, the economic analysis of a research subsidy is based on the fact that many of the benefits of new technology development are unlikely to be recouped by the investor in the new technology. Hence, subsidies should be given only to those industries in which the social benefits of the technology are significantly greater than the profits that will return to the entrepreneur. For the developing nation, an additional circumstance is appropriate. This is based on an analogue to the traditional economic criterion under which an infant-industry subsidy or tariff is appropriate — if there is a market imperfection making it hard for an industry to get started, and the industry can be expected to be efficient and to survive without protection after a start-up period, the subsidy or protection is justified. Economically, a developing nation can then reasonably take into account barriers that place its firms at a disadvantage compared with developed-world incumbents, and evaluate whether helping a particular industry has a reasonable probability of leading to a long-term industry that can participate profitably in the world economy. All the standard economic objections to government intervention apply to warn that such an approach is often unwise: governments are generally less good than the market at "choosing winners," political pressures often push in uneconomic directions, and it is politically hard to terminate the subsidy or protection. But the point remains: specific subsidies as well as general subsidies (i.e. education or broad tax incentives) are *sometimes* economically rational.

This standard favors strong support for scientific education and for basic research in areas that are important to the particular nation and neglected by world technological research. The criterion favors academic research in areas of local interest, and, where the nation has specific capability, of global interest. In all these areas, the focus must be managed carefully — decision-making for subsidy allocation must reflect both national needs and scientific expertise. The criterion also favors care in implementing Bayh-Dole type relationships between the public and the private sectors.

The criterion further favors policies that remove barriers to private sector investment in technology. These include the traditional need to build a climate favorable to investment. They also include the need for reasonable trade secret laws that ensure employee mobility and permit appropriate reverse engineering, the need to take research investment incentives into account in regulatory and privatization design, and the need to have a solid national antitrust/intellectual property capability.

Finally, the criterion favors focused subsidy in those cases in which a nation has a capability of producing a world-class industry and that industry is held back through global restrictions or inability to recoup the social benefits of the technology it creates. Such efforts have costs; care must be taken in deciding when to bear those costs. And there is risk for any governmental effort to "choose winners." But, there is both global and local value in increasing the intellectual and technological diversity of the leading entities in different research sectors.

(1) Issues requiring multilateral attention

Clearly, many areas require multilateral attention, and the summaries at the end of each of the preceding sections provide an agenda. The most important is to continue the move towards a seamless global scientific and technological community, such that each scientist or engineer, anywhere in the world, has an opportunity to make his or her optimal contribution to the science and technology needed by the planet. Also, of great importance is to increase support for the various initiatives underway, such as the medical Public-Private Partnerships (PPPs), to help achieve important world technological goals in the medical, agricultural, and environmental areas. And, it is important that the firms and research institutions in the developing nations have access to participate in the technological developments required to meet these goals.

The concepts contained in the proposed treaty on access to knowledge and technology are also desirable global goals. Among the most important are reciprocal access to science and technology subsidies, and narrowing, to the extent possible, barriers to the global flow of scientists and of scientific knowledge.

Finally, it is important to remove barriers to the free flow of technology as well as to the free flow of science. Among the barriers that need to be removed are source and most host nation restrictions on technology licenses and investment in technology-based firms, as well as the barriers implicit in the current WTO patterns of antisubsidy and antidumping principles. There are certainly appropriate exceptions to protect national security and probably some appropriate exceptions to make it easier for developing nations to build technology based industry, but these should be against a background of great freedom of flow. In the light of the current status of the Doha Round, it is not clear whether these goals are best sought in the context of a modified or expanded round or of detailed revisions and understandings within the existing WTO bodies. But it is important to seek them. Ultimately, the business perspective — of seeking global technological integration — is far better for the world than are political restrictions on the transfer of technologies.

(2) Issues deserving further study

Obviously, there are many unknowns in the analysis presented above. However several stand out:

One is the need for further study of specific industries, and of the relative success or failure of new entrants. The reasons why Mittal Steel is able to buy a European firm while developed world majors remain dominant in automobiles and pharmaceuticals deserve attention.

Better understanding of the links in developing nations between broad national research and educational support and actual industrial activity. What actually happens to the funds, students, and research findings developed under the broad programs? These issues are more often analyzed in developed than in developing nations — but the analysis should be extended. Might such information contribute to a better division of funding between broad programs and programs focused on specific industrial targets?

The generally correct criticisms of government efforts to support particular technology sectors have led to a current orthodoxy rejecting nearly all such efforts. Yet, government interventions have played important roles in the development of Japan and Korea (as well as of the United States and many European nations), and might play a similar role in other nations. What is the actual experience? When are such programs actually useful? Can the real political barriers to wise execution of such programs be overcome?

The impact of regulation on research incentives deserves much greater analysis. Why is energy apparently seeing less R & D recently, while pharmaceutical R & D is continuing? Many industries are properly regulated for many different reasons and in many different ways. The details affect R & D incentives.

Finally, it is important to analyze whether a number of areas of trade and WTO law are actually discriminatory or not. Among the areas that deserve analysis are intellectual-property based trade restrictions such as those of the U.S. § 337, and the WTO and trade law principles on the treatment of R & D subsidies. It would also be useful to examine the provisions of Bilateral Investment Treaties, which may go further than TRIMS, just as bilateral agreements often go further than TRIPS.

1. INTRODUCTION[3]

1.1. Goals of this paper

This paper describes how technology is today transferred to developing countries and the barriers that affect that transfer. It then identifies policy approaches that might overcome those barriers. It covers (1) the flow of human resources, as through international education, (2) the flow of public-sector technology support, as through research and licensing by international organizations, and (3) the flow of private technology, as through the sale of consumer products (e.g. medicines) that may incorporate embodied technologies through licensing, and through foreign direct investment. After an introduction, the paper will look at these three areas in turn. It concentrates on policy approaches directly associated with technology transfer, thus avoiding issues of the overall investment, legal, or political climate in specific developing nations.

1.2. How today's world differs from that considered in previous debates

During the 1970s, there was a major international debate about technology transfer.[4] The paradigm used in that debate involved technology licensing from a multinational firm to a host-nation subsidiary or licensee manufacturing for the local market. The concerns were that the costs of the technology (many of which were hidden through transfer prices or management fees) were too high, that host nation use of the technology was often hindered by restrictive clauses, and that the licensees often failed to receive the best technology. The response was to form national technology transfer offices to review inbound technology transfers, to prohibit a number of clauses typically contained in these licenses, and to attempt to cap the price of the technology. This was done at the national level and proposed, albeit never successfully, at the global level.

Today, the world is quite different because of two key changes. First, a number of developing nations have become much more technologically sophisticated. The comparison from 1976 say to 2006 is incredible in terms of the numbers of trained scientists and technologists, the level of science-based industry, and the magnitude of national scientific research and financing programs. This change is, of course, greater for the middle income and largest nations such as Brazil, China, and India and much weaker for the poorest nations, such as many of those of Africa. Nevertheless, there is an enormous change in the skills available to a large portion of the developing world.

Second, the world is now globalized in the sense that free trade has spread and that, in many industries, economies of scale now favor production facilities that serve more than one nation. The result has been increasing specialization and trade, both in components and in finished products that may have origins in a number of nations. Many feel that these changes are going to lead to an era of expanded growth for the more successful of these nations, as exemplified by the Goldman Sachs identification of the "BRICs" (Brazil, Russia, India, and China) as likely to become a larger force in the global economy.[5] Moreover, production chains are now often spread over a number of nations. Computer chips may be designed in one nation, manufactured in a second, diced and tested in a third, assembled into computers in a fourth, with software written in a fifth. Automobile component suppliers are becoming independent of automobile firms and doing a greater share of the overall R & D going into a car.[6] Hence, a multinational, in general, now invests in a developing nation in order to obtain a basis for export to a global market or production process. China is, in part, an exception because its domestic market is so large — but much of the investment and production in that nation is for export as well.

These developments have changed the incentives and barriers for indigenous developing world firms, i.e. those that are organized with primarily developing nation ownership and management (although they may enter into alliances and joint ventures with global firms). Such a firm must face global competition, not just local competition and it may have to find a place in an already elaborate international production structure. Moreover, not every nation can have firms leading in every area of technology — for many areas of technology, there can be only a few centers of excellence anywhere in the world.

The international regulatory structure is also different. Today, because of free trade rules, an indigenous firm in the developing world may be less able to begin through a protected market, as did the US industrial firms of the early 19th century. And because of intellectual property (IP) protections in TRIPS, the firm may be less able to begin by imitating existing technologies, as did Japanese firms in the middle of the 20th century. Moreover, technological flow has become strongly political, not only because of the global move towards IP but also because of technological protectionism. As one author states:

> While policymakers regard S&T [science and technology] as a race between nations in a zero-sum game, businesses see themselves as part of a global information network … Government officials are more concerned about stemming the flow of technologies to competitors and possible rivals who might use it for military objectives … However, firms and businesses prefer a system that leads to the dissemination of knowledge, including to political rivals.[7]

The fact that free trade provides mutual benefit is widely recognized, even if politically difficult to implement. Less recognized, at least among politicians, is the parallel point that exchange of knowledge leads to an equally — if not more — beneficial cross-fertilization and acceleration of the benefits of free trade.

1.3. How research is supported

Scientific and technological knowledge benefits all, by enabling the production of new products or the production of old products more cheaply. Yet, no firm can afford to pay the costs of performing research if the benefits of the research accrue as much to its competitors as to itself and if it does not achieve an economic return for its products that covers research costs as well as production costs. In economic terms, this requires a return beyond marginal cost. Firms in a highly competitive industry, in which there is easy entry, may thus be unable to fund significant research and product improvement. In contrast, firms that have a proprietary position that enables them to recover larger than "normal" competitive profits are able to fund research.

Because of this phenomenon, much research is supported publicly, i.e. in government or university institutions, or though subsidies to private sector institutions. (For the purposes of this paper, I treat private non-profit institutions such as universities and the Gates or Rockefeller Foundation together with public-sector institutions, because their economic motivations are similar to those of the government.)

Further, governments have defined various kinds of legal exclusivity, such as patents, through which private-sector institutions can gain an increased return from their research investments. In some industries, e.g. pharmaceutical, this IP-based incentive is crucial; in others, e.g. central processing units for computers, other kinds of market forces provide the special financial returns and incentives needed to make private research feasible. These include, for example, economic barriers to entry that permit oligopolistic profits, and customer interest in obtaining increasingly sophisticated products.

IP has two important economic aspects. On the one hand, it is designed to permit a firm to define a form of market exclusivity and thus

to gain a higher price for a product based upon the firm's research. Thus, the static effect is to maintain prices at a non-competitive level, exactly the opposite of the standard goal of antitrust policy, which is to push prices to a competitive level at which price equals marginal cost. But, on the other hand, if the IP system is well designed, this static effect will be balanced by second implication: a dynamic effect under which new research is encouraged. The consumer will lose in the short term from the higher prices and gain in the long term from the more-sophisticated and higher quality product. There is a special point for developing nations: especially for the poorer nations, the balance between immediate cost and long-term product quality may look different than for the more wealthy.

1.4. The technology transfer process

Whether from basic research to applied technology or from one firm to another, the transfer of technology is fundamentally a matter of the flow of human knowledge from one human being to another. This can be through education, the scientific literature, or direct human contact.[8] At the legal level, one thinks about licenses dealing with legal rights to use the particular technologies in the particular context — but it is the human level that dominates the managerial and economic reality. And the classic view of a flow from basic to applied technology is a great oversimplification – sometimes, for example, problems or insights arising at the production level give rise to new ideas that contribute to fundamental basic advance. At least in some sectors, close links between the basic researchers and the manufacturing experts, and even marketing personnel contribute to competitiveness and advancement.

1.5. Comparison with previous work

This paper differs in three major ways from preceding work. First, it emphasizes the dynamic aspects of technology development and transfer, rather than the static costs of products. In the UK Commission[9] study and in much of the debate about TRIPS, the emphasis was placed on issues such as pharmaceutical costs, precisely because this was the key issue for the poorest. This paper, in contrast, emphasizes the dynamic aspects of technology-based industries, and therefore is more relevant to the more scientifically sophisticated developing countries. Second, much prior work has concentrated on intellectual property, including the work on foreign direct investment (FDI).[10] Here, however, there will be an attempt to recognize other barriers such as, for example, those associated with restrictions on industrial subsidies. And third, much previous work has emphasized the areas of medicine and agriculture, areas of special concern to developing nations.[11] In contrast, this paper will attempt to cover a number of other technologies in order to help broaden the debate and raise the possibility of new kinds of international responses. It thus builds on previous efforts to develop policy options, including those conducted at the World Bank,[12] those proposed as part of the WIPO Development Agenda,[13] those being discussed at UNCTAD,[14] and those being considered as part of the WTO Working Group on Trade and Transfer of Technology.

2. HUMAN RESOURCES

2.1. Importance of human resources to technology development and application

Human resources are crucial both to the development and to the application of technology. Certainly, some inventions have been made by individuals with little education — but today the majority of inventions are made by those with substantial education in science or technology. The reduction of inventions to commercial application usually also requires skilled entrepreneurs and, depending on the particular field, skilled mechanics, lab technicians, or software writers. Many of the same skills are needed for the thoughtful adaption and application of a technology developed elsewhere. Hence, a broad range of scientific and technological skills is absolutely crucial for a nation to participate effectively in the international technological economy.

2.2. Important trends

Significant growth in scientific and technological education and in numbers of engineers and scientists

From this perspective, the world has radically changed over the last generation. The portion of the adult population with a college degree in Latin America has risen from 1.3% in 1960 to 7.7% in 2000; the corresponding numbers in East Asia are 1.1% and 8.1%.[15] The number of international students in the United States has essentially doubled since the late 1970s — and the United States currently hosts only about 40% of international students.[16] The number in the science and engineering areas is continuing to increase, despite the difficulties associated with access to visas after the attacks of September 11, 2001; thus, there were 179,000 students in these areas in the United States in 1999/2000 and 201,000 in 2004/2005.[17] Clearly, there are many more scientists and engineers with ties to the developing world, and many more are being educated, both domestically and internationally.

A highly globalized system

This scientific educational and research system is highly globalized. Most of all, this is a result of the fact that many students, particularly from Asia, have come to developed world institutions to study under a variety of programs sponsored by both developed and developing nations. Advanced educational institutions themselves are becoming more multinational than they once were. This is through deliberate choices to accept foreign students, through exchange programs for visiting faculty (going both from North to South and vice-versa), and through collaborative arrangements, ranging from sister campuses to joint research projects. Many faculty hold appointments at institutions in several nations at one time. Scientific and technological conferences are generally international, and the leading scientific and engineering journals circulate internationally.

2.3. Barriers, normative issues, and proposals

In spite of these encouraging developments, there remain a number of serious issues, some of which may give rise to reasonable proposals for domestic or international consideration.

Funding levels for advanced education

First, the funding available for advanced education, and particularly for advanced international education, remains far too small and under threat. In 1980, the UK completed a process of eliminating subsidies

for Commonwealth students to study relatively inexpensively at universities such as Oxford and Cambridge.[18] The UK is now aggressively recruiting international students, but appears to be expecting at least most of them to pay substantial fees.[19] And, the levels and quality of scientific publication in even the most scientifically interested developing nations are still low: Chinese scientific publications receive 1.56% of the world's scientific citations; India and Brazil are below 1%.[20] Many of these nations face a difficult trade-off between improving elementary and secondary education, crucial for economic development, and alternatively improving advanced education, which is crucial for technology, but also generally favors the wealthier members of the society. Programs to improve developing-nation education are likely to be extremely valuable. In some cases, the primary and secondary levels may be most important; in others, the university level may be more important. Some of these improvements are certainly a task for national governments; others deserve international donor support.

Linkages between universities, public research centers, and industry

In some nations, there has been historical antagonism between industry and academia, with academia traditionally on the left and industry on the right. Moreover, developing nation governments, in general, find it easier to fund and to conduct the improvement of their public sector scientific capability than to similarly improve their private sector technological capability. One can look at the various steps taken to increase the number of science and technology graduates, for example, and be relatively encouraged in many nations. This increase is essential to the attraction and creation of technology-based industry. But there is also the possibility that it will contribute more to academia than to industry. This is partly a cultural issue — university faculty are likely, implicitly or explicitly, to encourage their best graduates to remain in academia, and particularly in the global scientific community. Clearly, this is right for some graduates. But others need to start companies or contribute to existing firms.

It is, of course, important — and a central role of academic freedom — for faculty at a university to be independent and able to criticize what is happening in the broader society. But it is also important that university technology be beneficial to the society. This means that there must be enough communication between the sectors that university scientists can understand local industry's need and that industry can know what technologies are being developed that might be useful. Such communications can be fostered by, for example, programs of regular scientific and technological societies and meetings that include both industry and academic representatives. They can also be supported by regular interflow of personnel between the two communities. This is also one of the areas in which society benefits from the availability of scientists and engineers that have entrepreneurial or business background along with their technical background. It would be wise to examine the actual use of a variety of science-oriented programs to evaluate their relation to industry. Further, it is important to have strong linkages between academia and the real world, as through programs by which those in practice in industry can study in the university, students can work as externs in industry, faculty can consult, and industry can sponsor research projects. These are all important parts of scientific and engineering education — for it is sometimes the case that industry is technologically ahead of academia, and it is always the case that the two can benefit from one another.

There might be useful new international proposals for linking industry (particularly in the developed world) with academia (particularly in the developing world). Consider the benefits, for example, of programs to enable developing world students to be interns in start-ups in the developed world.[21] This has already happened informally as Indian and Taiwanese graduates have participated in Silicon Valley firms, and have then gone home to start their own firms.

A broader program to facilitate such experience would help integrate graduates not just into the academic scientific world, but also into the industrial world that commercializes the technology developed in academia. In the United States, there is a serious difficulty arising from the "deemed export" issue, a regulatory requirement that governmental approval must be obtained for certain technologies to be divulged to certain foreign employees. This regulation derives ultimately from national security concerns. Governmental exemptions or case-by-case reviews would be necessary to facilitate an international intern program.

Visa restrictions

Concerns over terrorism have made it very difficult for students from many nations to study within the United States. The restrictions include denial of visas, elaborate procedures for obtaining visas, and requirements on universities to track the academic activity of students. In some cases, participants in academic conferences have been denied visas. There have also been government proposals — since dropped — for restricting foreign student access to certain kinds of research areas and information. The result has been a short-term drop in the number of students seeking to study in the nation; fortunately, this drop is in the process of turning around.[22]

Although this concern about terrorism is quite understandable, there are serious questions about the legitimacy and wisdom of some of these travel restrictions. Officers of the International Council for Science (ICSU) have stated that certain of the activities violate scientific freedom.[23] And university officials have emphasized that the restrictions may harm U.S. competitiveness. Nations are certainly extremely hesitant to accept restrictions on their visa policies, but it might be possible to define some set of reasonable protections for students and scientists, perhaps, for example, a requirement that decisions be made within a particular time, ensuring the availability of an appeal process, and helping resolve the practical problems that arise when university procedures and visa procedures collide. The details can only be defined after careful analysis of the actual process in a number of nations, but the need to simplify travel and scientific exchange is crucial.[24]

Brain drain and remittances

One of the most intractable problems in the area is that of the "brain drain," i.e. the flow of skilled human resources from poor nations to rich nations. Such travel is very understandable for the humans involved, for they can often provide much better for their families with the opportunities they can find in the wealthy nations. The travel, however, arguably wastes educational expenditures in the developing world source nation; for that nation is likely to have invested public funds in educating the person who now brings his or her skill to the developed world. And, in at least some sectors, this possibility of going abroad can enable the relevant scientific or professional community to demand higher local salaries in the source nation economy.

At the same time, it must be remembered that the person who goes abroad often sends back substantial economic remittances to his or her home nation. Obviously, the remittances from scientists and engineers are only a part of all remittances, but they are still a significant counterbalance. More important, there may be a return flow of scientists and of entrepreneurial opportunities as the source nation's technological status takes off and opportunities increase, something that was absolutely crucial for Taiwan, and is almost certainly significant for India and China as well.[25] This phenomenon will increase with the growing tendency of multinationals to place research laboratories in the developing world. The return flow might also be facilitated through visa arrangements that make it more feasible to go back and forth.[26] And there are many other proposals for dual citizenship and for source country inventories of the skills of the overseas scientists and engineers.[27]

Few would want to deny the freedom of the skilled person to take advantage of the global skills market. After all, there is an economic

argument that, at least in principle, the skilled person contributes more to the global economy and society when he or she can work with the best facilities and complementary resources — which is often most likely to be in the developed world. The graduate who works for a local multinational research laboratory is also exporting his or her skills, and the graduate who goes abroad may still engage in research that ultimately benefits his or her home nation. As the scientific and educational processes continue to globalize, it will become harder and harder to distinguish activity that benefits one nation from activity that benefits another.

For the poorer nations, however, the brain drain remains. If any response is appropriate, it is to require the person who goes abroad to make some form of payback of educational costs. Whether this is feasible or wise or not is not clear. It could be facilitated by formal international agreements requiring and simplifying the transfer; it might already be effectively happening as a result of the transfer of remittances; it might be an unwise barrier to the freedom of movement.

Summary of possible human resources areas for international discussion

A summary of possible topics for international consideration on human resources issues includes:

- Improved support for developing-world technical education, whether through international lending and financing programs or through stronger linkages between developed and developing nation institutions.
- Possible international clinical programs to assist developing nation science and technology graduates to obtain experience in business. Both this and the previous point might be discussed at UNDP or at UNESCO.
- Arrangements to ease access to visas for students and scientists. This might appropriately be considered in follow-on discussions on the flow of professional services in the context of the General Agreement on Trade in Services.

3. PUBLICLY-DEVELOPED TECHNOLOGY

There are two quite different sources of funding for new technologies: the public sector (including universities) and the private sector. Each funds research in its own sector as well as research in the other sector. The balance varies heavily from industry to industry, time to time, and nation to nation. In pharmaceuticals, for example, the balance is shaped by the budget of public sector establishments such as the U.S. National Institutes of Health and by the magnitude of research and clinical testing by the pharmaceutical industry. The early development of computers was subsidized heavily by the government, while contemporary research and engineering of computers (other than for military applications) is supported primarily by the private sector.

In the United States, overall, the government, universities, and non-profit institutions fund roughly $95 billion of research and industry funds approximately $181 billion.[28] This is 34% public and 66% business. In many developing nations, the balance between public and private sector expenditures in more weighted in favor of the public sector. The balance in Sao Paulo, for example, is 46% public and 53% business.[29] For Brazil as a whole and for India as a whole, the public sector proportions are much higher, approximately 59% in the first case and 77% in the second.[30]

The numbers almost certainly show that developing world public sector research far outweighs developing world private sector research. But it is probably also the case that the developing world public sector supplies far less technology to the developing world economy than does the international private sector. Thus, the role of public sector support is generally more one of building a capable infrastructure than of creating new developing world industries. There is an obvious exception in areas like agriculture, where much of the research is carried out in the global and national public sectors. And public sector support may sometimes be useful in "jump-starting" a new industry, as exemplified by nuclear power development in a number of nations.

3.1. Current mechanisms of supporting research and trends

Government support

Developed world

In the developed world, the public sector supports research in a variety of ways. The most obvious is the direct funding of research at universities and national laboratories. Much of this funding is typically concentrated on basic research, in which industry would be unwilling to invest because the time to commercialization is so long. There is usually strong scientific and sometimes political support for the subsidy — and the subsidy is economically justified where the social returns of the research are greater than those that would be available to a private firm.

There are also many programs to support specific industries. Sometimes, as in agricultural and medical research, government support is based on achieving particular social goals. Where the government is the leading purchaser of the products of the technology, the government will have to pay the costs of research and engineering in any event; the key issues in designing these subsidies involve the contractual structure of reimbursement for these costs and the incentives created by that structure. For example, military and space technology is often directly supported with grants to industry or through purchase contracts that enable industry to recoup its R & D expenses. In the cases of semiconductors and large transport aircraft, it is at least alleged that such military purchases provided the basis for firms to gain a substantial technological base that was later used as a way to gain competitive advantage. (U.S. government purchases still make up 40 to 60% of U.S. aerospace sales.[31]) Similar arrangements have been used to help develop nuclear power technology, as in the United States and France.

There are also subsidies seeking such goals as more environmentally-acceptable automobiles. Moreover, industry is sometimes granted tax advantages for research. All these subsidies have international competitive implications.

In many respects, the formal structure of these subsidy programs is far less significant than the total amount allocated and the mechanism of allocation. They are typically structured to maintain political support in the face of other social demands. And because expertise brings insight into the needs, it is important to include the scientific and technological community in the decision-making, as in the peer review programs used in making some grants. Yet, there is an obvious risk that these communities, including contractors in industries such as defense and space technology, will capture the decision-making. This may especially be a risk with a highly independent and powerful scientific academy system — if there is such a system, there needs to be a way to ensure that it responds to real world needs. Moreover, some irrationality and redundancy in support structure may be wise as a way to let alternative perspectives enter the decision-making structure.

Developing world

The developing world is copying many of these subsidization approaches. There are, of course, many efforts to imitate U.S. or European subsidy programs to universities or to particular national research institutes. China has a major system of scientific academies, and is expanding and improving its support for science and technology under its "863" program and under its new 15 year "Medium to Long-Term Science and Technology Development Plan."[32] Korea has created national research institutions. Several nations have set up programs for supporting academic and industrial research, typically subject to peer review, but not necessarily focused on a particular scientific or industrial sector. Some of these programs have been supported by World Bank funding. According to a 2004 study, the World Bank has lent $8.6 billion between 1980 and 2004 for such scientific and technological programs, of which 40% of the loans went to East Asia and 20% to Latin America. The agricultural sector accounted for 42% of the projects; most of the others were for general scientific and technological support, as for education.[33] This focus on agriculture presumably reflects the facts that crops have to be adapted to specific ecosystems and that agriculture has long received public support.

There have also been efforts, typically through national research establishments, to support particular technologies, and then to apply the technology, often within the government sector. This is the way that many nations developed vaccine production facilities within their public health establishments. It is the way that India developed its nuclear power program, under Homi Bhaba in the 1950s and 60s. It is also part of the way that Brazil attempted to encourage home-developed computers in the 1980s. And, China is clearly using this strategy extensively (although, as will be seen below, China is also making a serious effort to increase the role of private-sector funding in research).[34]

Foundation support

Foundation support has been especially significant in agriculture and medicine. The Green Revolution was fundamentally a foundation-sponsored development, as were many medical developments before World War II. Since the war, government funding of technology has grown much more rapidly, and has greatly outstripped foundation funding (even though groups like the Howard Hughes Foundation have played a major role in health research). Although this remains generally true, it has changed for international health with the advent of the Gates Foundation. The foundation is now able to undertake its own sophisticated research projects, without having to worry about maintaining political acceptability with a supporting legislature. And, it has radically changed the structure of international medical research, providing new opportunities that will be discussed below.

Examples of special purpose technology development

To provide additional content to the relatively abstract picture just presented, it is useful to consider three specific examples in which publicly-funded research is especially important (albeit always working with the private sector). These are agriculture, medicine, and energy.

The CGIAR system in agriculture

At one time, agricultural research was almost entirely funded by the public sector. Thus, one of the missions of the U.S. land grant colleges, created by 1862 legislation, was to conduct research for the benefit of the society, a society that was largely agricultural at the time. This was followed by the creation of substantial public sector research elsewhere, and particularly by European colonial authorities in the various nations they controlled. There was significant technology transfer as a result of these institutions, in both French and UK colonies.

During the 1940s, these activities were supplemented by foundation sponsored work at the predecessor of the International Maize and Wheat Improvement Center (CIMMYT) in Mexico and then in 1960 by the creation of the International Rice Research Institute (IRRI) in the Philippines. It was research in these institutions that led to the new "Greeen Revolution" varieties, which were then diffused through much of the developing world. Soon additional research institutions were added, and the funding expanded to include governmental and World Bank support as well as foundation support. Donors were encouraged to coordinate and focus their support through the CGIAR, the Consultative Group on International Agricultural Research, an informal group, created in 1971. It was supported by a Technical Advisory Committee, now called a Science Council. In most cases, the research institutions are located in the developing world, essential in order to test local crops under local climates and growing conditions. These institutions are funded well enough to attract global-quality scientists.

Over the years, the activities of national agricultural research programs have expanded in comparison with those of the CGIAR centers. Thus, today, the world's largest public sector agricultural research program is that of Empresa Brasiliera de Pesquisa Agropecuária (EMBRAPA), Brazil's program, and the national programs in China and India, as well as in Thailand and other smaller nations are all quite significant. This evolution may allow the CGIAR institutions to concentrate on the earlier phases of crop development, and then to turn varieties over to national programs for final breeding and improvement for the particular nation's agronomic conditions.

The CGIAR system has been under two pressures over this same period. First, it has had to accept a shrinking budget, presumably a result of donor fatigue and of the emergence of competing priorities, particularly with respect to the environment and to medicine. Thus, its budget levels have been declining in real terms and it now represents only about 5% of the public sector research done for developing nations.[35]

The other pressure is the rise of biotechnology-based commercial agricultural research. There has long been significant private sector research, especially since the development of hybrid maize in the 1930s. But this has substantially expanded since the development of biotechnology, a development that took place in the public sector, and the commercialization of that technology in the private sector. The private commercialization was in significant part the result of a series of expansions of patentability that began with Diamond v. Chakrabarty, 447 U.S. 303 (1980). Since then, the agricultural biotech industry has globalized and consolidated to become one that includes only a very small number of oligopolistic players. In many markets (more so, of course, in the developed world) these firms have such strong patent positions that it has become difficult for anyone, even venture-capital funded start-ups to enter. And because of these patents, university scientists are hesitant to move into some areas of crop development.

Thus, the key issues are now two-fold. One is funding for public sector research for the developing world. It is certainly possible that many of the important new varieties of the future will be developed within the private sector or within nations that are able to work around IP rights. Nevertheless, there is need for public sector research in areas of little commercial interest. Some of this may be in the CGIAR and some in national programs. And of recent importance was the Rockefeller Rice Biotechnology Program, which was terminated in 1999 after contributing greatly to the supply of scientists and of fundamental knowledge, such as the rice genome. It may have been the most significant source of technology buildup for the national agricultural research program of Asia. With all these programs combined, the public sector investment in developing world agriculture has become greater than that in developed world agriculture.[36] But, almost certainly, more is needed.

The other problem is to obtain the benefits of the global private sector and to find a way around the limitations imposed by that sector's concentration and intellectual property. In many cases, particularly for the market sectors of middle income countries, the private sector will provide new varieties; in the case of Sub-Sahara Africa, the private sector is probably willing to cooperate with the public sector, because the commercial market is so distant. But cooperation with the private sector has not always been easy; for example, it is reported that patent disputes with a multinational prevented the release of a transgenic rice variety developed by an Indian university.[37] As will be seen below, there are efforts at developing open source systems, as an alternative to the patented technologies. Another possible approach to ensure the availability of some forms of new varieties might be a compulsory license. The developing nations must define their own research programs (and may need support for them) and must also define their own approach to dealing with the multinationals.[38]

Public-private partnerships in medicine

The pattern in medicine has been quite different. There is a long tradition of medical research within the developing world, as exemplified by the work done on plague by Haffkine in Bombay, on yellow fever by Finlay in Havana, and by the variety of Institut Pasteur and Rockefeller Foundation activities throughout the developing world during the first half of the 20th century. But, during much of the later part of that century, the research tended more and more to centralize within the developed world. This is partly a result of relatively declining support for public health in many nations, as contrasted with the growth of enormous public sector research institutions such as the National Institutes of Health (NIH) in the United States and the Medical Research Council (MRC) in the UK. It is probably also a result of strengthened regulatory standards for pharmaceuticals, standards which gave rise to today's pattern of large-scale and expensive clinical trials, which led development to be centered around large scale institutions such as the major pharmaceutical firms.

Although there were some long-standing programs involving developing-world researchers, such as the International Centre for Diarrhoeal Disease Research in Bangladesh, and the World Health Organization's Tropical Disease Research Program, the key changes in research have been in the last 10 years, with the development of "public private partnerships" (PPPs) for obtaining new medical products of value to the developing world. These PPPs, sponsored at first by the Rockefeller Foundation and then by the Gates Foundation, amount to virtual drug or vaccine development entities. Examples of these PPPs are the International Aids Vaccine Initiative (IAVI), the Medicines for Malaria Venture, and the Institute for One World Health. The PPPs contract out the research, the product testing, the conduct of clinical trials, and production, sometimes to universities or public sector entities and sometimes to pharmaceutical or biotechnology firms. They, of course, protect the intellectual property rights that are needed for product development and application in the developing world. They are significantly integrated with the world's pharmaceutical industry, often, for example, funding clinical trials for developing world applications for products that the

pharmaceutical industry has identified but is not pursuing developing world applications.[39] The foundation world provides a very large share of the funding of these entities; very little comes from governments.[40]

It is, at this point, unclear how successful these programs will be. They face essentially the same scientific uncertainties as do pharmaceutical firms, and have to make careful judgments about how many early-phase products to explore in order to have a good chance that at least one product will survive all the stages of testing from early to late. Moreover, it is not clear how they will market the successful products. At this time, the global public medical sector, exemplified by the Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM) and the President's Emergency Plan for AIDS Relief (PEPFAR), has not yet been able to afford to support distribution of all the products that are already available and needed for the control of serious disease in the developing world. It is certainly possible that this funding will be expanded as a result of Gates Foundation initiatives.

It is important to consider how these institutions will interact with the scientific sector of those nations. Presumably, the PPPs will normally look to the most capable groups in the world for the different scientific inputs that they need. They will certainly be inclined to purchase clinical trial services and product manufacturing services within the developing world. At this point, about a quarter of the PPP projects in the drug sector involve developing nation firms as a partner.[41] One of the early successes involves an off-patent drug for visceral leishmaniasis produced in India and tested for the Indian market.[42] More broadly, a number of developing nations, including India and Thailand, are seeking to become major exporters of clinical trial services. The NIH has licensed a variety of technologies to a variety of developing nations, presumably for further trials and development.[43] And there is certainly a research-based industry emerging in India, as some of that nation's generic firms become research-based in response to the application of pharmaceutical patents in 2005.

From a broader perspective, it is clear that there is a current commitment to developing important new drugs and vaccines, and that the non-profit medical research sector has found ways to proceed. What is not so clear is how the new products will be paid for, when available. The world has found ways to do so for vaccines, where UNICEF has used its purchasing power to encourage safe and efficient developing-world manufacturing, and to obtain childhood vaccines at reasonable prices. The new arrangements for therapeutics, such as the GFATM and PEPFAR, are not succeeding in meeting the demand. Moreover, analogous support arrangements will be essential should new products be invented for developing-world application in the environmental sector.

Energy, including nuclear energy

The energy industry demonstrates another completely different relationship between the public and the private sectors. Many parts of the energy system, including the production of petroleum and, in many nations, the production of electricity, have long been in large part in the public sector, operated by governments or by government controlled entities. Even where parts of the research are carried out in industry, this is often in cooperation with the government, as exemplified by nuclear energy. Consider, for example, the long involvement of the government in the development of atomic energy, in France, the U.K. and the U.S.

For some developing nations, acquisition of electrical technology has been simply a matter of purchasing an electrical generation plant, whether thermal or nuclear, from a major supplier. There are a variety of funding and operational mechanisms to make this possible, as exemplified by the "turnkey" approach in which the facility is manufactured and sold ready to be turned on and operated, or the "Build Operate Transfer" (BOT) approach in which an international firm builds the plant, operates it for a period in order to gain the income to pay for the plant's construction, and then transfers it to the developing nation.

Although the turnkey and BOT techniques provide the purchasing nation with a power

plant, it does not provide the nation with a technological capability. Moreover, these purchases are designed to serve the local market — since that market is not globalized, the seller does not have powerful incentives to provide the best technology possible. In a sense, the incentive structure is like that of the import substitution process of the 1970s. To obtain the technology, the nation must get involved in the design and construction process, and build its own capabilities. This has already happened for the more advanced developing nations. Arranging such participation may require review of the contracts involved, and choice among bidders on terms that include technology access as well as price.

In a number of cases, a developing nation has gone further to organize a major national effort to develop a particular energy capability. For example, Brazil pioneered the use of biomass as an automobile energy source. Here, it intervened heavily in the economy, through a combination of subsidies, agreements with foreign automobile manufacturers, and structuring of the sugar cane production system.[44] It seems very likely that there will need to be similar efforts to develop environmental technologies for national power systems.

Another example is nuclear power. India has organized a long term extensive public program, originated by Homi Bhabha in the 1960s. This began with the operation of small nuclear research reactors built in the mid-1950s with foreign assistance. It then imported two U.S. commercial reactors in the 1960s (Tarapur), and two Canadian power reactors at about the same time (Rajasthan). Building on this experience, it produced a number of its own reactors in the 1980s and 1990s.[45] Clearly, activity in the nuclear industry reflects national security concerns as well as economic concerns, and some nations have undoubtedly built energy related nuclear fuel cycles as a way to maintain a nuclear weapon option. This has led to significant international political concern within the context of the International Atomic Energy Agency (IAEA). But the mix of objectives has necessarily led to a structure in which the public sector is deeply involved in engineering research, a structure found in the developed nations as well as the developing ones.

Although globalization has been the dominant source of change in many areas of technology, for energy, it is privatization that has been the crucial source of change, particularly during the 1990s.[46] Privatization responds to fiscal demands and donor pressures, and also to a variety of problems in the publicly-controlled operations, including corruption and failure to provide adequate levels of service. As a result of the privatization, many national electricity production operations are now foreign-owned. The international operator may have good access to technology, but may not have great incentive to make that technology available. Hence, there is a need to structure the privatized industry to encourage technology transfer, and continued modernization to achieve efficiency and improved environmental performance. One effort in Brazil, for example, involves a requirement that the private firms invest certain amounts in R & D; the program appears to have had mixed success.[47] Thus, ways to improve performance under privatization deserve attention. (In the parallel telecommunications sector, the initial technology boost from privatization and foreign operation is likely to be very substantial, considering the poor state of many traditional national telecommunications firms. Moreover, in this sector, competition can be maintained after privatization, although it rarely has been. In electricity, such competition may be harder to maintain.)

Because many of the most important energy technologies have been developed with substantial public sector support, research levels reflect political pressures. And, where the industry is regulated, private sector research incentives are significantly influenced by the structure of the regulation. There is evidence, for example, that in the United States energy research declined by more than 50% between 1980 and the mid-1990s.[48] This may reflect research opportunities; it seems more likely that it reflects the restructuring of the energy markets that occurred during this period, possible responses to changes in energy prices, and changes in government support. Considering

the needs to respond to environmental concerns and to limitations on access to petroleum, it seems like a strange time for that research to decline.

Two points emerge from this example. First, in some sectors, targeted public sector research and development programs may play an important role in advancing technology, providing services, and sometimes in building a private industry. Transportation, communications, and the environment may all benefit from similar interventions. In all these sectors, there is a world market for components; in many, some parts of the systems will necessarily be operated or regulated by the government. The targeted government action can sometimes create the necessary technology in a way that is reasonably efficient economically. There is a legitimate counter-concern that the government will often choose programs unwisely and may be pushed by political concerns into actions that are economically unsound. But public sector programs have been a part of developed-world economic development, and, in some cases, will be appropriate in scientifically sophisticated developing nations as well. Not all focused research should be privatized. In any situation in which an industry is being built in the public sector or with mixed roles for the public and the private sectors, it is crucial that the technological incentives be carefully analyzed. Thus, if the government is helping establish a power industry, what are the arrangements for technology flow between the public and private sectors of the energy industries? Are the incentives well-thought-out? Are the local technologies likely to be better or worse than the global state of the art; if the latter, is the deficiency acceptable in light of broader social goals?

Second, regulation of many industries is essential, as exemplified by the same group of industries. In subtle ways, regulatory structures affect the incentives for the private sector to carry out research, and it appears possible that privatization of energy systems has reduced research incentives in this sector. Similarly, whatever health care reforms are undertaken will affect research incentives. It is important, therefore, to design the regulation in ways that maintain such incentives (or to replace the private sector research with public sector research).[49] The world needs analysis of these regulatory effects on incentives; it also needs inventories of levels of research being done in different sectors with a view toward focusing global public sector research where most needed.

3.2. Barriers, normative issues, and proposals

Public-private relations

Commercializing publicly-funded technologies: Bayh-Dole

One of the most important issues in the development of publicly funded technology is to ensure that it actually reaches the working economy. After all, it is generally true that the private sector will, in the long run, be more efficient in actually utilizing new technological developments; but, it is also clear that the public sector is sometimes most able to support the development of new technologies and is usually the sector more able to support basic research. In the United States, improvement of technology transfer from the public to the private sector was envisioned as the main reason for the 1980 Bayh-Dole Act for technology developed in universities under public funding and the Stevenson-Wydler Act for technology developed in government laboratories.

The basic pattern envisioned in these laws was to give institutions receiving public research funds the right to obtain and exploit patents on inventions developed in the course of the research. University employees, for example, are required to sign an agreement under which they assign to the university all rights under the patents. Universities having a substantial research program then set up an office to license out the technologies to industry. This is intended to give the national economy, and potentially the world, the benefit of commercializing the technologies and to give the university the benefit of the financial return

on the technology. Typically, financial returns are used first to cover the cost of the technology licensing office, and then divided between the human inventor, the inventor's department, and the university. In practice, the overall returns are extremely skewed — a few "blockbuster" patents provide a very substantial share of the return, and many universities do not cover the costs of their technology licensing offices. Even for the most successful universities, the returns are typically on the order of a few percent of the underlying research budget, i.e., a university receiving 100 million dollars per year of government grants obtains on the average about 3 to 5 million dollars per year in licensing revenue.[50]

Many developing nations are seeking to copy this concept, sometimes as a way to help support government research in times of budgetary stringency. Nevertheless, there are important questions about the applicability of the concept to developing-world research. First, the process works only if there is a private sector interested in obtaining the technology. The U.S. process depends in significant part on the presence of venture capital communities, such as that of Silicon Valley. Moreover, there must be an ultimate market — one of the reasons that U.S. universities have done so well in licensing inventions in the biotechnology area is the fact that health-care providers are willing to pay for new technologies and products. If a local community is absent, the developing nations may have to consider licensing their inventions to a multinational — sometimes this may be the best way to benefit the local and global society with a new technology, but sometimes it will appear to be a misuse of a subsidy program intended to help stimulate local industry. Second, there are questions whether the desire to obtain profits will redirect research in socially less productive ways. This is a charge often raised in the U.S. context, although there has been little evidence of actual diversion of research. But the issue may be more important in the developing world, where both the social needs and the budgetary pressures are greater. Third, as noted above, the financial returns are likely to be small.[51]

Public-private issues beyond Bayh-Dole

The Bayh-Dole licensing pattern is only one of the ways in which the public and private sectors interact. Often, for example, industry may support research at universities or in the public sector, whether designed to meet immediate needs or designed to help build the basis for new technologies. Yet there are tensions inherent in such programs, as exemplified by the "cooperative research and development agreements" (CRADAS), created under the U.S. 1986 Federal Technology Transfer Act. In such arrangements, it is difficult, for example, to balance principles of open science and open access to the activities of government research against principles of respect for industrial confidentiality. Hence, it is essential to have solid principles for dealing with the potential conflicts of interest.

Research tool patents and freedom to operate for the public sector

Patents sometimes make it difficult for public researchers to carry out their research or to make the products of that research available. Many of the relevant patents are in force in just the developed world, so the problem is less serious for research carried out in the developing world — but, in some cases, the patents are in force in the scientifically-leading developing nations or may affect the products of research as well as the process of research. Hence, this is a real issue. It is intensified by the tendency of some publicly-funded research laboratories to avoid use of a patented technology without permission, even in nations where no relevant patent is in force.[52] This tendency presumably derives from misunderstanding of patent law, concerns of offending the entity which holds patents on the technology in the developed world, and concerns of offending donors.

There have been several efforts to deal with this patent problem on a broad scale. Thus, the Rockefeller Foundation has been working both to support a complete agricultural genetic engineering transformation technology at CAMBIA, a plant biotechnology research center in Australia, and to create an agricultural patent pool specifically for Africa, the African

Agricultural Technology Foundation. There is also a public sector move toward "compassionate licensing," exemplified by the Public-Sector Intellectual Property Resource for Agriculture (PIPRA), under which universities and possibly industry would make their technology available for use in the developing world. It should be recognized, however, that industry may not be motivated to place its technology in such a pool, save perhaps for the benefit of the poorest. Such arrangements will probably be more successful for technology designed to meet fundamental needs of the poorest, than for technology intended to help more scientifically advanced developing nations become globally competitive.

For these more advanced nations, the key approaches to obtaining technology will almost certainly be a combination of negotiating licenses and taking advantage of the possibility of doing research in locations in which the relevant patents are not in force. The negotiation of licenses is central to the approaches of the PPPs, which have carried out elaborate studies of the patent situations of particular technologies (such as those relevant for a malaria vaccine); they seem to have been generally successful in the process. Moreover, as developing world institutions become more sophisticated, they will hold counterbalancing intellectual property which can be used in the negotiations. A clear example is the technology held by Cuba on a Meningitis B vaccine. And there is always the possibility of a compulsory license.

Perhaps most important, there are a number of ways in which global patent standards and each nation's patent system can be designed to decrease the likelihood that they will deter research. These include care in the definition of patentable subject matter, in the non-obviousness or inventive step standard, in the utility or industrial applicability standard, and in the definition of exceptions such as the research exemption.[53] These topics are appropriate for discussion at WIPO.

Open-source efforts, publicly sponsored pools etc.

As noted previously, the Rockefeller Foundation is attempting to develop an agricultural plant transformation process that would be completely in the public domain, i.e. "open-source." This is an effort to follow the LINUX model. LINUX is a computer operating system which is completely in the public domain, and whose developers attempt to protect the system's open character by requiring those who use the language to provide similar openness for the software they develop. LINUX has been quite successful, and, for many programmers (both commercial and academic), it has become the language of choice.

Whether the model can be followed in other areas is unclear. Success will certainly require that the public domain include enough tools to make a complete and useful package. Thus the Rockefeller agricultural biotechnology effort seems likely to succeed only if it provides a complete patent-free package of all the technologies needed to transform plants. Moreover, the motivations in the biotechnology sector are different from those in the software sector, where there has been a tradition of great rebellion against proprietary rights. And it is not clear that the large expenses needed to obtain regulatory approval for a biotechnology project can be supported without either intellectual property rights or a subsidy.

Web access and scientific publication

One problem on which there is significant progress is that of web-access and scientific publication. Not long ago, limited access to scientific journals led to enormous problems for developing nation scientists. Although there is still room for improvement, this is changing as most journals are now going on-line, and many are making special arrangements for developing nation entities to obtain free access.[54] If these efforts are successful, they will be enormously beneficial to developing nations.

National security issues and restrictions on exports of particular technologies

International controls designed to protect national security and to prevent the proliferation of important technologies may also restrict the flow of technologies with peaceful uses. Few would argue with such restrictions with respect to nuclear weapons, chemical warfare or biological warfare technologies. In these areas, there is typically both an international treaty, exemplified by the Nuclear Non-proliferation Treaty, and a group which attempts to control the international transfer of certain important materials, e.g. the Nuclear Suppliers Group in the nuclear power case, which tries, for example, to restrict the shipment of components useful for making nuclear weapons.

But there are important extensions beyond these restrictions — and the extensions have less broad political support. The key issue is "dual use" technologies, i.e. technologies that have both peaceful and military uses. These include, for example, advanced computational capabilities and certain biotechnological capabilities. The export of such technologies from the United States is restricted under the Export Administration Act, which requires licenses for such activities as exporting particular kinds of products, providing consulting services for a facility in a foreign nation, and showing unpublished technological information to a foreign national within the United States. This has been supplemented by efforts for voluntary restrictions on scientific publication.[55] And it is also supplemented by the restrictions discussed above on visas for foreign scientists to come to the United States.

Obviously, the United States is unlikely to be willing to negotiate away these restrictions (nor should it negotiate away all of them), but it is conceivable that, in some circumstances (and perhaps with specific nations), the restrictions can be loosened on a voluntary basis or replaced with multilaterally-supported restrictions. And it might be possible to obtain some form of review process to ensure that the restrictions serve genuine national security purposes rather than technological protectionist purposes. Where this fits within the WTO framework is unclear, but it might be discussed as part of the Trade in Services context or in the existing Technology Transfer context. In general, however, these issues are discussed less in commercial contexts than in security contexts such as the Waassenaar Arrangement, a post-Cold-War coalition of generally developed nations working to control the export of militarily sensitive materials and technologies.

Inadequate funding in important areas and possible treaties in such areas

Clearly, there are areas of research of importance to the developing world that are being funded inadequately. The obvious examples are those of diseases and neglected diseases of importance to the tropics. Is it possible to increase this funding?

One part of the answer depends on particular donors. Might, for example, the World Bank consider supporting developing nation research for specific research projects beyond the agricultural area? There may be political fear in some areas that such support will draw the opposition of donor nations concerned to protect their own industries, but support for specific research programs certainly seems plausible in the health areas and in the environmental areas. Here is where an inventory of current public and private research by industrial sector would be valuable.

Another approach would be a treaty. There are several proposals. One would encourage all nations to support research on medical needs by setting minimal support levels.[56] Another is the French proposal for a surtax on airline tickets to be used to fight pandemics. There are obvious problems of obtaining political support for such efforts, and it seems unlikely that developed nations will give up their budgetary flexibility by making relatively long-term commitments to specific large support levels for research for developing nation needs. Yet, there has been support for technology funding in the environmental area, through activities

such as the Global Environment Fund, which contributes approximately $500 million per year to help developing nations meet environmental needs. Some of this funding is used for technology transfer, in areas such as boiler and refrigeration efficiency.[57] Moreover, there may be possible mechanisms for continuing support for specific projects goals. An example is the advance purchase commitment proposed for the G-8 meeting in St. Petersberg in 2006. Under this arrangement, donor nations would promise to purchase specified quantities at specified prices of new drugs of significant value to the developing world, and thus guarantee a basic market for a new product.

Cooperative research agreements

One way in which global support for public sector research might be encouraged is through cooperative research agreements designed to meet specific goals. This is the way, for example, that the European Organization for Nuclear Research (CERN) and the international space station are funded. Clearly, these efforts are not easy — they often involve significant tension as to whether each nation will pull its weight in providing funding as well as tension over whether the employment and scientific benefits are shared in roughly the same ratio as the funding costs.[58] However, they can build political support from the constituencies in the various nations that are benefited. It would seem most feasible to focus these efforts on technologies of significant social benefit to the developing nations, such as malaria, and on the environment, where there is strong support in both developed and developing world.

Possible treaty on scientific access

There has also been a proposal for an international treaty on access to knowledge and technology negotiated on the basis of the type of reciprocity found in normal international trade negotiations, such as those conducted by the World Trade Organization.[59] The concept is meant to be non-zero-sum in the sense that, like free trade in goods, free trade in scientific ideas benefits all, and it is certainly possible that such arrangements could be made bilaterally as well as multilaterally. Although the precise choice of subject is a matter for negotiation, a number of the specific topics discussed in this paper could certainly be included to create a balanced package (or one which would be balanced by reciprocal concessions in other areas.) Certainly, among the topics that might be considered are: reciprocal access by researchers in each nation to public scientific research support granted in other nations, and restrictions ensuring that security-based barriers to flow of scientific ideas and people be justified and not be protectionist. There is also the possibility of including provisions on the more commercial issues discussed in the next major section of this paper. The main question about such an arrangement is that the United States plays such a great role in the support of scientific research that the bargain is nearly bilateral between it and the rest of the world. This does not mean that a bargain is impossible, nor does it mean that there might not be a multilateral arrangement among another group of nations.

Implications for international negotiations

There are many points in here that might provide a basis for negotiations. Among those particularly deserving attention are:

- Improving mechanisms for access to technology held by global agricultural biotechnology firms. This may involve opening markets to private sector products, licensing in technology, or possibly compulsory licensing. The international agricultural community is facing this issue for Africa; the issue is more complex in wealthier developing nations where the markets are of interest to the private sector.
- Increasing developed and developing nation government support for medical research of importance to developing nations and, particularly, for covering the costs of distributing the products of that research in the developing world. This is happening in the international medical community, but more is needed.

- Recognizing, in international technology support programs, such as those for energy and environmental technologies, the possible need for major public sector involvement in recipient nations and, where appropriate, organizing these programs so that developing nation firms are encouraged. This is particularly an issue for donor institutions like the World Bank.
- Organization, perhaps by the World Bank, of a global research inventory, by sector, to assist in defining areas, e.g. pharmaceuticals for the developing world or more efficient energy sources, in which increased public-sector research investment is needed.
- Clarification or modification of patent law to expand research exemptions and to minimize the negative impact of patents on research, an issue for WIPO.
- New negotiated arrangements to minimize the impact of national security restrictions on the freedom of science and of international technological development, perhaps an issue for the WTO services discussions.
- New mechanisms of funding research for global public goals.
- A treaty on access to knowledge and technology including reciprocal commitments in a number of the above areas. This is perhaps a WTO issue, but both it and the previous issue might best be dealt with at the political level, as at the G-8 discussions that considered the concept of advance purchase commitments for medicines.

4. PRIVATELY-DEVELOPED TECHNOLOGY

As noted previously, outside a few specific sectors such as parts of agriculture, the primary means of technology transfer to developing nations is probably through commercial transfer from the developed world private sector through licensing or FDI. Participation in this private-sector network is the normal way for a developing nation firm to gain its first technology. Depending on the sector and the nation, the firm may go on to gain a substantial role in the international production chain, sometimes with its own technology, and may ultimately produce its own product for the domestic market for export. This sequence is exemplified by the Chinese auto industry.[60]

4.1. The developed-world mechanisms

In the developed world, as noted above, the majority of research is supported by the private sector. Developed-world governments use several kinds of incentive programs to encourage this research, in addition to providing indirect support through subsidizing education and basic research, and in addition to direct subsidies.

General

One group of incentives includes tax or regulatory advantages to encourage research. There may be tax credits or other tax advantages for research. There may be arrangements, such as the U.S. pediatric drug exclusivity, in which an extended period of regulatory or patent protection is conferred in return for the conduct of research. A historically successful example is the old Bell Labs, which benefited from the willingness of phone regulators to permit the firm to use consumer funds to support research, and the current Electric Power Research Institute (EPRI), which receives funds from electric utilities to support research in electric power and in reducing the environmental costs of such power. Unfortunately, research funding in both cases has declined, probably as an indirect result of changes in the regulatory regimes.

Another approach has been exceptions from antitrust rules to encourage industrial firms to cooperate with one another in the development of new technologies. Although there is debate over its effectiveness, SEMATECH is an effort to enable the semiconductor industry to collaborate to compete. In the short run, it actually led to a decrease in industry research,[61] and proved far better at helping define new standards that would help each of the layers of the industry, such as production equipment manufacturers, chip producers, and software writers, communicate more effectively and earlier in the development process for a particular generation of chip.

Patents and other forms of exclusivity

Proprietary position and market demands for continuously improving products are probably the dominant economic bases for private R & D expenditures. There are many possible bases for the proprietary position that makes such an "excess" return available. Often, the basis is the fact that the industry is difficult to enter, so that there is an oligopoly of relatively few participants, which are, because they constitute an oligopoly, able to charge a price above marginal cost. This is the case, for example, in sectors such as semiconductors, automobiles, and aircraft; rarely in these cases are patents a significant way of ensuring a return on research investment. Rather the return is created by the facts that barriers to entry make it possible for prices to be above the competitive level and that customers are willing to pay for improved quality. The result is substantial research investment and a continually improving level of product performance. This is exemplified in Moore's law that transistor density doubles every 18 months — a trend which implies that the cost of a unit of computational capability or of computer memory is falling constantly.

In sectors where initial research investment is necessarily high and the cost of imitation is low, however, these mechanisms may fail,

and intellectual property protection becomes essential. The classic examples of such industries (and the paradigm examples of the way the intellectual property system is intended to work) are the pharmaceutical industry using patents and the software and entertainment industries using copyright. Even in these sectors, there is sometimes incentive to innovate without intellectual property protection, as in the case of the Linux computer operating system, but there often remains need for intellectual property protection.

Industrial firms will naturally exercise their intellectual property rights in ways that benefit themselves, even where the rights are not essential for technological development. Thus, the real economic working of the system varies radically from industry to industry. In the semiconductor industry, for example, each firm probably infringes other firms' patents, but also maintains a portfolio of patents that its competitors infringe, and is prepared to use that portfolio against a competitor that threatens to sue it using its own portfolio. And, there are firms who do nothing but acquire patents and then use them to sue the actual participants in the industry — clearly an unproductive implication of the system. Moreover, firms use tiers of protection. Thus a software program may be protected by patents on particular features of the program, by copyright on the software itself, by a license agreement that seeks to prohibit copying, and by internal program features that make copying difficult. Similarly, a seed may be protected by patents, by a license contract that prohibits reuse of the harvested crop as seed, and by being a hybrid, implying that biologically it does not breed true to type. Such restrictive provisions in the license agreements may or may not be legally effective, depending on the particular provision and the particular jurisdiction.

4.2. Current developing world patterns

As will be recalled from above, in developing nations, even the most scientifically sophisticated ones, there is generally relatively less private-sector research, as compared to public-sector research. It must be recognized, however, that there is enormous variance in corporate research intensities among different developed nations — ranging from over 9% of sales in Sweden to under 3% in the U.K. and Italy.[62] Similar variation can be expected in developing nations. Further, the actual strategies vary radically from nation to nation; thus both Korea and Taiwan have been successful, but the first emphasized large firms and the second emphasized small ones.[63] And there is evidence that nations early in the technological development process will benefit from more specific government intervention in specific sectors while more advanced nations will benefit more from broad support for fundamental research.[64]

Indigenous firms

Limited private investment in research

It is not clear why developing-nation firms generally invest less in research than do their developed-world counterparts. Several factors seem likely to be relevant. First, since these firms are often technology followers, they may be more able to obtain technologies by license than through their own research — and if this is a cheaper approach, it is, at least in the short-run, economically wise. Further, these firms may face less competition, and are hence not pressed by market forces to invest in new technologies. If there is a high effective interest rate, as may result from political uncertainty about the investment climate or the availability of many alternative investment opportunities, there is less incentive to invest in research that has a payoff only in the long-term. And there may be a lack of the necessary human resources.

Licensing

Very often, a developing-world firm will need to license in some or all of the technology it needs for a particular product. This is especially likely with globalization, for a firm that hopes to export to the developed world may need

a license of developed-world patent rights covering the technology. Even if it is marketing locally, it may face local competition from developed nation firms who hold local patents; the firm needs to obtain a license to use the relevant technology, unless it can find a way to design around those patents. And, the licensing of existing technology will often be cheaper and faster than re-engineering that technology.

In negotiating to obtain such a license, the bargaining position of the local firm depends on the economics of the specific situation. For the licensor (and to a certain extent for the developing nation's economy as well), licensed production is an alternative to FDI — a foreign firm can supply a global or a local market through its own facility in a developing nation or alternatively through license to a firm in a developing nation. Economics favors FDI over the license when technologies are changing very rapidly. This is because the relationship between the foreign supplier and the local manufacturer can be updated more easily through managerial negotiations within one entity than through formal revisions of a contract between two entities. The license is favored when the licensee brings special knowledge of the local environment, or when the technologies are changing in such a way that new licensors or licensees with new core expertise are needed from time to time. Thus, if the local firm holds important comparative advantages, such as the semiconductor production skills held by Taiwanese firms, then it is in a position to negotiate effectively for a cooperative agreement under which it obtains the necessary licenses. And, TRIPS probably favors FDI over licensing.[65]

If the agreement is to produce a product for a global market, the licensor will be interested in providing the best possible and most up-to-date technology. The globalization paradigm overrides the traditional product cycle model. In some cases, however, the purpose of the license will be for production for a local market. This is likely for service industries; it is also likely for very large markets such as China. In such a situation, the traditional 1970s concerns still apply: a foreign firm may be motivated to supply a less advanced technology for production for the local market, while holding its more advanced technologies for use for global markets and seeking to protect itself from local production with more advanced technologies. Such reticence to supply technology is also likely when the local license is compelled by regulations that, for example, require local partners and restrict FDI. These are contexts in which especially careful negotiation of specific licenses is essential, for the economic incentives of the two parties are less closely aligned than for production for export.

For many of today's technologies, particularly in the computer and communications sectors, new products require a variety of skills, more than available in any single firm. Hence, there is a need for strategic alliances and innovative licensing arrangements in order to produce a product — and a new developing- world firm may be able to develop and contribute one of the relevant areas of expertise. To make these efforts work, it is important to facilitate cooperative research efforts between firms and research entities of different nations. In many industries, strategic research alliances are a measure of the success of firms; they demonstrate that science and technology are moving faster than can industrial organizations alone. In the biotechnology sector, these are both national and international and lead to what amounts to an integrated North Atlantic industry. In the semiconductor sector, the same kind of integration occurs across the Pacific. Such arrangements will be even more important for developing nations, who will often need access to foreign centers of excellence.

Other forms of technology access

Technology can be acquired in other ways, as, for example, from public sector research as discussed above, from human flow, and from reverse engineering. And in a few cases, compulsory licenses may be appropriate.

Human flow is a key way to obtain technological skill, i.e. hiring it from scientists and engineers who have worked in successful (normally developed-world) industries. This mechanism was central for the computer industry in Taiwan

and for the software industry in India. There is no question that the new expertise builds upon expertise held by the firms in which the relevant personnel learned their skills. But again, that is not itself an infringement of any law. The issue is whether the new product they develop is genuinely new and does or does not infringe specific intellectual property rights of the prior employers, or agreements with the holder of the intellectual property.[66]

This explains the need for a nation to have a solid trade secret protection system that protects licensees and investors against direct theft of their technology. A technology supplier's choice to license or invest or not reflects the economic benefits and costs it sees from the transaction, and it must take into account the risk that the technology will leak to competitors or be used to create a new competitor. In the global market, it may be able to protect itself with intellectual property rights; if the local market is significant, the availability of solid rights in that market may matter as well. Although this may primarily involve rights on the final product, it will also involve trade secret law and rules governing the possibility that employees will leave and take the technology elsewhere.

A balance is essential. In the United States, some states permit employers to demand contractual commitments from their employees that the employees will not work for competitors (at least for a reasonable period); California, however, generally prohibits such commitments. The result in California is a greater ability for scientists and engineers to move from job to job and to bring a cross-fertilization of new ideas — something that may have contributed to the state's high technology success.[67] This is also an appropriate legal choice for developing nations.

Reverse engineering involves careful analysis of a product to determine how it might be successfully copied or how a better competing product might be made. In cases of material products, this might involve taking apart the product or conducting chemical analysis of components of it. In software, it might involve "decompilation" of a program in order to understand how the program operates. Traditionally, at least as viewed by U.S. courts, such "reverse engineering" is not a violation of intellectual property law.[68] But this freedom is under attack. In some cases, there are licenses, such as the "click-wrap licenses" that seek to provide a contractual restriction on reverse engineering — some jurisdictions will enforce such restrictions and others will not. In addition, there have been recent laws, such as the U.S Digital Millennium Copyright Act and the European Software Directive, that have sought to restrict such reverse engineering (typically with some exceptions), and the U.S. Trade Representative has argued against permitting decompilation of computer programs. Such extension of trade secret law is not in the interests of the developing nations — or of the world as a whole. Nations should protect the freedom to reverse engineer, while recognizing the intellectual property rights embodied in the product. For example, reverse engineering could lead to a computer program that is genuinely different from the one studied and does some of the same things but does not infringe on the copyright of the program. If the components of the invention protected by intellectual property rights are respected, such a process is entirely legitimate. Clearly, direct copying of parts and products protected by intellectual property rights is not legitimate.[69]

Foreign direct investment

FDI integrates global technology with local production skills and comparative advantage. It is favored by global multinationals. TRIPS was presented to developing nations as a way to encourage FDI; a careful analysis suggests that there is some truth to this point, but that the impact is not very strong and is certainly highly sector specific.[70]

As noted above, unless the purpose of the FDI is primarily to satisfy local markets, there will be a strong incentive to provide the best technologies to the local production operation. This is a change from the old pre-globalization days. Clearly, the incentive is stronger in the case of wholly-owned investments than in the case of partially owned investments. And even

if local markets are envisioned, there may still be an incentive to use the best technologies if those markets are competitive, as when there are several competing foreign ventures or imports of global-quality products. This suggests most strongly that nations should not seek to attract foreign investment by offering monopolies. The point is particularly significant in sectors like telecommunications, where one of the basic reasons to bring in foreign firms is to obtain access to advanced technologies that the traditional firms or government entities did not have. It is important to avoid the temptation to offer a monopoly in order to gain the fiscal benefits of a higher privatization price — this approach amounts to a form of taxation that deters the improvement of technology.[71]

Clearly, in much FDI, the foreign firm's technology provides a substantial reward to the economy — an effective communications system or secure electricity supply, for example, is a superb boost to all kinds of economic development, and a new export operation is clearly positive. But there is also an important question whether the imported technology can become the basis of further local technological development. The risk is that the FDI sector will become an enclave that does not lead to broader technological development throughout the society. It has been argued, for example, that this was the case in China, at least until recently, in that a large part of development occurred through foreign affiliates exporting products made by assembling imported materials or materials produced by other foreign affiliates.[72]

Traditionally, nations sought to avoid these enclave risks by encouraging or requiring local participation in the project, and by imposing local content rules or technology contribution rules. These provisions may be part of a technology transfer law, of a joint venture law, of a foreign exchange law, or of a government procurement law. Many such laws may raise issues under the WTO Agreement on Trade-Related Investment Measures (TRIMS), although there is a developing nation exception in that agreement. All these laws also give rise to a tension with the investor or licensor who may not want to provide the technology. Thus, each such requirement on the activities of the FDI entity may decrease the competitiveness of that entity. At the same time, it may be that the technology that local affiliates ultimately develop (i.e. for a later generation of products) will be better than that imported. Both the technology-importing entity and the foreign technology provider face difficult choices in these situations.

Off-shore research by multinationals & outsourcing of R & D

One of the new trends in the world technology regime is the rise of off-shore R&D facilities owned by major multi-national corporations. These entities had long been found within the North Atlantic community, particularly in the pharmaceutical and electronics sectors. They are now reaching the more scientifically sophisticated developing nations as well, as exemplified by new offshore research facilities in China, Singapore, Hong Kong, India, and Taiwan. The National Science Foundation statistics, for example, show a rise of U.S. offshore research in Singapore and other (non-Japan and non-Australia) Asian and Pacific Nations from $82 million in 1989 to $1964 million in 2000. The similar numbers for Latin America show an increase of $169 million in 1982 to $685 million in 2000. These are dramatic growth rates, and a very comprehensive recent UNCTAD study shows a robust continuing increase in the share of offshore research allocated to developing nations, especially those in East Asia.[73] But the numbers are still small compared to that for comparable investment in Europe ($12,938 million for 2002).[74] Globalization of industrial research is occurring, but even the most advanced developing nations are only a following part of the process. And there is still a strong emphasis on doing research at home.[75]

The move to offshore research into developing nations probably sometimes serves political and marketing goals of facilitating access to local markets. But, the more important factor is almost certainly that advanced science and engineering research can often be conducted more cost-effectively when using the lower-cost skill pools in these more advanced developing

nations. This is likely to create a strong continuing pressure toward further offshoring of research.[76] In the case of the trend to conduct pharmaceutical clinical trials in developing nations, access to a pool of research subjects may also be significant; there may be similar special factors in some other sectors.

As with FDI, the key long-term question for the host nations is whether these research centers will be enclaves or will be the nuclei of new broader technological centers, Silicon Valleys of their own, so to speak. This will certainly depend on the trade secrecy legal context as discussed above. It may also depend on the technological sector. In the "old" electronics industry or the "old" pharmaceutical industry, there was relatively little economic spin-off from the research activities of the major firms — but in today's software and biotechnology worlds, such spin-off is probably more substantial. But it can probably be most influenced by the available human resources and by the resources available to the spin-offs, including access to venture capital (an issue to be discussed below) and to universities, and the possibility of high personnel mobility from company to company.

4.3. Barriers, normative issues, and proposals

Issues relating to embodied technology (e.g. medicine access issues)

Although developed nations purchase many products that include embodied technology, e.g. computers and communications systems, the terms of such procurement have become a major political issue in the medical sector.

Patent questions and TRIPS

Certainly, the medical debates have focused on patents, but it is hard to look at the actual history of drug access to developing nations and not to conclude that the key issues are now based on financial considerations rather than on intellectual property considerations. Indeed, it is arguable that the Doha declaration and the follow-on agreement at Hong Kong in 2005 to amend TRIPS resolved the patent issue. The Doha balance is a reasonable recognition of the fact that the poor should not pay as large a share of pharmaceutical R & D costs as do the rich. The serious issues now are whether this balance will be undercut in bilateral and regional negotiations,[77] and whether the funding institutions such as GFATM and PEPFAR will be adequately supported by donors. From the perspective of potential developing world suppliers, such as the Indian generic manufacturers, the question is whether they will purchase generics when brand-name products are available. Both entities appear to have worked out compromises on the issue. In the parallel case of UNICEF and vaccines, the actions of global procurement entities during the 1990s led to the closing down of many small uneconomical (and unsafe) national vaccine plants, and to a substantial shift in global procurement from the traditional developed-world suppliers to a group of large-scale suppliers in Brazil, India, Indonesia, and Senegal.

Data protection

But this does not mean that the TRIPS issues should be forgotten. There is a clear trend in bilateral negotiations to strengthen intellectual property protections beyond those of TRIPS and, in particular, to use data protection requirements to achieve an alternative exclusivity for pharmaceuticals. The logic is that a firm maintains an ownership right in the information it has supplied to regulatory authorities, and should therefore be able to prevent another firm from relying on that information to obtain regulatory approval for an equivalent product. This is, in many respects, a legal fiction; its legal role in the United States goes back to a legislative compromise, the 1984 Hatch-Waxman Act. Under this Act, generic drugs can be approved on the basis of the original developer's clinical trial; in turn, the original developers were given an extension of exclusivity to allow for time lost during the regulatory process. Economically, the grant of rights over clinical data should depend on whether such exclusivity is reasonably needed

as part of encouraging the availability of drugs. TRIPS has, of course, required some recognition of these rights; from the viewpoint of developing nations, the recognition should be as minimal as possible unless new clinical trials are needed to evaluate a product for use in the developing world or there is a new global compromise between the research-based and the generic pharmaceutical industries. And, more broadly, ways should be considered to restrain bilateral and regional agreements, particularly in light of the apparent failure of the Doha Round and the possibility that bilateral and regional agreements will become the dominant mode of trade negotiation.

Subsidies and other interventions for technology development and acquisition

Many developing nations are seeking to subsidize their private research sector. In the developed world, the economic analysis of such a subsidy is based on the fact that many of the benefits of new technology development are unlikely to be recouped by the investor in the new technology. Hence, although governments often fail to live up to the principle, subsidies should be given only to those industries in which the social benefits of the technology are significantly greater than the profits that will return to the entrepreneur.[78] For the developing nation, an additional circumstance is appropriate. This is based on an analogue to the traditional economic criterion under which an infant-industry subsidy or tariff is appropriate — if there is a market imperfection making it hard for an industry to get started, and the industry can be expected to be efficient and to survive without protection after a start-up period, the subsidy or protection is justified. Economically, a developing nation can then reasonably take into account barriers that place its firms at a disadvantage compared with developed-world incumbents, and evaluate whether helping a particular industry has a reasonable probability of leading to a long-term industry that can participate profitably in the world economy. Among the barriers that can certainly be included is the need to start at the top of the learning curve and work down. All the standard economic objections to government intervention apply to warn that such an approach is often unwise: governments are generally less good than the market at "choosing winners," political pressures often push in uneconomic directions, and it is politically hard to terminate the subsidy or protection. But the point remains: specific subsidies as well as general subsidies (i.e. education or broad tax incentives) are *sometimes* economically rational.

Beyond support for education and for basic research, there are many ways in which a government can encourage the private sector to invest in technology development. It can make direct grants to firms for the purposes of developing or implementing specific technologies, offer tax incentives, or encourage the creation of a venture-capital based industry. It can also use its buying power or impose restrictions on those seeking to invest in or supply technology to the nation.

Grants and loans, sometimes loans that have to be repaid only if the project is successful, are the most straightforward, and therefore generally the most efficient means of encouraging private sector investment. Their wisdom depends, of course, on how well they are focused on firms whose research meets the criteria presented above, and it is important that the decision-making seek to follow such criteria rather than political or faddish goals. Such financing is one of the key means that China has used to encourage private entities to invest in research as part of its "15 Year Comprehensive Long-Term Science and Technology Plan," and has been particularly successful in the software and computer sectors.[79] These procedures can often be combined with efforts to encourage linkages between the public and private sectors or between indigenous firms and foreign ones.

Tax concessions are complicated. Tax deductions for research investment are unlikely to be a particularly strong incentive, for, under normal accounting principles, research investments can be directly deducted from income anyway. Hence, the normal pattern of government tax support is a tax credit, under which a portion of the amount of research investment is directly

deducted from taxes, not just from income. This is a more effective way of encouraging research investment than are broader tax benefits, such as those for location in a special economic zone. It is more effective for stable businesses than for start-ups, which may not have profits until sometime after they invest in research. Obviously, there are special design issues in whether the credit should be available for the purchase of research or technology from abroad — and the answer depends on the relative weights to be given to encouraging local research as compared to encouraging local technological capability. Moreover, for a foreign investor, it is important to consider how the host nation's tax benefit will affect the foreign firm's overall tax situation under that firm's home nation's taxation rules.

In many economies start-up firms and "small and middle sized enterprises" (SMEs), provide a large portion of new employment and of research. They are often also the firms most likely to bring radical technological changes. In high-tech sectors, these businesses can be encouraged through a venture capital network. The problems are that an effective venture capital process has many requirements. There must be not only venture capital funding for the start-ups, but there has also to be a network of marketing, technological, financial, and legal skills to enable the start-ups to grow. Most of all, there has to be an "exit," i.e. a way in which the venture capitalists can recoup their investment, typically either by selling the start-up to the public on a major stock market or by selling it to a major firm already in the business. It is crucial to have the entire spectrum of prerequisites. The key benefits of incubators and research parks are not so much in the real estate as in the package of skills and infrastructures, such as conveniently available business and legal expertise and assured pure water, electricity, communications, and transportation capabilities. There is generally greater success with location near a university or research institution. And the combination of a number of firms may create a market for such skills that might otherwise not have been served. Employee flow and cross-fertilization matter, and, certainly in the case of Taiwan, and probably in China and India as well, networks to Silicon Valley played a large role in facilitating the new centers.[80]

Often, buying power is used to strengthen local technological development. Thus, a major government acquisition is conditioned on there being a specific percentage of local production or local acquisition. An example is the current transaction between Alstom and China in which Alstom will transfer locomotive technology to a Chinese partner; the typical pattern is that the first vehicles will be made in Europe, but studied in China and by the end of the contract, the vehicles will be made essentially completely in China.[81] This is clearly much more feasible for China than for a smaller economy. The obvious economic question in imposing such conditions on procurement is whether the resulting increased cost in the procurement is justified by the benefits of the creation of the local industry. And the provisions of the WTO Agreement on Government Procurement must, of course, be taken into account. Article V includes an exception for the benefit of developing nations; determining whether it is adequate requires further analysis.

Trade-related investment measures, such as domestic content restrictions, have often been used to encourage the transfer of technology — certainly in Japan's and Korea's technological development, and more recently in Brazil, India,[82] and China. Such measures may be, in significant part, restricted in the WTO TRIMS agreement, although that agreement includes a developing nation exception. The measures may also be restricted by the terms of Bilateral Investment Treaties (BITs).[83] As implied by the discussion above of the wisdom or not of support for specific industries, these measures may sometimes simply increase costs and create inefficiencies. But sometimes, they may provide a mechanism to help a local industry bring new technology to a global market in an efficient way. Further study is needed on when they can be wisely employed. Moreover, in general, a direct subsidy is economically better than a regulation-based way to encourage the transfer of technology.

Finally, as noted above in connection with privatization, it is not a good idea to offer a monopoly as a way to encourage firms. This applies to the terms of privatization, it applies to FDI, and it applies to reject any temptation to favor state-owned firms at the expense of outsider competitors.

Competitiveness issues for developing-nation firms, including trade-secrecy questions and market barriers

A further question is the possibility of legal barriers that discriminate against developing nations. There are several examples. Perhaps the most obvious issue, highly significant for small developing-world firms, is that the cost of access to the developed-world patent system is prohibitive. A subsidy program permitting small inventors and entrepreneurs in the developing world to obtain less costly access to developed-world patent systems would be helpful in providing access to developed world markets.

Second, many of the traditional import barriers are now being used heavily against developing-nation products. These include the anti-dumping laws, which are often implemented in a way that penalizes low-cost producers, for the definition of dumping is not one of selling below the price in the home market but one of selling below a "normal value," and the ways of calculating that value are often unfair to the producer. Particularly important are the principles for allocating R & D costs.[84] Government procurement requirements in developed nations may cut against developing nation firms. Similarly, the U.S. § 337, used to exclude goods that infringe U.S. intellectual property rights is heavily used against products from developing nations;[85] it would, of course, require substantial analysis of actual cases to determine if the result is unfair. Many of these arrangements are harmful to both the exporting and the importing nation; it is unfortunate that they are often being copied by developing nations.

Another problem is that of subsidies. For industries marked by frequent international sales below cost (such as steel during the low parts of the business cycle), by substantial subsidies (such as small passenger aircraft),[86] or by steep learning curves, it may be essentially impossible for a developing nation to enter the sector without subsidizing the industry. Yet the result will be that countervailing duties will be imposed as a trade barrier against the industry. Clearly, there is a problem here, and this is an area in which adjustment of the WTO countervailing duty/subsidies code would be appropriate. As it entered into force in 1995, the Agreement on Subsidies and Countervailing Measures included an exception, Article 8, which covered certain research subsidies; that exemption was provisional, expiring in 2000, and has not been renewed. This is an issue of great importance.[87]

A future possible problem is that developed-world fears of reverse engineering may lead to trade sanctions or efforts to bar from developed-world markets developing-world products based on such imitation. As argued above, reverse engineering can be a legitimate form of product development if the products developed through reverse engineering do not infringe other property rights. This is, of course, a difficult line to draw fairly. A global understanding as to the law here might be wise; although given the pressures on that understanding, it may better be achieved by litigation in developed-world courts than by negotiation in a global context.

Finally, developed nations are now resisting the purchase of their own firms by developing nation firms, as exemplified by the 2006 tensions over Mittal's acquisition of Acelor. This reflects a tradition, exemplified by a 1987 battle when a Japanese firm sought to purchase Fairchild Semiconductor, and by Congressional debates in the same era over agreements that would give Japanese firms increased access to aircraft technology. Clearly, there may be genuine security concerns in some of these cases, and any resolution must recognize these concerns. Yet, it would be wrong to allow developed world firms to acquire developing world firms but not the reverse. Again, this is an issue for the WTO.

Standards and patents

Among the most important barriers to entry, particularly in the software area, are standards. Microsoft Windows benefits, for example, from "network externalities." Put overly simply, everyone writes applications software for Windows, because everyone has Windows. And everyone buys Windows because so much of the software is written for it. Similarly, economic pressures support the standards for DVDs and cell phones. Sometimes such standards are de facto imposed by a dominant firm; sometimes they are negotiated by standards bodies, often made up of a group of firms that have relevant economic interests.

In some cases, exemplified by the DVD and MPEG3 standards, it is necessary to use a patented technology to comply with the standard. Sometimes, such technology is readily licensed, but the result is a royalty tax that favors the "insiders" who developed the standard and penalizes the outsiders who have to pay the royalties. And sometimes there is a standards battle between two or more competing technologies. In general the standards are likely to be set by dominant firms, which are typically firms in the developed world. Hence the royalty tax paid by the outsiders amounts to a tax on the developing nation firms. This was the case, for example, for East Asian manufacturers of DVD devices, who had to pay what seemed to them to be an exorbitant royalty.[88] The link between patents and standards has given rise to a range of legal proposals to attempt to ensure that the patents involved can be licensed in a "reasonable and non-discriminatory" manner.[89] The issue, however, is highly controversial, and it is not clear that there will be a practical international legal solution.

One possible response for these firms and nations is to become important enough in the product development process that they can set a standard of their own. This is what China has sought to do in the local area network (LAN) domain, where it has fought for its own authentication system (WLAN Authentication and Privacy Infrastructure, or WAPI). The logic in the particular case is that the details of the standard were to be disclosed to only a number of Chinese firms; foreign firms would have to cooperate with these firms and provide technology to them. Other ways to obtain similar benefits are to choose a standard on which local firms have key patents, or even just to use the fact of difference as a way to provide a home market that may not be invaded by foreign firms. The costs are that the monopoly will almost certainly be harmful to the national economy; a separate standard really makes sense only when the alternative is "better" than the global standard, in the sense that it provides for greater functionality. The best long-term strategy is therefore to encourage firms to become strong enough that they will hold intellectual property rights on aspects of the newest technologies and have a say in setting the global standard, so that they become royalty recipients rather than royalty payers.

Neoprotectionism in the digital environment, including outsourcing and cross-border services

There is a contemporary developing world concern about offshoring in the high-technology and professional sectors. Yet, such offshoring is generally economically beneficial to both developed and developing nations, and provides a beneficial services export for developing nations. In order to provide the benefits of free trade, such restrictions on offshoring are inappropriate. There also remain restrictions on trade in services in those sectors where the services might be delivered through labor migration; again, there is no reason not to work for the benefits of free trade through future steps in negotiations in the services sector.

Antitrust issues

There is an unavoidable tension between antitrust law and intellectual property law. The intention of intellectual property law is to create a market entry barrier to permit a firm to gain an extra profit that can serve as an incentive to invest in creation or innovation. Ideally it provides the consumer with a better product in the future, at the expense of a somewhat higher price. Antitrust law is designed, in contrast, to

enable the consumer to obtain a product at the lowest price possible. The optimum balance between the two bodies of law depends in part on the consumer's discount rate that balances the present against the future; it will therefore differ as between wealthier and poorer societies.

During the period from the mid-century until about 1980, U.S. law was balanced strongly in favor of the antitrust concerns and against the intellectual property concerns. This led to the classic list of nine "no-nos," i.e license clauses that were viewed as anticompetitive, a list that influenced the Draft International Code of Conduct on the Transfer of Technology and many parallel national laws and regulations. With a change in perspective and economic analysis about 1980, U.S. law shifted to recognize many of these clauses as often quite legitimate — the clauses were viewed as ways to increase the monopoly rent associated with the exercise of intellectual property rights and therefore as ways to increase incentives to innovate. This is not the case for all such clauses — some clauses, for example, seek to expand the monopoly beyond that authorized by the particular intellectual property or to exercise illegitimately-obtained intellectual property rights. Thus, some of these arrangements remain prohibited by antitrust laws.

The change in perspective led to changes in the legislation of developing nations as well. Hence, for the purposes of this paper, there is little need to develop a list of prohibited license practices in the technology transfer context. This is not politically feasible at this point, nor is it wise economically, save perhaps in the context of some technologies intended for use in national rather than global markets. The current key issues instead involve dealing with global oligopolies that may restrict developing world entry and with multinational acquisitions of local firms.

Power of developed/developing world oligopolies

From the viewpoint of the developing nation's desire to obtain technology, the most important international antitrust issue arises from the fact that many technology-based industries are marked by near monopolies or by oligopolies of a relatively small number of firms, that may be willing to cross-license their technologies to one another, but are less willing to license their technologies to a proposed new entrant into the oligopoly, such as to a contending developing nation firm. The pattern is exemplified by the computer operating system sector, the semiconductor sector, and the agricultural biotechnology sector.[90]

There is a plausible antitrust law argument that concentration of an industry into a monopoly or oligopoly may lead to suboptimal incentives to invest in research, and that, under such circumstances, some actions of the leading firms may amount to antitrust violations. The antitrust argument is strongest if the leading firm attempts to gain market power beyond that authorized by its intellectual property (a standard argument in the Microsoft litigation) or if firms are willing to license their technology to existing powerful competitors but refuse to do so a new competitor. The economic force of such arguments is a matter of debate, and some of the arguments are not yet broadly accepted among developed-world antitrust authorities, but there are reasonable and plausible antitrust principles that new entrants should be allowed in some such circumstances. Of course, there is major debate as to the appropriate scope and circumstances for such a response, as exemplified by the global criticism of the proposed Chinese Anti-Monopoly Law, which might permit overriding of intellectual property rights in cases of "abuse." This definition is almost certainly too broad.

In those circumstances in which antitrust arguments call for overriding intellectual property rights, the appropriate response is a compulsory license. The circumstances will be rare, and the standards subject to reasonable debate, but TRIPS allows such licenses in a reasonable range of anti-competitive situations.[91] A nation can, of course, include such a principle as part of its own antitrust law, giving its firms access to the local market in competition with the monopolist or oligopolies. It would, however, need the effective agreement

of developed world antitrust authorities in order to obtain access to the developed-world market. This is a point reasonably considered in the WTO context.

Take-over rules within developing nations

Another important antitrust issue for developing nations is whether to allow a multinational to take over a local firm. Such an acquisition may be a normal step in the global movement of an industry towards larger-scale operations. Moreover, it can often bring new technology, through the technological inputs provided by the multinational. This is especially likely to be the case in sectors like telecommunications and agricultural biotechnology. However, such an acquisition can also reduce competition. The need, therefore, is to balance these two effects. To do so wisely requires an antitrust authority with a substantial economic capability.

Summary of negotiation implications for the private research area

The most important topics from the above analysis to be considered for further international negotiations include:

- International arrangements guaranteeing that trade secret law not infringe the rights of employees to change jobs (including changing jobs internationally) or the rights of firms to reverse-engineer products, provided that the rights of the former employer or of the original designer of the product are respected. There is an important strategy issue as to whether it is best to raise this group of issues diplomatically or in developed-world judicial proceedings, or simply to proceed with local legislation that reflects the principles.
- Consideration of the purchasing policies of global health (and other) procurement entities to determine whether they are adequately open to developing nation supply tenders (and it is possible that these entities might provide additional assistance in helping firms meet necessary quality standards).
- Development of a mechanism to discourage bilateral agreements that modify the balance struck in TRIPS. This could be a requirement of some form of review or impact statement — the WTO Article XXIV or Trade Policy Review mechanisms might provide a starting point for designing a response.
- Negotiation of TRIMS-like provisions to ensure that developing-nation firms can buy developed-nation firms as well as the reverse.
- Evaluation and possible renegotiation of the technology-related provisions of the WTO antidumping codes, subsidy codes, and possibly of TRIMS and of Bilateral Investment Treaty provisions.
- Consideration of additional provisions or commitments in the services area to ensure the ability of developing nations to compete in the offshoring sector and in other forms of international delivery of services.
- Antitrust issues associated with the international flow of technology and with the international competitive structure of technology-based industries.

5. OVERALL IMPLICATIONS

5.1. Key policy issues for nations themselves (developed and developing), including national technology policies

In a sense, the subsidy criterion described previously must be the basis for all national technology policy. It clearly favors strong support for scientific education and for basic research in areas that are important to the particular nation and neglected by world technological research. The criterion favors academic research in areas of local interest, and, where the nation has specific capability, of global interest. In all these areas, the focus must be managed carefully — decision-making for subsidy allocation must reflect both national needs and scientific expertise. The criterion also favors care in implementing Bayh-Dole type relationships between the public and the private sectors.

The criterion further favors policies that remove barriers to private sector investment in technology. These include the traditional need to build a climate favorable to investment. They also include the need for reasonable trade secret laws that ensure employee mobility and permit appropriate reverse engineering, the need to take research investment incentives into account in regulatory and privatization design, and the need to have a solid national antitrust/intellectual property capability.

Finally, the criterion favors a focused subsidy in those cases in which a nation has the capability of producing a world-class industry and that industry is held back through global restrictions or inability to recoup the social benefits of the technology it creates. Such efforts have costs; care must be taken in deciding when to bear those costs. And there is risk for any governmental effort to "choose winners." Brazil's alcohol program was far more successful than its computer program.[92] And the value of the alcohol program depends on the prices for energy alternatives. But, there is both global and local value in increasing the intellectual and technological diversity of the leading entities in different research sectors.

5.2. Issues requiring multilateral attention

Clearly, many areas require multilateral attention, and the summaries at the end of each of the preceding sections provide an agenda. It is most important to continue the move towards a seamless global scientific and technological community, such that each scientist or engineer, anywhere in the world, has an opportunity to make his or her optimal contribution to the science and technology needed by the planet. Also of great importance is to increase support for the various initiatives underway, such as the medical PPPs, to help achieve important world technological goals in the medical, agricultural, and environmental areas. And, it is important that the firms and research institutions in the developing nations have access to participate in the technological developments required to meet these goals.

The concepts contained in the proposed treaty on access to knowledge and technology are also desirable global goals. Among the most important are reciprocal access to science and technology subsidies, and narrowing to the extent possible the barriers to the global flow of scientists and of scientific knowledge.

Finally, it is important to remove barriers to the free flow of technology, as well as to the free flow of science. Among the barriers that need to be removed are source and most host nation restrictions on technology licenses and investment in technology-based firms, as well as the barriers implicit in the current WTO patterns of anti subsidy and antidumping principles. There are certainly appropriate exceptions to protect national security and probably some appropriate exceptions to make it easier for developing nations to build

technology based industry, but these should be against a background of great freedom of flow. In the light of the current status of the Doha Round, it is not clear whether these goals are best sought in the context of a modified or expanded round or of detailed revisions and understandings within the existing WTO bodies. But it is important to seek them. Ultimately, the business perspective noted at the beginning of this paper — of seeking global technological integration — is far better for the world than are political restrictions on the transfer of technologies.

5.3. Issues deserving further study

Obviously, there are many unknowns in the analysis presented above. But several stand out:

- One is the need for further study of specific industries, and of the relative success or failure of new entrants. The reasons why Mittal Steel is able to buy a European firm while developed world majors remain dominant in automobiles and pharmaceuticals deserve attention.
- Better understanding of the links in developing nations between broad national research and educational support and actual industrial activity. What actually happens to the funds, students, and research findings developed under the broad programs? These issues are more often analyzed in developed than in developing nations — but the analysis should be extended. Might such information contribute to a better division of funding between broad programs and programs focused on specific industrial targets?
- The generally correct criticisms of government efforts to support particular technology sectors have led to a current orthodoxy rejecting nearly all such efforts. Yet, government interventions have played important roles in the development of Japan and Korea (as well as of the United States and many European nations), and might play a similar role in other nations. What is the actual experience? When are such programs actually useful? Can the real political barriers to wise execution of such programs be overcome?
- The impact of regulation on research incentives deserves much greater analysis. Why is energy apparently seeing less R & D recently, while pharmaceutical R & D is continuing? Many industries are properly regulated for many different reasons and in many different ways. The details affect R & D incentives.
- Finally, it is important to analyze whether a number of areas of trade and WTO law are actually discriminatory or not. Among the areas that deserve analysis are intellectual-property based trade restrictions such as those of the U.S. § 337, and the WTO and trade law principles on the treatment of R & D subsidies. It would also be useful to examine the provisions of Bilateral Investment Treaties, which may go further than TRIMS, just as bilateral agreements often go further than TRIPS.

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The Rhetoric and Reality of Regulatory Reform

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The Rhetoric and Reality of Regulatory Reform

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Abstract

In January 2007, President George W. Bush stirred up widespread controversy by issuing amendments to an executive order on regulatory review adopted initially by President Clinton. The Bush amendments variously require agencies to issue written regulatory problem statements, assign gate-keeping responsibilities to Regulatory Policy Officers within each agency, and undertake analytic reviews before adopting certain kinds of guidance documents. Both legal scholars and policy advocates charge that the Bush amendments place significant new burdens on administrative agencies and will delay the issuance of important new regulatory policies. This paper challenges the rhetorical claims of obstructionism that have emerged in response to the Bush amendments. It begins by comparing criticisms of the Bush amendments with criticisms of previous regulatory reforms, showing that concerns about delay date all the way back to the creation of the Administrative Procedure Act of 1946. Notwithstanding the perennial nature of charges of delay and obstruction, the U.S. regulatory state has grown dramatically in both size and impact over the last six decades. In addition, the extant social science literature has failed to find any systematic delays associated with the specific procedure affected by the Bush amendments, namely regulatory review by the Office of Management and Budget. Overall, the burdens associated with regulatory reforms appear to be far smaller, or more manageable, than critics usually suppose. This paper concludes with several explanations for persistent reality of regulatory growth in the face of the persistent rhetoric of obstruction. These alternative accounts not only help explain the rhetoric-reality divide over regulatory reform in general, but they also provide reason to expect the Bush amendments will have, at most, only a trivial impact on the overall regulatory process.

The Rhetoric and Reality of Regulatory Reform

Cary Coglianese[†]

Executive Order 13,422[1] leaves in place most of the existing review process established earlier under Presidents Reagan through Clinton.[2] But it makes several controversial changes to Clinton's Executive Order, such as requiring that agencies specify in writing the regulatory problems they seek to solve, giving presidential appointees certain gatekeeping functions as regulatory policy officers, and imposing new review requirements on certain guidance documents.[3] Although these amendments add to or modify only a very small amount of the text in the pre-existing Executive Order on regulatory review, the changes have provoked a firestorm. Critics charge that the new Order solidifies presidential control over rulemaking and will hamper agencies' ability to issue timely regulations in the service of social welfare.

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1 Exec. Order No. 13,422, 72 Fed. Reg. 2763 (Jan. 18, 2007) (hereinafter referred to in the text as "the Order" or "13,422").

2 Exec. Order No. 12,291, 3 C.F.R. 127 (1982), 46 Fed. Reg. 13,193 (Feb. 17, 1981); Exec. Order No. 12,866, 3 C.F.R. 638 (1994), 58 Fed. Reg. 51,735 (Sept. 30, 1993), *reprinted in* 5 U.S.C. § 601 (2000).

3 In addition to these changes, 13,422 also includes provisions about reporting cumulative regulatory benefits and costs as well as about the use of formal rulemaking procedures.

In this essay, I focus specifically on the concern that the Order will burden and delay the regulatory process. I compare the criticisms of 13,422 with criticisms of past procedural changes to the regulatory process, and I juxtapose the perennial concern about administrative burdens and delay with the growth in federal regulation over the past half-century. If procedural controls, such as those in 13,422, really do impose on regulatory agencies a "paralysis by analysis," then why is the federal government still producing so many high-impact regulations? This essay raises possible explanations for the disjunction between the rhetoric and reality surrounding regulatory reform, including the possibility that the ultimate impact of the Bush amendments will be largely symbolic.

I. Rhetoric Reacting to Executive Order 13,422

For a short presidential decree on administrative rulemaking, Executive Order 13,422 has received a remarkable degree of public attention, including a front-page story in *The New York Times*,[4] a broadcast on MSNBC,[5] and two congressional hearings[6]—not to

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4 Robert Pear, *Bush Directive Increases Sway on Regulation*, N.Y. TIMES, Jan. 30, 2007, at A1 (reporting that "[c]onsumer, labor, and environmental groups denounced the executive order" and feared that it "would hinder agencies' efforts to protect the public").

5 *Countdown with Keith Olbermann: Executive Order 13,422* (MSNBC television broadcast Jan. 30, 2007), *available at* http://olbermannnation.com/index.php/2007/01/30/executive_order_13,422 *and* http://www.youtube.com/watch?v=Sz6NEoKZRMY (conversation between host Keith Olbermann and guest John Dean highlighting potentially "outrageous" consequences of 13,422, including its "hurdles" for new regulatory actions).

6 There have been at least two congressional hearings *so far*. The House Science and Technology Committee's Subcommittee on Investigations and Oversight held hearings on February 13, 2007 and April 26, 2007. *See Amending Executive Order 12,866: Good Governance or Regulatory Usurpation? Parts I and II: Hearing Before the Subcomm. on Investigation and Oversight of the H. Comm. on Science and*

mention the passage of a House appropriations bill blocking its implementation.[7] In the course of the highly visible debate over 13,422, critics have advanced two rhetorical arguments. The first emphasizes the balance of power between Congress and the President, tapping into broader critiques of the Bush Administration's positions on executive authority in domestic and foreign affairs.[8] The second, and the one on which I focus here, is a variation on what economist Albert Hirschman calls the "rhetoric of jeopardy."[9]

Executive Order 13,422, the argument goes, "deals a body blow to the ability of our agencies to do their jobs."[10] Its requirement that agencies state the problem they seek to solve imposes "another hurdle for agencies to clear" before they can adopt good public policies "protecting public health and safety."[11] Its provisions on guidance documents give

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Technology, 110th Cong. (2007), *available at* http://democrats.science.house.gov/publications/hearings_markups_details.aspx?NewsID=1269 *and http://democrats.science.house.gov/publications/hearings_markups_details.aspx?NewsID=1777*.

7 Financial Services and General Government Appropriations Act 2008, H.R. 2829, 110th Cong. § 901 (2007). The Senate did not pass similar legislation.

8 *See, e.g.*, Peter L. Strauss, *Overseer or "The Decider"? The President in Administrative Law*, 75 GEO. WASH. L. REV. 696, 732-38 (2007).

9 ALBERT O. HIRSCHMAN, THE RHETORIC OF REACTION: PERVERSITY, FUTILITY, JEOPARDY 84 (1991). Although Hirschman focuses most of his attention on the rhetoric of conservatives, he readily acknowledges that progressives make parallel rhetorical moves. *Id*. at 149-54 (labeling the progressives' parallel to the jeopardy argument the "imminent danger thesis"). Conservatives' rhetoric of jeopardy emphasizes the dangers of *action*, while progressives' parallel rhetoric of imminent danger focuses on the dangers of *inaction*. *Id*. at 153.

10 *Amending Executive Order 12,866: Good Governance or Regulatory Usurpation?: Hearing Before the Subcomm. on Investigation and Oversight of the H. Comm. on Science and Technology*, 110th Cong. (2007) (Statement of David C. Vladeck, Associate Professor, Georgetown University Law Center), *available at* http://democrats.science.house.gov/Media/File/Commdocs/hearings/2007/oversight/13feb/vladeck_testimony.pdf.

11 Pear, *supra* note 4, at A19 (quoting Gary D. Bass, Executive Director of OMB Watch).

the Office of Management and Budget (OMB) the ability "to keep the agencies in an endless loop of analysis and [will] lead to endless regulatory delays."[12] The Order's relatively obscure, if somewhat puzzling, provision on formal rulemaking procedures causes at least one prominent administrative law scholar to wonder if its purpose is "[j]ust to help one's friends slow things down—throw a good dose of sand into the gears of rulemaking."[13]

According to critics, 13,422 generates "gridlock"[14] or "a new bureaucratic bottleneck."[15] It "codifies regulatory delay"[16]—and hence "lead[s] to the further

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12 OMB WATCH, A FAILURE TO GOVERN: BUSH'S ATTACK ON THE REGULATORY PROCESS 22 (2007), *available at* http://www.ombwatch.org/regs/PDFs/FailuretoGovern.pdf. Even an otherwise supportive treatment of 13,422 expresses concern that the revised "process could slow or stop the issuance of some guidance that serves a useful social purpose." *Amending Executive Order 12,866: Good Governance or Regulatory Usurpation? Part II: Hearing Before the Subcomm. on Investigation and Oversight of the H. Comm. on Science and Technology*, 110th Cong. 4 (2007) (statement of Robert W. Hahn, President, AEI-Brookings Joint Center for Regulatory Studies), *available at* http://democrats.science.house.gov/Media/File/Commdocs/hearings/2007/oversight/26apr/hahn testimony.pdf.

13 *Amending Executive Order 12,866: Good Governance or Regulatory Usurpation? Part II: Hearing Before the Subcomm. on Investigation and Oversight of the H. Comm. on Science and Technology*, 110th Cong. 12 (2007) (Statement of Peter L. Strauss, Professor, Columbia University School of Law) *available at* http://democrats.science.house.gov/Media/File/Commdocs/hearings/2007/oversight/26apr/strauss_testimony.pdf.

14 Union of Concerned Scientists, Presidential Mandate Centralizes Regulatory Power, Endangers Citizens, http://www.ucsusa.org/scientific_integrity/interference/executive-order.html (last visited Nov. 18, 2007).

15 Public Citizen, Latest White House Power Grab Puts Public at Risk: Problems of the Jan. 2007 Executive Order and Bulletin on Guidance (Jan. 2007), http://www.citizen.org/documents/new-eo-and-guidance-overview.pdf.

16 OMB WATCH, UNDERMINING PUBLIC PROTECTIONS: PRELIMINARY ANALYSIS OF THE AMENDMENTS TO EXECUTIVE ORDER 12,866 ON REGULATORY PLANNING AND REVIEW 3 (2007), *available at* http://www.ombwatch.org/regs/EO12866_amendments_analysis.pdf.

ossification of an already overburdened administrative process."[17] One member of Congress claims 13,422 provides "another avenue for special interests to slow down and prevent agencies from protecting the public."[18] Still another declares that it "make[s] it harder for agencies to take virtually any action."[19] A former OMB regulatory policy administrator predicts that due to 13,422, along with recent OMB bulletins and standards, "fewer regulations can be issued."[20]

II. Rhetoric and Reaction in Administrative Law

The kinds of criticisms that have been leveled against 13,422 are hardly new. Burdens and delays have figured prominently in the rhetoric against a variety of administrative law reforms. When President Reagan first established formal White House review of rulemaking under Executive Order 12,291,[21] critics raised separation of powers

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17 Vladeck, *supra* note 10, at 19.

18 Press Release, Subcomm. on Investigation and Oversight, H. Comm. on Science and Technology, Miller Leads Subcommittee Hearing into White House Exec. Order that Gives More Political Control Over Public Health, Safety Regulations (Feb. 13, 2007), *available at* http://democrats.science.house.gov/press/PRArticle.aspx?NewsID=1328 (quoting Hon. Brad Miller).

19 153 CONG. REC. E 1438 (June 28, 2007) (statement of Rep. Waxman).

20 *Amending Executive Order 12,866: Good Governance or Regulatory Usurpation?: Hearing Before the Subcomm. on Investigation and Oversight of the H. Comm. on Science and Technology*, 110th Cong. 9 (2007) (Statement of Sally Katzen, Adjunct Professor, University of Michigan Law School), *available at* http://democrats.science.house.gov/Media//File/Commdocs/hearings/2007/oversight/13feb/katzen_testimony.pdf.

21 Exec. Order No. 12,291, 3 C.F.R. 127 (1982).

questions[22]—but they also complained that OMB review would impede agencies' ability to make new regulations.[23] A widely cited article published in the *Harvard Law Review* during the Reagan years declared that "OMB control imposes costly delays that are paid for through the decreased health and safety of the American public."[24] Even after President Clinton changed the Reagan Order to reserve OMB review for a more limited set of significant rules and to place time limits on the review process,[25] scholars continue to

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22 *See, e.g.*, Morton Rosenberg, *Beyond the Limits of Executive Power: Presidential Control of Agency Rulemaking Under Executive Order 12,291*, 80 MICH. L. REV. 193 (1981).

23 Felicity Barringer, *If Rules Are Made To Be Broken, So Are Rulemakers*, WASH. POST, June 25, 1981, at A21 (describing the Reagan Order as "requiring further delays and studies of all pending rules"); Philip Shabecoff, *Reagan Order on Cost-Benefit Analysis Stirs Economic and Political Debate*, N.Y. TIMES, Nov. 7, 1981, at 28 (noting that the Reagan Administration had issued only about thirty new major regulations compared with "100 to 200 such major regulations" in previous years, and quoting observers who suggested that OMB review was "stemming regulation" and serving as a means to "obstruct regulations"). *See also* Christopher C. DeMuth & Douglas H. Ginsburg, *White House Review of Agency Rulemaking*, 99 HARV. L. REV. 1075, 1087-88 (1986) ("[M]ost criticism has focused . . . on the delay that OMB review entails."); OMB Watch, OMB Control of Rulemaking: The End of Public Access 13 (Aug. 1985) (on file with author) ("The required cost/benefit analyses impose[ ] often heavy burdens on the regulatory agencies"). Even earlier efforts of presidential oversight were said to obstruct rulemaking. *See* OMB Watch, *supra* at 3 (stating that Nixon's "[h]ighly controversial" review process stood "accused of delaying the already lengthy environmental regulatory process").

24 Alan B. Morrison, *OMB Interference with Agency Rulemaking: The Wrong Way To Write a Regulation*, 99 HARV. L. REV. 1059, 1064 (1986). Publishing in the same issue of the *Harvard Law Review*, Christopher DeMuth and Douglas Ginsburg lauded OMB review because it "encourages policy coordination, greater political accountability, and more balanced regulatory decisions." DeMuth & Ginsburg, *supra* note 23, at 1081. DeMuth and Ginsburg both served as Administrators of the Office of Information and Regulatory Affairs within OMB. DeMuth & Ginsburg, *supra* at 1075. Their claims, and those of other supporters of OMB review, can and should be scrutinized along with the claims of critics—especially since empirical studies generally "have failed to show that economic analysis and OMB review have significant effects on the cost-effectiveness of government regulations." Cary Coglianese, *Empirical Analysis and Administrative Law*, 2002 U. ILL. L. REV. 1111, 1123 (2002). *See also id*. at 1123 nn.54-57 (citing studies of the impact of economic analysis on regulatory decisions).

25 The Reagan Executive Order required agencies to submit *all* rules to OMB for review. Exec. Order No. 12,291, §§ 3(c)(3), 3(e)(2)(C), 3(f)(2). In contrast, the Clinton Executive Order only required agencies to submit *significant* rules to OMB. Exec. Order No. 12,866 §§ 6(a)(3)(A), 6(a)(3)(B), 6(b)(1). Furthermore, unlike the Reagan Order, the Clinton Order stated that when reviewing proposed and final rules

claim that OMB review slows down the regulatory process, and even grinds it to a halt in certain instances.[26]

OMB review is not the only procedure to stand accused of obstruction. What critics say about OMB generally, and 13,422 specifically, mirrors the charges leveled against many other administrative procedures. For example, environmental impact statements required by the National Environmental Policy Act purportedly postpone many federal actions.[27] The Freedom of Information Act allegedly imposes high costs on federal agencies.[28] Critics of recent proposals for peer review and other checks on information

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"OIRA shall . . . notify the agency in writing of the results of its review . . . within 90 calendar days." Exec. Order No. 12,866 § 6(b)(2), 3 C.F.R. 638, 642 (1993), *reprinted in* 5 U.S.C. § 601.

26 *See, e.g.*, Richard B. Stewart, *Administrative Law in the Twenty-First Century*, 78 N.Y.U. L. REV. 437, 447 (2003) ("OMB regulatory analysis and other forms of regulatory impact review have also contributed to 'paralysis by analysis.' Agencies increasingly turn to less formal, less accountable, and more opaque methods of making regulatory policy."). It has even been said that "OMB's review of agency rulemaking has proved far more intrusive during the 1980s and early 1990s than either judicial or congressional review." Thomas O. McGarity, *Some Thoughts on "Deossifying" the Rulemaking Proces*s, 41 DUKE L.J. 1385, 1429 (1992).

27 *See, e.g.*, Sharon Buccino, *NEPA Under Assault: Congressional and Administrative Proposals Would Weaken Environmental Review and Public Participation*, 12 N.Y.U. ENVTL. L.J. 50, 52 (2003) ("Some critics blame the NEPA process for delay and inefficiency."); Bradley C. Karkkainen, *Toward a Smarter NEPA: Monitoring and Managing Government's Environmental Performance*, 102 COLUM. L. REV. 903, 906-7 (2002) (NEPA "demands the impossible" and "places extreme demands on agency resources"); James T.B. Tripp & Nathan G. Alley, *Streamlining NEPA's Environmental Review Process: Suggestions for Agency Reform*, 12 N.Y.U. ENVTL. L.J. 74, 75 (2003) ("[C]ommentators and the agencies bound by [NEPA's] requirements have often decried the Act as a time- and resource-consuming annoyance.").

28 *See, e.g.*, Antonin Scalia, *The Freedom of Information Act Has No Clothes*, REGULATION, Mar./Apr. 1982, at 15, 16 (FOIA requests "have greatly burdened investigative agencies"). Scalia's argument against FOIA, along with criticisms of delays caused by NEPA, suggest how arguments about the burden of administrative procedures can cut across ideological lines.

quality claim that they will unduly delay regulatory policy-making.[29] It has become widely accepted that judicial review under the arbitrary and capricious standard has "burdened, dislocated, and ultimately paralyzed" certain agencies' rulemaking.[30]

"Paralysis by analysis" has become a cliché in regulatory circles today.[31] This appealing rhyme, though, is itself far from new, dating at least to the first half of the twentieth century when it appeared in religious sermons and writings.[32] The underlying

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29 *See, e.g.*, Thomas O. McGarity, *Our Science is Sound Science and Their Science is Junk Science: Science-Based Strategies for Avoiding Accountability and Responsibility for Risk-Producing Products and Activities*, 52 KAN. L. REV. 897, 935 (2004) (arguing that "the result [of the Information Quality Act] can only be added expense and delay in the decisionmaking process"); J.B. Ruhl & James Salzman, *In Defense of Regulatory Peer Review*, 84 WASH. U. L. REV. 1, 6 (2006) (quoting a critic of peer review who predicted that regulatory peer review will "introduce potentially massive costs and delay, thus injecting paralysis by analysis into the regulatory process").

30 Jerry L. Mashaw & David Harfst, *Inside the National Highway Traffic Safety Administration: Legal Determinants of Bureaucratic Organization and Performance*, 57 U. CHI. L. REV. 443, 443 (1990). *See also* Cass R. Sunstein & Adrian Vermeule, *Interpretation and Institutions*, 101 MICH. L. REV. 885, 932 (2003) ("[Judicial] review has contributed to the 'ossification' of notice-and-comment rulemaking, which now takes years, in part as a result of the effort to fend off judicial challenges. In light of the risk of invalidation, many agencies have turned away from notice-and-comment rulemaking altogether.").

31 *See, e.g.*, Daniel A. Farber, *Rethinking Regulatory Reform After* American Trucking, 23 PACE L. REV. 43, 51 (2002) ("Environmentalists respond that cost-benefit analysis is a recipe for 'paralysis by analysis.'"); Thomas O. McGarity, *The APA at Fifty: The Expanded Debate over the Future of the Regulatory State*, 63 U. CHI. L. REV. 1463, 1523 (1996) (noting the "fear that many of the cognitive regulatory reforms . . . will lead to 'paralysis by analysis'"); Chris Mooney, *Paralysis by Analysis*, WASH. MONTHLY, May 2004, at 23, *available at* http://www.washingtonmonthly.com/features/2004/0405.mooney.html.

32 *See, e.g.*, ELI STANLEY JONES, THE CHRIST OF EVERY ROAD: A STUDY IN PENTECOST 40 (1930). Although the phrase appears to have been employed most commonly by Christian writers and preachers during the early part of the twentieth century, it came into more general usage after Martin Luther King, Jr. made it part of his call for racial justice. *See* MARTIN LUTHER KING, JR., STRENGTH TO LOVE 17 (1963). The rhyme appeared within the pages of the *Federal Register* as early as in 1952, used by a Republican appointee to the Federal Communications Commission. *See* Dissenting Opinion of Comm'r Robert F. Jones, 17 Fed. Reg. 4093, 4094 (1952) ("The Commission has had the paralysis of analysis for 1 year, not consumed in drafting the general rules and standards [for television service], but consumed in a search for a city-to-city allocation plan which it can freeze on the country by rule-making proceedings.").

concern the rhyme conveys about administrative process also dates back to the early part of the last century. In an article published in the *Harvard Law Review* in 1938, an administrative law scholar asked whether New Deal changes in rulemaking procedures would lead at least to "a partial paralysis . . . by reason of excessive formality and litigation."[33]

At the time of the New Deal, proposals for government-wide procedural reform triggered the "fear of unduly hampering" agencies."[34] Of course, today the informal rulemaking provisions of the Administrative Procedure Act (APA) of 1946 are held up as a model of administrative simplicity and efficiency,[35] only to have been spoiled by developments in judicial and regulatory oversight in the last several decades.[36] It is little known that the APA was itself once viewed as a major source of ossification. Scholars in the 1940s feared that its uniform procedures would "severely cramp the style of government regulation."[37] The right to file a rulemaking petition under § 553(e) was of

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33 Ralph F. Fuchs, *Procedure in Administrative Rule-Making*, 52 HARV. L. REV. 259, 280 (1938).

34 *Administrative Law—Developments 1940-45*, 44 MICH. L. REV. 797, 803 (1946).

35 KENNETH CULP DAVIS, ADMINISTRATIVE LAW TREATISE 283 (1970) (describing informal rulemaking under the APA as being among the "greatest inventions of modern government"). This phrase of Davis's continues to be quoted today.

36 McGarity, *supra* note 26, at 1385 ("Professor Kenneth Culp Davis captured the prevailing sentiment . . . when he called informal rulemaking 'one of the greatest inventions of modern government.' Twenty years later, the bloom is off the rose. . . .[The] rulemaking process has become increasingly rigid and burdensome [due to an] assortment of analytical requirements . . . and evolving judicial doctrines . . . .") (citation omitted).

37 Fritz Morstein Marx, *Some Aspects of Legal Work in Administrative Agencies*, 96 U. PA. L. REV. 354, 354 n.2 (1948).

"doubtful value," especially since agencies could be "swamped by frivolous requests having delay as their sole objective."[38] It is hard to imagine now, but at the time of the APA's adoption some academic observers forecasted "disastrous" effects from the law, characterizing the Act as nothing short of a "sabotage of the administrative process."[39]

III. The Reality of Regulatory Growth

So we have heard complaints about procedural burdens many times before. What, then, should we make of the rhetorical similarities between criticisms of 13,422 and of administrative procedures more generally? The perennial nature of the refrain about delay and obstruction might well make anyone suspicious that the criticisms of 13,422 are nothing more than the rhetorical ploy trotted out by the opponents of any reform. But as Hirschman reminds us, the mere fact that a rhetorical argument is repeated or even overused does not necessarily make it wrong.[40] The impact of OMB review, with or without 13,422, is ultimately an empirical question that requires looking at what agencies have actually done in terms of rulemaking.[41]

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38 Foster H. Sherwood, *The Federal Administrative Procedure Act*, 41 AM. POL. SCI. REV. 271, 279 (1947).

39 Frederick F. Blachly & Miriam E. Oatman, *Sabotage of the Administrative Process*, 6 PUB. ADMIN. REV. 213, 213 (1946).

40 HIRSCHMAN, *supra* note 9, at 166.

41 *See generally* Coglianese, *supra* note 24.

Yet here is where suspicions about the rhetoric of paralysis grow strongest, because the regulatory state has increased considerably in size and impact since the establishment of the APA and subsequent reforms, including OMB review. The sheer volume of rules, as measured by pages in the Code of Federal Regulations (CFR), has increased about five times since 1946 and has continued to grow since the advent of OMB review. For the past couple of decades, the federal government has issued an average of about 4,000 new rules each year in the *Federal Register*. The 2006 CFR contains about 33% more pages than did the 1980 volume of the CFR.[42]

Pages of rules are only one way to measure regulatory activity. When estimated monetarily, the impact of federal regulation has also increased. Not only do new rules deliver substantial benefits to society, they also impose substantial costs. According to the estimates collected by OMB during its review process, government regulations issued since 1981 have imposed $127 billion in annual costs on the economy.[43] According to a retrospective study conducted by the National Highway Traffic Safety Administration, the

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42 The values reported in this paragraph draw on data on file with the author that were collected by and obtained from the Office of the Federal Register. A recent study by Anne Joseph O'Connell similarly "calls into question much of the existing debate on regulatory 'ossification'" and reports data on rulemaking frequency that "strongly suggest that the administrative state is not ossified." Anne Joseph O'Connell, *Political Cycles of Rulemaking: An Empirical Portrait of the Modern Administrative State*, 94 VA. L. REV. (forthcoming June 2008).

43 OFFICE OF MGMT. & BUDGET, DRAFT 2007 REPORT TO CONGRESS ON THE COSTS AND BENEFITS OF FEDERAL REGULATIONS 34 (2007), *available at* http://www.whitehouse.gov/omb/inforeg/2007_cb/2007_draft_cb_report.pdf. The same report indicates that annual average regulatory costs have tended to be lower during the second Bush Administration than during previous administrations, although of course these data precede the issuance of Executive Order 13,422. *Id.*

annual costs attributable to mandatory federal auto safety standards have increased from $255 per car during the 1968-78 period to $760 per car in the 1991-2001 period, even controlling for inflation.[44] An independent study has reported that the annual costs associated with environmental regulations more than quadrupled between 1972 and 1992, roughly a decade before and a decade after the establishment of OMB review.[45]

Given the overall increase in pages of regulation and their costs, government regulators have clearly not been paralyzed. Have they nevertheless been hobbled? Is it possible that regulatory growth would have been greater still in the absence of OMB review? Several empirical studies have tried to determine whether OMB review slows down the rulemaking process, thus making it harder for agencies to issue as many rules as they otherwise would. Although it might seem intuitive that OMB review would increase the time and expense of issuing new rules, researchers have not found systematic evidence that OMB review imposes any significant delay on the regulatory process, notwithstanding careful analysis of both large-sample datasets and matched case studies. For example, political scientists Cornelius Kerwin and Scott Furlong published a regression analysis of the determinants of EPA rulemaking duration in which they found little by way of any

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44 Marcia J. Tarbet, Cost and Weight Added by the Federal Motor Vehicle Safety Standards for Model Years 1968-2001 in Passenger Cars and Light Trucks, NHTSA Report No. DOT HS 809 834 at 145, Table 5A, *available at* http://www.nhtsa.dot.gov/cars/rules/regrev/Evaluate/809834.html (reporting all data on unit costs in 2002 dollars).

45 Adam B. Jaffe et al., *Environmental Regulation and the Competitiveness of U.S. Manufacturing: What Does the Evidence Tell Us?*, 33 J. ECON. LIT. 132, 140 (1995).

statistically significant effect from OMB review.[46] Stuart Shapiro, another social scientist, analyzed a series of matched *state* agencies and found that even seemingly cumbersome rulemaking procedures, like economic analysis review, did not affect the rate of regulatory change, although the partisan control of the political branches did.[47] More recently, political scientist Steven Balla and his colleagues studied the determinants of the duration of OMB review and found that, contrary to claims that special interests try to capture OMB review to delay rules, reviews were actually shorter when only narrow sets of businesses were in contact with OMB.[48] To be sure, no broad-based empirical study can rule out that

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46 Cornelius M. Kerwin & Scott R. Furlong, *Time and Rulemaking: An Empirical Test of Theory*, 2 J. PUB. ADMIN. RES. & THEORY 113 (1992). The Kerwin and Furlong study analyzed determinants of the duration of 150 non-routine U.S. Environmental Protection Agency (EPA) rules issued during the period October 1, 1986 through September 30, 1989, drawing on data collected from the EPA's internal regulatory management system. *Id*. at 122. The authors reported results from three separate regression models. In two of these models, the OMB review variable was not significant at all. *Id*. at 130. In the model of duration between proposed and final rules, OMB review was statistically significant, but only had an effect that for every day a rule was under OMB review, the duration of the process was lengthened by two days. *Id*. Even with this one apparent statistical relationship, the variable for OMB review could be serving as at least a partial proxy for the overall complexity or political salience of rules. *Id*. at 132. In other words, at least part of any statistically observed delay may stem from the fact that rules that go to OMB for review are simply more complex and controversial to begin with than the ordinary rule.

47 Stuart Shapiro, *Speed Bumps and Roadblocks: Procedural Controls and Regulatory Change*, 12 J. PUB. RES. & THEORY 29 (2002). Shapiro studied day care regulation in eight states, selecting states in pairs that otherwise were geographically and economically similar. He chose to study day care regulation because it is a domain that has largely escaped federal preemption, thus helping to maximize the possibility of variation across states. Contrary to prior expectations, Shapiro found that regulators in states with purportedly cumbersome regulatory procedures were not deterred from issuing new regulations. Instead, he found that the key determinant of the level of regulatory activity was the political environment within the states. When the political alignment in the legislature and executive branch favored regulatory change, change generally occurred, even in states with higher procedural hurdles. *Id*.

48 Steven J. Balla et al., Outside Communication and OMB Review of Agency Regulations, presented at the 2006 annual Midwest Political Science Association meeting, Chicago, Illinois. The authors examined nearly 2,000 OMB reviews undertaken from 2002 through 2004 to determine whether contacts between OMB and outside parties over specific rules tended to correspond with the duration of OMB review of those rules. *Id*. at 6. Based on OMB logs of staff contact with outside parties, the authors reported that

OMB review might have the effect of slowing the issuance of an individual rule now and then. The existing work does fail, though, to find clear evidence of any *general* effects consistent with the *general* rhetorical claims made about OMB review.[49]

IV. Explaining the Rhetoric-Reality Divergence

How, then, can the bold rhetoric about 13,422 and OMB review be reconciled with the stark reality of continued and substantial outflows of regulation from the federal government? Perhaps additional research is needed to uncover the real, but more subtle effects that procedures like these have on regulatory behavior. Or perhaps OMB review truly has failed to delay rulemaking so far, but the implementation of 13,422 will take the administrative process past a tipping point to where rulemaking does finally begin to slow down, if not grind to a standstill. Or perhaps ultimately the rhetoric surrounding 13,422 and OMB review is just that, rhetoric.[50]

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contacts took place in only about 7% of the rules. *Id*. Although reviews where contacts occurred did take longer on average than reviews without any contacts, once other variables were controlled for, contacts with business groups were not associated with a lengthening of the OMB review process. As Balla et al. state, "contrary to widely held expectations, . . . outside communications do not operate in a way that particularly advantages business firms and trade associations seeking to derail prospective agency regulations." *Id*. at 15.

49 *See* MATTHEW D. ADLER & ERIC A. POSNER, NEW FOUNDATIONS OF COST-BENEFIT ANALYSIS 87 (2006) (noting that "existing evidence and the political economy of rulemaking call into question the claim that [cost-benefit analysis] produces substantial incremental delay"). In one recent paper, two political scientists report results suggesting that OMB review can "actually speed up agency rulemaking—a finding directly contrary to what ossification theory predicts." Jason Webb Yackee & Susan Webb Yackee, Is Federal Agency Rulemaking "Ossified"? The Effects of Procedural Constraints on Agency Policymaking, paper presented at the 2007 meeting of the Midwest Political Science Association, at 24 (on file with the author).

50 *See* CURTIS W. COPELAND, CHANGES TO THE OMB REGULATORY REVIEW PROCESS BY EXECUTIVE ORDER 13,422, at 5 (Congressional Research Service No. RL33862, Feb. 5, 2007) (noting that

These are all certainly possibilities. But I find more interesting three other possible explanations that might offer theoretical insights about the relationship between administrative procedures and regulatory decision-making. The first possibility might be that administrative procedures like 13,422 are epiphenomenal, or at least so highly malleable to make them merely symbolic. That is, rulemaking procedures may look like they impose burdens on agencies, but the real burdens depend entirely on whether or how they are implemented—not on the existence of procedure *qua* procedure. As a result, an administration that wants to regulate a lot will regulate a lot, and an administration that wants to slow down regulation will slow down regulation—regardless of what procedures are on the books.[51]

A second possible account is that the behavioral effect of a law or procedure is real, rather than illusory, but just simply trivial (at least for certain effects of interest). For example, even if state laws requiring consumers to pay a five-cent deposit for soda bottles and cans reduce roadside litter and increase recycling, it is hard to see that these so-called bottle bills place any meaningful barrier in the way of the purchase of soda, and hence it

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"concerns about the usurpation of congressional standards for rulemaking and unnecessary delay may be exaggerated"). *See also* Stuart Shapiro, *The Role of Procedural Controls in OSHA's Ergonomics Rulemaking*, 67 PUB. ADMIN. REV. 688, 697 (2007) (describing the limited, even symbolic, role of various procedural steps in the development of OSHA's ergonomics rule in the 1990s).

51 Stuart Shapiro has suggested as much, concluding that "the new regulatory procedures [put in place during the Bush-II administration] may either be irrelevant to regulatory outcomes or may be used by future pro-regulatory presidents to achieve their own regulatory goals." Stuart Shapiro, *Presidents and Process: A Comparison of the Regulatory Process under the Clinton and Bush (43) Administrations* 22, (AEI-Brookings Joint Center for Regulatory Studies, Working Paper No. 06-30), *available at* http://aei-brookings.org/admin/authorpdfs/redirect-safely.php?fname=../pdffiles/RP06-30_topost.pdf.

seems unlikely they would lead to any discernible decline in soda sales in states after these laws are adopted.[52] In a similar vein, some administrative procedures probably have only trivial effects on rulemaking because agencies can satisfy them by publishing boilerplate language in their *Federal Register* notices. If agencies come to satisfy 13,422's new written problem statement requirement using boilerplate language or by creating check-boxes on a form, the requirement's impact will surely be inconsequential in terms of the pace and cost of rulemaking.

A third possibility is that procedures do have both real and consequential effects, but these effects are drowned out by other behavioral factors moving in the same direction. For instance, on the assumption that Reagan's regulatory review order was truly more burdensome than Clinton's Order,[53] the additional burden may not have had much of an effect on agency behavior in an administration where appointees were already less inclined to regulate. If it turned out that agencies issued fewer or less costly rules during the Reagan Administration than the Clinton Administration, these results may well have stemmed not so much from procedure than from the ideology of the political appointees heading the agencies.

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52 In other words, while a price increase can have real effects on purchasing behavior, it would be hard to imagine the demand for soda is so highly elastic that a five-cent deposit has anything but the most trivial effect on overall sales.

53 *See supra* note 25. For a further discussion of some of the differences between the Reagan and Clinton Orders, see Steven Croley, *White House Review of Agency Rulemaking: An Empirical Investigation*, 70 U. CHI. L. REV. 821, 827-29, 849-50 (2003).

For much the same reason, if other legal rules, professional norms, or political exigencies already are pushing agencies to take benefit-cost analysis seriously—something Cass Sunstein has suggested[54]—then any additional, incremental stringency of a regulatory review order may yield at best only a small and diminishing behavioral return. In other words, if agencies are already, for other reasons, engaging in exactly the kind of analysis called for by the new Executive Order, the Order will impose no (or negligible) additional costs and delays. To predict the extent of any delay from 13,422's provisions on guidance documents, for example, we need to know more about what analysis of these non-binding documents agencies conduct anyway. It would not be surprising to discover that many agencies already conduct analysis of their most significant guidance documents, precisely the ones covered by the new Executive Order. If this is true, the additional time and effort needed to satisfy OMB review under 13,422 will most certainly turn out to be much smaller than has been widely imagined.[55]

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54 CASS R. SUNSTEIN, THE COST-BENEFIT STATE (2002).

55 Moreover, OMB's review of significant guidance documents may turn out to be much more limited than critics apparently assume it will be. *See* OMB Regulatory Policy Chief Anticipates New Draft of Risk Assessment Guidance, BNA Daily Report for Executives, May 10, 2007, at A-24 (quoting OMB regulatory director, Susan Dudley, as anticipating review of guidance documents will be "a quick turnaround thing. . .not the same as [reviewing] a regulation."). If so, it seems still more conceivable that agencies' pre-existing level of analysis behind guidance documents will often satisfy OMB, thus rendering 13,422's new requirement largely superfluous.

Conclusion

For these reasons, scholars and policy decision makers should exercise caution before concluding that Executive Order 13,422 will have anything more than the most minor effects on actual agency operations. The Order's requirement for a written problem statement and its provisions calling for OMB review of guidance documents, for example, may well be easily met or add only superfluously to what agencies already do. Such an outcome would be consistent with the longstanding disjunction between the rhetoric and reality of regulatory reform. Alarms of delay and paralysis have sounded in response to nearly every major regulatory reform since the establishment of the Administrative Procedure Act of 1946—and yet the regulatory state has nevertheless marched rather dramatically onward over the last six decades.

As it applies to the operation of government bureaucracies, administrative law is embedded within a complex web of politics, institutions, and organizational behavior. Within this web, law is but one factor influencing behavior in government agencies among a variety of institutional, professional, social, financial, and political factors that interact with each other, and even adapt and change over time. Social scientists who have devoted their careers to the empirical study of bureaucracy have yet to create a parsimonious theory of bureaucratic behavior.[56] Their failure to do so, combined with the obvious expansion of

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56 JAMES Q. WILSON, BUREAUCRACY: WHAT GOVERNMENT AGENCIES DO AND WHY THEY DO IT xi (1989) ("After all these decades of wrestling with the subject, I have come to have grave doubts that anything worth calling 'organization theory' will ever exist.").

regulation in the face of repeated warnings to the contrary, should make both institutional designers and their critics more circumspect about their predictions—and their rhetoric—concerning the impact of regulatory reform.

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DEREGULATION

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1. Introduction

Over the last thirty years the U.S. and many other countries have experienced a revolution in the extent and nature of the mechanisms used by government to regulate the structure, behavior and performance of many markets for goods and services (Winston 1993, 2006; Peltzman and Winston 2000; Joskow 2004). This era of reform is often referred to as the era of "deregulation." However, the phrase "deregulation" is a simplistic characterization of a much more complex process that involved the relaxation of government controls over prices and entry, industry restructuring to facilitate competition in some industry segments and better regulation in others, stricter but more effective environmental regulation, and ongoing efforts to find ways to improve the performance of product quality and safety and workplace safety regulations to increase the net benefits to consumers. Many of these reforms have been beneficial to our economy and ongoing reforms have the promise of further enhancing economic performance.

The generally favorable assessments of regulatory reform over the last thirty years have been tainted by the ongoing financial market crisis and its adverse effects on the real economy. There is what seems to be an ever growing list of explanations for the causes of the ongoing financial market mess. There is an even longer list of proposed

[1] This paper was the basis of the 2009 Distinguished Lecture sponsored by the AEI Center for Regulatory and Market Studies on February 10, 2009. The views expressed here are my own and do not reflect those of the Alfred P. Sloan Foundation, MIT or any other organization with which I am affiliated.

regulatory, institutional, and governance reform initiatives to mitigate the problems in the short run and keep them from reoccurring in the long run. The ongoing financial market crisis was clearly caused by a combination of public policy failures reinforced by behavioral failures by private sector financial institutions, intermediaries, rating agencies, creditors, and regulators. However, my own view is that we still do not yet fully understand these public policy and private sector failures and the interactions between them that caused the problems. We necessarily know even less about the appropriate long run public policy and private sector institutional reforms to keep these problems from emerging again. As with the Great Depression, scholars will be studying this period for many years. Similarly, if history is any guide, the rush to implement public and private sector policy reforms to respond to the immediate crisis without fully understanding its causes and then developing comprehensive reforms to fix the market failures is likely to lead to at least some "quick and dirty" regulatory initiatives that fail to solve the problems and may even make them worse. This is especially problematic in the case of financial product, financial institution, and financial market regulation because the relevant markets are global.

Ironically, one of the few important sectors of the economy that has not been subject to comprehensive regulatory reform during the last thirty years is the financial services sector and the associated financial products and financial markets where they are traded. Yet financial institutions, financial instruments, the markets where they are trade, and the geographical expanse of trading have all changed dramatically over the last thirty years. While it has become routine to place a large share of the blame for the current financial crisis on "deregulation," the list of state and federal regulatory agencies with

jurisdiction over banks, insurance companies, brokerage firms, mutual funds, hedge funds and other financial institutions, the products and markets where they trade is as long as my left arm. The one thing that we can be sure of is that we have no shortage of regulatory agencies with overlapping responsibilities for investor protection, financial market behavior and performance, and systemic risk mitigation (prudential regulation) that collectively were supposed to work to keep this kind of financial market mess, as well as scams that were allegedly employed by Madoff and others, from occurring. These regulatory agencies have overlapping jurisdictions, opaque goals, arbitrarily limited authorities, and histories that can often be traced back to Great Depression era financial markets and economic conditions. These regulatory institutions have evolved over the last seventy-five years in a haphazard fashion that has not responded effectively to the evolution of financial institutions, products, and markets but more as a series of fingers in the dike to try to keep new leaks from damaging the integrity of the entire dam. Regulatory changes, such as the 1999 repeal of the provision of the Glass-Steagall Act of 1933 that prohibited bank holding companies from other types of financial services companies, the SEC's decision ton end of the uptick rule for short sales, and decisions to allow "sophisticated investors" to fend for themselves, have been idiosyncratic. The reforms have been idiosyncratic (and initially cautious, such as the repeal of Regulation Q in 1980) and increasingly driven more by ideology as financial markets began to change quickly than by the kind of comprehensive framework for regulatory reform that has now become widely accepted by microeconomists in other industry contexts.

I think that history will show that there is plenty of blame to go around for the current financial mess, implicating diverse interest groups, legislators, regulators, and the

administrations which appointed them. In hindsight they will encompass ideological perspectives from the left to the right. Blaming these problems simplistically on "deregulation" of financial instruments, financial markets and financial institutions will not prove to be a useful framework for identifying good public policy reforms in this area. Accordingly, the policy problems that contributed to the current financial market crisis are more properly conceptualized as a failure to engage in comprehensive reform of the entire regulatory framework governing financial institutions, products and markets to better match the development of new financial instruments, trading platforms, market participants, and the globalization of financial markets rather than as "deregulation." Some new regulations that were intended to control financial risk (e.g. bank capital requirements under Basel II) may have actually contributed to the financial crisis by creating incentives to create financial instruments (e.g. credit default swaps) that appeared to turn certain risky assets into safe Tier I capital. Poorly designed regulatory instruments can make a potentially bad situation worse.

But my talk today is not primarily about the financial market crisis and the short run and long run policies that are appropriate to stop the bleeding in the short run and to respond to the lessons that have and will be learned from it with appropriate public and private regulatory and institutional reforms. Rather, it reflects my concern that the ongoing efforts to understand and resolve the financial market crisis, and what appears to be a widely accepted view that it can be blamed generically on "deregulation" and a "free market" mentality, is gradually being used as a platform by opponents of market liberalization generally for launching a "reregulation" process in many other sectors of the economy that were "deregulated" over the last three decades. This au courant and

undifferentiated trashing of “deregulation” more generally in the media has in turn provided a convenient opportunity for those self-interested in “reregulating” other industries and sectors or slowing down ongoing regulatory policy reforms to blame “deregulation” for a long list of problems in order to feather their own nests..

Let me note as well that the modern deregulation, industry restructuring and regulatory reform era did not start with George Bush or Ronald Reagan. If one must date it, the market liberalization and regulatory reform era started with Jimmy Carter and has been pursued by centrist Democrats and Republicans since then. Many of the deregulation, market liberalization, and market-friendly regulatory reforms of the last thirty years in the U.S. and many other countries have yielded significant benefits for their citizens and their economies. While these reforms have certainly not been perfect, reversing most of them would be harmful to our economy in the aggregate, though they might feather the nests of some interest groups.

I fear that we may be at a cross-roads where we are moving from too much unprincipled relaxation of regulatory oversight in a few sectors to too much unprincipled and poorly designed regulation in many others. And I attribute part of the blame for this unfortunate situation to the increasingly mindless debates about the role of government in the economy based on ideology rather than on clear goals and careful theoretical and empirical analysis of both market imperfections and regulatory imperfections. This trend has been reinforced by the increasing ideological polarization of so-called “think tanks” and their increasing dependence on financial support from special interest groups. Of course, this Center has, from the beginning, stood for just the opposite --- objective analysis of important regulatory issues based on clearly articulated goals, careful

theoretical and empirical analysis, respect for principled differences of opinion, and willingness to change one's mind based on evidence. This is why I have been proud to have been associated with this Center from the beginning.

In this paper I will make and support several points:

1. I take as a given that even imperfectly competitive markets are extremely powerful institutions for allocating scarce resources efficiently both statically and dynamically. Few markets satisfy the structural, behavioral, or performance assumptions of textbook perfectly competitive market. Thus, markets are never perfect in this textbook sense, but they are typically better than the next best alternative.

2. There is a sound intellectual framework for evaluating when it makes sense to impose some form of government regulation on a particular market for goods and services, including regulation of financial institutions, financial products and financial markets. The framework requires a good theoretical and empirical understanding of market imperfections and regulatory imperfections and the costs of each. The issues here are not properly characterized as "regulation" vs. "deregulation," but rather involve the application of a disciplined framework for identifying the whether, where and how government regulatory policies can, on balance, improve market performance taking both the costs of market imperfections, the benefits of regulatory constraints associated with reducing these costs, and the costs of regulatory imperfections into account. The "regulation" vs. "deregulation" mantra reflects an ideological debate not a serious framework for evaluating the performance of real markets and real regulatory institutions. The proper framework for considering these issues is familiar to

serious microeconomists who have studied regulation, deregulation, and regulatory reforms of various kinds.

3. These framework can and should be applied to financial institutions, products and the markets reflecting the specific types of market and institutional attributes of these market institutions and any associated market imperfections. Financial markets do have special attributes and their performance broad implications for the performance of the rest of the economy. Accordingly, reasoning by analogy to ordinary markets for goods and services (e.g. surface freight transportation) to develop and apply a good regulatory and institutional framework for financial institutions, financial instruments and financial markets can be very dangerous.

4. Deregulation, privatization and regulatory reform initiatives, or the European term that I prefer, "market liberalization" initiatives, that have affected the markets for good and services in many sectors of the U.S. economy and those of other countries over the last three decades have generally been beneficial for the economy and for consumers. These benefits include lower costs, enhanced rates of product and process innovation, better matches between consumer preferences and product quality and safety, and more efficient price structures (not always lower prices as some of the worst regulatory programs kept prices too low and caused shortages). These market liberalization and regulatory reform initiatives have not always been successful (e.g. the privatization, restructuring and regulatory reform policies applied to the British railroad system), in the sense that they created more problems than they solved, and there is as much to learn from failed market liberalization efforts as from successful efforts.

Future regulatory reforms should be based on objective analysis of the costs of market imperfections, the benefits of alternative regulatory constraints aimed at mitigating these imperfections and the costs (direct, but more importantly, indirect) of alternative regulatory mechanisms, recognizing that both the costs and benefits are uncertain. Broad brush ideological calls for reregulation or deregulation are dangerous. The fundamental question that we should be seeking to answer is "what is the best that we can do in an imperfect world?"

. 5. Whatever conclusions one comes to about the need for and nature of regulation or deregulation or regulatory reform policies, these conclusion should be specific to particular industry, product, firm, and consumer decision making attributes specific and subject to periodic reevaluation as these attributes change and new information emerges about the performance of prevailing public and private institutions..

2. What is government regulation?

If we are going to think about deregulation I suppose that we should start by defining what "regulation" means. No markets in modern developed economies are completed "unregulated" by government-created institutions in any meaningful sense. Markets in all modern developed market economies operate within a basic set of governance institutions or what Williamson has called the basic institutions of capitalism (Williamson 1985). These include in the U.S., common law institutions like property rights, liability rules, contracts, and the institutions for enforcing them. There are also basic firm and market institutions created by statute, such as those created by corporate law, including the framework for creating limited liability corporations, antitrust laws,

bankruptcy laws, employment laws, environmental laws, etc. We can discuss the pros and cons of the details of alternative structures for these basic institutions of capitalism and how they are implemented and enforced, but there are no 21st century developed market economies without them, so spending a lot of time talking about doing away with them completely is not too constructive.

So, when we talk about regulation, deregulation, regulatory reform or market liberalization we are talking about it within a basic set of legal institutions that are general accepted as providing a "minimal" framework for markets to work well. What is it then that we are "regulation," "deregulating" or "liberalizing?"

Scholarly analysis of government regulation focused for many years on government regulation of price levels, price structures, and entry into markets for particular goods and services (Kahn (1970), Joskow (2007). These government regulatory actions are not included in the list of basic institutions of capitalism. Going back to the late 19th century, we can construct a long list of goods and services that have been subject to price and or entry regulation: oil, natural gas production, oil and natural gas pipeline transportation, telecommunications services, surface freight transportation, electricity supplies, interest rates, bus and street car services, water and sewer services, taxi prices, milk prices, residential rents, etc. While some of these price and entry regulations were justified as being necessary responses to the "natural monopoly problem," (Joskow 2007) one does not have to be too much of a free market advocate to find the natural monopoly argument for many of these goods and services to be implausible. Clearly there was something else going on there than protecting consumers from monopoly prices and inefficient duplication of network facilities. And what is

typically going on here is the consequence of powerful interest groups using the power of government to benefit them at the expense of others (Stigler 1971) and to hide the associated "taxation by regulation" in a complex and non-transparent regulatory process (Posner 1971).

Another dimension of government regulation has focused on product and service quality and safety and workplace safety. These regulations include information disclosure rules, licensing and certification procedures, quality standards, etc. At the federal level these regulations are implemented by a long list of regulatory agencies like the Federal Trade Commission (FTC), the Occupational Safety and Health Administration (OSHA), the National Highway Transportation Safety Commission (NHTSA), the Consumer Products Safety Commission (CPSC), the Food and Drug Administration (FDA), etc. The regulations that these agencies issue are typically also subject to a "gatekeeper" at the Office of Management and Budget (OMB) called the Office of Information and Regulatory Policy (OIRA) which is supposed to review the benefits and costs of regulations proposed by Executive branch agencies. Indeed, much of the criticism one hears about "deregulation" is more criticisms of how regulatory responsibilities are enforced and costs and benefits calculated and balanced. The economists' rationale for regulation in these areas turns on market imperfections associated with the provision and effective utilization of information necessary to make wise decisions; information costs, information processing costs, bounded rationality and transactions costs generally. As noted, in most of these cases the scholarly discussion turns less on whether there should be some type of regulation and more on identifying regulatory mechanisms that can help consumers and businesses to balance costs and

benefits of alternative levels of product quality and safety in risky environments characterized by imperfect and asymmetric information.

A third important area of government regulation is environmental regulation. And most of what we talk about in this area, at least at the federal level, has evolved over the last forty years. The federal government now regulates or can regulate, directly or indirectly, emissions of virtually everything into the air, water, and ground. Here again, the primary questions of interest have not been so much whether some type of regulation makes sense, but what is the most effective regulatory mechanism and how stringent should the regulations be? Answering the latter question in turn requires evaluations of regulatory costs and benefits and these are both uncertain and controvercial.

A fourth (or fourth and fifth) area of regulation of contemporary relevance involves regulatory requirements of various kinds placed on corporations, financial intermediaries, financial products and the financial markets where they are traded. It is useful to divide these regulations into regulations (arguably) motivated by "investor protection" goals and those motivated by "prudential" regulation goals, though the two cannot be separated completely. The Securities and Exchange Commission (SEC), the Commodities Futures Trading Commission (CFTC), and the Financial Industry Regulatory Authority (FINRA, formed in July 2007) fall in the "investor protection" category and the Federal Reserve Board (Fed) and the Federal Deposit Insurance Corporation (FDIC) fall in the prudential regulation category.

The responsibilities of the "investor protection" agencies, or at least the impacts of their efforts to fulfill their responsibilities, overlap as they affect the structure, behavior, and performance of financial products, financial intermediaries, the markets in

which they trade these products, and the information available to investors about both the products and the counterparties they deal with. Many of the regulatory agencies and regulations can be traced back to the Great Depression and reflect rationales similar to product quality and safety and workplace safety regulations. These regulations include financial disclosure rules, accounting rules, corporate governance rules, securities registration requirements, and the certification of securities ratings agencies.

The rationale here is the view that absent good information about the financial attributes of firms that issue securities to the public, associated accounting standards, appropriate financial products, and rules governing the behavior of financial markets and who can participate in them, investors will be unable to make wise investment decisions. As these regulations have evolved, they have also reflected a view that the "little guys" need more help than the "big guys" who are better able to obtain and process the information necessary to make wise investment decisions. In reality, financial service firms have also had a lot of political power to exert influence over how these regulatory institutions have evolved either to protect themselves from competition or from regulations that they find objectionable.

"Prudential regulation" of banks and other financial institutions has been introduced to dampen macroeconomic shocks caused by whatever they are caused by, including systemic credit market dysfunctions. Prudential regulation flows from the view that unregulated markets for financial services will not adequately control bubbles, bank runs, systemic risks, financial market collapses, and the adverse effects of dysfunctional credit markets on the real economy. I must point out how the development, analysis and implementation of regulation in this area has been relegated to the field of

macroeconomics and, to a lesser extent, finance economists, including international finance economists. It is striking how little of the learning about economic regulation and quality and safety regulation that has emerged over the last 40 years based on research by microeconomists has crossed the bridge into macro/finance land. The market imperfections vs. regulatory imperfections framework for examining the case for regulation and the choice of regulatory instruments that I will turn to presently has barely seeped into the area of prudential regulation.

Let me note here that while I have classified the SEC as, arguably, an investor protection regulatory agency, its actions can have implications for prudential regulatory issues as well in that its decisions may have implications for the kinds or magnitude of macroeconomic dislocations that are the motivation for prudential regulation because they affect the information available to investors and some aspects of the behavior of corporations, financial intermediaries and financial markets. However, it is not clear that the SEC, staffed heavily by lawyers and accountants, and focused historically on accounting standards, disclosure standards, and legal enforcement actions, had the capability to properly evaluate the wider impacts of some of its regulatory actions (e.g. the decision to end of the "uptick" rule for short-selling in July 2007, the focus on unsophisticated investors, and the predominance of an enforcement mentality rather than a monitoring and analytical perspective). This is simply one example of the failure of the U.S. to develop a comprehensive regulatory framework for the financial sector with clear goals, responsibilities and appropriate authorities.

3. Market Imperfections vs. Regulatory Imperfections

How do we make an intellectually respectable case for implementing various types of government regulation, for removing them, or for changing the way we regulate? Competitive markets are powerful mechanism for allocating resources efficiently. In a sense, competitive markets combined with the basic legal institutions of modern developed market economies represent the null hypothesis against which the case for additional regulation must be tested. The case for government regulatory interventions must start, but not stop, with the identification and quantification of one or more market imperfections (Winston 2006). It is impossible to regulate intelligently, even under the best of circumstances, if one cannot clearly articulate what the nature of the market imperfections are whose costs you are trying to ameliorate.

However, most markets are characterized by some type of market imperfection in this sense. Few if any markets are perfect in the sense that they satisfy the assumptions underlying textbook models of perfect competition or the performance associated with the textbook models of perfect competition. But the social costs of these market imperfections vary widely from the trivial to the very large --- compared to the performance of hypothetical textbook perfectly competitive markets, and ignoring for now the direct and indirect costs of trying to mitigate these market imperfections. The fact that one can identify one or more market imperfections does not make a case for imposing government regulations on the relevant market unless one believes in the existence of the benevolent perfectly informed regulator that we all know well from economic theory. If the benevolent perfectly informed government regulator existed in reality we would regulate every market. She does not exist.

Thus, we must look at the other side of the equation. What are the imperfections and costs of government regulatory mechanisms and institutions? On balance, when the benefits of reducing the costs of market imperfections are compared to the costs of regulation, are we on balance better off? Regulation carries with it its own costs --- direct implementation costs, but more importantly, indirect costs that can make market performance even worse than it was when we simply lived with imperfect markets without trying the improve performance by regulating them in some way. One of the worst mistakes made by policymakers is to assume that government regulatory institutions pursue some well-defined public interest, are well informed, can easily and costlessly mitigate the market imperfections identified and are not influenced by interest group politics.

The decision to regulate and the decision to change regulatory policies, whether it is to eliminate a set of regulatory constraints or to change the form of those constraints, must turn on a careful balancing of the likely costs of market imperfections and the likely costs of alternative forms of regulation designed to mitigate them (imperfectly). This assessment should be dynamic, recognizing that technological change will affect consumer, firm, product, process and industry attributes and, in turn, that regulation can affect the rate and direction of the changes in these attributes, often negatively, but sometimes positively.

The right approach to thinking about regulation and deregulation was articulated very clearly by my undergraduate advisor Alfred Kahn: What is the best that we can do in an imperfect world (Kahn 1979)?

There is a fairly standard list of market imperfections that may lead to a case for some form of enhanced government regulatory intervention.

a. Market power, with so-called natural monopoly being an extreme case (Joskow 2007). The political case for regulation here is probably stronger than the "welfare economics" case because voters are not indifferent to the apparent first-order distributional consequences of higher prices charged by monopolies. That is the "rectangles" related to the distribution impacts of monopoly pricing are much more important politically than are the Harberger "triangles" that measure dead-weight losses. Of course, the welfare analysis becomes more interesting when we recognize that a monopoly is likely to expend some of the monopoly rents on costly strategies to protect its monopoly position.

b. Externalities arising from the positive and negative impacts of agents' behavior on others that are not fully reflected in their supply and consumption decisions. Environmental regulation is the standard case. Externality problems are ultimately "missing market" problems arising from the transactions costs of internalizing these positive and negative impacts through bilateral bargaining in the presence of basic common law institutions of property rights, torts and contracts (Coase 1960). I suspect as well that prudential regulation of banks and other financial intermediaries is motivated by externality issues related to the social costs of systemic collapses of financial markets, though it would be helpful to have a clear definition of systemic risk, what causes it, and what it's costs are in, order to better inform the design of both investor protection and prudential regulation institutions.

c. Information costs, information asymmetries and consumer/investor decisionmaking imperfections, bounded rationality and transaction costs generally (Williamson 1975).

d. Incomplete contracts arising from bounded rationality and transactions costs (Williamson 1985, Joskow 1987).

e. Corporate governance imperfections arising from the separation of ownership and control associated with large modern public corporations.

The last three all lead to well studied moral hazard and asymmetric information problems that can be very costly (problems that may exist naturally in some markets or can be created by government regulatory imperfections in others).

And the list of market imperfections goes on ….

But the imperfections and associated costs of government regulatory policies designed to mitigate these market imperfections must be carefully articulated and measured as well. These direct and indirect costs of government regulation must be part of any sensible cost benefit analysis of regulation, deregulation, or regulatory reform. As I have already emphasized, the perfectly informed regulator that rigorously pursues a widely accepted articulation of the public interest does not exist in reality. Good and effective regulation that improves upon even imperfect market outcomes is difficult indeed. This is a consequence of the realities of regulation in practice:

a. Even if they have the right goals, regulators are necessarily imperfectly informed about the firm and consumer attributes, including attitudes toward risk, that are necessary, even in theory, to regulate well (Laffont and Tirole 1993, Joskow 2007). Indeed, regulators are typically less well informed than are the firms that they regulate,

and often less well informed about the attributes of the consumers they may be seeking to protect, leading to the potential for costly distortions in costs, product attributes, and the rate and direction of innovation (regulator induced moral hazard)

b. The regulatory process is characterized by bureaucratic costs, can take long periods of time to make decisions, and is inherently conservative in its treatment of new product and process technologies, risk, and new and better ways of regulating. Regulators also easily become self-protective of the traditional regulatory mechanisms that characterize the status quo of the importance of their places in the world. This becomes more and more of a problem as regulatory agencies age.

c. The regulatory process is subject to interest group capture, political influence, and tremendous pressure to engage in (hidden) taxation by regulation (Stigler 1971, Posner 1971, Noll 1989). The modern field of political economy based on rational actor models of political behavior did not start with studies of regulation by accident. This phenomenon goes well beyond simplistic models of capture by regulated firms and reflects the fact that regulatory agencies have things that they can do to help one interest group and harm others, naturally leading them to become targets of political competition. This phenomenon is exacerbated over time as young “expert” regulatory agencies become dominated by commissioners and senior staff who have come up through the political process and are sensitive to the same political considerations as are their sponsors in the executive and legislative branches. In my view, this has become a more serious problem over time as “independent” regulatory agencies once heavily populated by reasonably independent technocratic experts with clear goals have increasingly come

to be populated by commissioners and senior staff with narrower political goals ---- whether it is on the right or on the left.

A useful framework for evaluating proposals to regulate, to deregulate and the change the way be regulate can be captured by asking and answering a set of simple questions, though providing precise answers to these questions may often be quite difficult. I will articulate the questions from the perspective of proposed new regulations but a similar set of questions can be applied to deregulation and adoption of new regulatory mechanisms.

- Precisely what are the market imperfections that the proposed regulations are trying to fix and what are the causes of these market imperfections?
- What are the social costs of these market imperfections and who bears them?
- Exactly what would be regulated and how?
- What alternative regulatory arrangements may be available to mitigate the market imperfections and why is one likely to be better than the other?
- What information and authority would a regulator need to implement the proposed regulations effectively?
- How much will the costs of market imperfections be reduced if the proposed regulations are implemented successfully?
- What are the likely direct costs of implementing the regulatory framework?
- What potential indirect costs may be incurred by implementing the proposed regulations given imperfect and asymmetric information on the part of regulators with good intentions?

- On balance what will be the likely net benefits or the likely net costs of the proposed regulations be in practice?

4. What is the record?

With all of the recent hysteria about the evils of "deregulation," one would think that the market liberalization and regulatory reforms of the last decade have imposed enormous costs on the economy. To the contrary, with a few exceptions just the opposite has been the reality and some of the most significant costs have resulted from too little deregulation, privatization, and regulatory reform (Peltzman and Winston 2000, Winston 1993, Joskow and Rose 1989, Joskow 2004).

a. Price and Entry Regulation

Let me start with so-called "economic regulation." By "economic regulation" I refer to the various forms of price and entry regulation typically implemented by state and/or federal regulatory agencies and sometimes by municipalities. It is useful to think back to 1978 to recall how much price regulation and often companion restrictions on competitive entry existed in the U.S. at that time: crude oil and petroleum products; natural gas production, transportation and distribution; surface freight transportation by trucks, trains, and barges; commercial passenger and freight airline service; telecommunications services; electricity generation, transmission and distribution; cable television services; residential rents; milk prices (as well as broader agricultural support policies to keep prices from falling); interest rates on bank accounts, etc..

Almost every one of these industries, services or products has been subject to dramatic changes in the regulatory framework that existed only 30 years ago:

deregulation of prices and entry, better regulation of remaining regulated segments, and supporting industry restructuring programs. Overall, the results have been very good from a broad economic welfare perspective (Winston 1993, Peltzman and Winston 2000, Joskow 2004). While there are things that might have been done better, and potential for further reform still exists in some sectors, and there were some unanticipated consequences, both good and bad, I find it hard to imagine that any right thinking person would want to reverse these changes and return to the heavily regulated era of 1978.

Of course there have been unanticipated consequences associated with some of these reforms; some good and some bad. Where there have been problems they can generally be associated with the poor regulation of key network segments that competitive markets depend upon to operate efficiently and regulations that inefficiently restrict the development of competition in the deregulated segments. To oversimplify, there was probably too little deregulation of prices and entry, too little supporting regulatory reform and too little supporting industry restructuring in the sectors that have experienced transition problems.

Has everyone been made better off? Of course not. The business traveler whose airfare was paid by his employer has not benefited from airline deregulation. The wheat shipper close to a main line who could get rail transportation service at below-cost regulated prices from a bankrupt railroad is not better off. The local television stations that once had to compete for viewers and advertisers only with a very small number of other local channels for viewers and advertising and now face competition from distant signals and new channels delivered over cable systems are not better off. High sulfur

eastern coal mines are worse off because they now face more intense competition from low-sulfur western coal, at least partly as a consequence of railroad deregulation.

Making everyone better off from regulatory reforms is not the right standard. If it were, we would never change anything. It just tells us why some groups favor regulation and oppose deregulation and vice versa. But when you add up the long term benefits to consumers, to producers, including the effects of product and process innovations, the economy overall is generally much better off as a consequence of deregulation of prices and entry and associated regulatory and institutional reforms in most of these sectors.

In the area of economic regulation it is convenient to consider two groups of industries: (a) those which were or potentially were structurally competitive in all horizontal segments, where "competitors" are properly defined, and (b) those which had both competitive horizontal segments and, at least initially, one or more horizontal network segments that had natural monopoly characteristics and would require some type of continuing regulation to allow competition to flourish in other horizontal segments.

In the first group we have oil and natural gas production, trucks, trains, and barges shipping freight, airlines transporting passengers and freight, etc. These are the cleanest cases of simple deregulation. The results have generally been as anticipated: improvements in productivity, faster technological innovation, more efficient prices (not necessarily lower prices), better quality service, increased investment to expand supply, etc. (Peltzman and Winston 2000, Rose 1987, Debande 1999, Belman and Monaco 2001, Hubbard 2003).

In this regard, people do and will raise questions about airline deregulation. This has not worked out exactly as had been anticipated. People seem to have fond memories

of the quality of service provided under the old regulatory regime, but forget how costly it was. Since 1978, airline productivity is higher, costs per seat mile are lower, airfares are lower, load factors are much higher, and the quality of service is lower, though many fail to recall that one of the arguments for deregulation was that load factors, service quality, and the associated costs were too high under regulation (Morrison and Winston 2000). I don't think that it was expected in 1978 that the extensive price discrimination (non-pejorative) that has been observed would emerge or that a competitive equilibrium for airlines would be characterized by a smaller number of large national airlines rather than a much larger number of small airlines.

We understand much better today the attributes of imperfectly competitive markets with scale and network economies and diverse consumer preferences for quality than we did in 1978. I don't think that this better understanding would have affected the normative case for deregulating prices and entry for airline service. However, it might have changed other policies that would have provided better infrastructure and institutional support for a competitive airline industry. The most costly disappointments of price and entry deregulation in airlines can be traced to some other institutional factors. Air traffic has expanded dramatically over the last 30 years. Passenger enplanements have increased by about 180%. Departures (and presumably landings) have increased by about 125%. Yet airport capacity has hardly expanded at all, inevitably leading to more crowded airports and delays. Only one new major hub airport has been built since 1978 (Denver). It takes 10-15 years to build a new runway at a major airport. Three new runways were completed in 2008, after roughly 12 years of planning, regulatory reviews, and construction. The government has been reluctant to

implement sensible policies to ration scarce airport capacity so we get queues and long delays. We have an antiquated air traffic control system owned and controlled by an agency of the federal government that undermines the efficient use of scarce airspace and further contributes to delays, especially when weather is poor. Other countries have commercialized their air traffic control systems with superior results (McDougall and Roberts 2009). We have a global commercial air transport industry but the U.S. and most other countries place major barriers in the way of creating global air carriers that can compete across the globe with one another. In short, we have not created the supporting government controlled and regulated network infrastructure that would be most desirable to support a competitive commercial air traffic market and have not fully opened up entry to potential competitors from other countries.

Finally, policymakers have not been aggressive enough in imposing and implementing regulations that require the airlines to be more transparent about what their responsibilities are when they enter into a contract with a customer --- called a confirmed airplane ticket. When I buy seat M16 at Symphony Hall in Boston for a Saturday night performance I expect that my seat will be there when I arrive and not a "sorry we are overbooked" sign. At least some of the trials and tribulations of air travel would be more tolerable if the terms and conditions of carriage were transparent and applied consistently. And the focus of "reregulation" has properly been on something like a flier's bill of rights, though general transparency requirements might be all that is needed.

The bottom line is that I don't think that a good case can be made for reregulating the commercial airline industry as it was in 1978. I do think that a good case can be made for doing a better job with the necessary infrastructure for supporting competition

and for requiring more articulation of consumers rights associated with the tickets that they purchase.

Another case about which questions are raised is deregulation of railroad rates, entry, exit and the extensive reorganization of the railroads that has occurred through merger and exit since 1980 (Grimm and Winston 2000). These mergers have generally lead to lower costs (Bitzan and Wilson 2007). Transport rates for important classes of shippers have declined (Vachal et. al. 2006). Some shippers argue that they are being overcharged by the railroads in the sense that the railroads are charging more than the "competitive level," whatever that may be. Maybe they are in some cases where rates have risen. Intra-modal and inter-model competition faced by railroads is certainly not perfect competition. Moreover, given the economic characteristics of railroad costs, there are necessarily varying degrees of market power observed, in the textbook sense that prices for some services are greater than their short-run marginal costs. However, a price structure involving second and third-degree price discrimination is a necessary attribute of an industry with these attributes both to satisfy a breakeven constraint and to do so efficiently.

Moreover, the earlier regulatory regime is not a model of good performance. It led virtually every U.S. railroad into bankruptcy, halted their incentive and ability adequately to invest in their networks, modern rolling stock, and stymied innovation, including more effective integration with truck transportation. These adverse consequences of regulation were enormously costly to our economy. Even after deregulation, railroads have not, overall, earned excessive rates of return. And so-called captive shippers still can make their case for lower rates if they choose to do so, and two

years ago, the Surface Freight Transportation Board adopted new rules to reduce the cost and time of litigation associated with these residual railroad rate cases. The railroad industry, perhaps more than others, also encountered integration problems associated with the extensive merger and restructuring wave that was expected as the industry rationalized. Perhaps the deregulation process could have anticipated this better, but I doubt it. Overall, railroad deregulation has been a big win for the U.S. economy and for the environment.

Let us turn now to the other group of industries subject to deregulation of prices and entry, restructuring requirements, and network regulatory reform. These are telecommunications, natural gas transportation and distribution, cable TV, and electric power. It would be wrong to characterize the reforms that have been introduced in these sectors over the last two or three decades as simply "deregulation." This oversimplifies a much more complex process of industry structure and regulatory reform that took place over many years. Calling it deregulation seriously understates the nature of the reform challenge and what has been accomplished as a result of these reform programs.

I do not have space here to engage in a detailed discussion of all of these industry cases. They share some common themes, though Cable TV is probably a special case with its own peculiar history of being in Brownian motion between regulation, deregulation, and various combinations of both. Under the old regulatory regime each of these sectors was characterized by extensive vertical integration from the upstream production to the downstream delivery level either through common ownership or through very long-term regulated contractual arrangements. The entire chain or production was subject to price and entry regulation either by federal or state regulators

or sometimes by both. The argument for regulation was generally that there was a natural monopoly or oligopoly problem that called for regulation to mitigate real or imagined market power.

However, during the 1970s and 1980s, there was a growing recognition that while some vertical segments of these industries (e.g. natural gas transportation) might have natural monopoly characteristics that might indicate a need for continuing, perhaps better, price and entry regulation, other segments (e.g. natural gas production, processing, marketing, and storage) were or could be quite competitive. The basic reform model for regulated industries with these characteristics has been (a) to separate (structurally or functionally) the potentially competitive segments from the monopoly/oligopoly network segments that would be regulated, (b) to remove price and entry regulation from the competitive segments, (c) to unbundle the sale of regulated network service from competitive services, (d) to establish transparent prices for access to and use of the network, and (e) to allow end-users (local distribution companies or consumers in the case of gas and electricity, and end-use consumers in the case of telecommunications) to choose their suppliers of competitive services and have them arrange to have it "shipped" to them over an open access network with a regulated cap on the prices for providing transportation service.

This is the basic regulatory reform model applied to most of these industries, though the devil is in the details and the details vary from industry to industry. Moreover, as time passes, technology change may and has in many cases undermined the initial assumptions about where the "natural monopoly" segments begin and end. The prospect of product and process innovations requires, in theory, a regulatory framework

that encourages innovation and can adapt quickly to them. This kind of dynamic regulatory framework has been difficult to design and implement in practice and represents the greatest cost of continuing regulation of residual segments of these industries. Sunset provisions might provide just the kind of incentives regulators need to take these kinds of changes more seriously.

The regulatory and structural reforms that have been applied to the natural gas industry are not widely publicized, understood, or even studied these days (MacAvoy is an exception, e.g. MacAvoy 2000). This is unfortunate because the natural gas industry provides an excellent model for how regulatory and structural reforms can be implemented successfully in industries with these characteristics. Some history is required. Municipalities and some states began regulating local gas distribution companies during the mid-1800s. Most of these local gas companies manufactured low-heating value gas from coal for local distribution primarily for use in lighting and cooking. As large deposits of natural gas were discovered, typically in conjunction with the exploration for and production of oil, and long-distance high pressure pipeline technology advanced, interstate pipeline networks began to be built to transport what was often “waste gas” that was being flared in the field from production regions to consuming areas. The early development of the natural gas industry was largely unregulated from a price and entry perspective.

The federal government (the Federal Power Commission (FPC) which became the Federal Energy Regulatory Commission (FERC)) began to regulate the price of interstate pipelines service beginning in the late 1930s as part of the general expansion of federal regulation to public utilities and holding companies. Interstate activities were becoming

much more important in the electricity, natural gas, and telecommunications industries and technological change fostered expansions in the geographic expance of trade beyond state boundaries. Federal regulation filled a perceived regulatory gap resulting from state regulation of these industries. At that time, interstate pipelines acquired gas through contract from independent or affiliated producers at unregulated market prices and resold it to local distributers and large customers under contract. Local distribution companies then resold the gas to end-use customers at state regulated prices, passing through the costs they paid for gas they purchased from pipelines.

The natural gas industry expanded rapidly after the Second World War and new pipelines brought growing volumes of gas to cities in the Midwest, Northeast and other areas that had previously relied primarily on coal and oil for heating and as a boiler fuel. Natural gas was cleaner, more efficient and more convenient to use that coal, oil or manufactured gas and where it was available it became the fuel of choice in many end-use applications and in the generation of electricity in areas that did not have access to cheap coal.

The increasing demand for natural gas led to higher gas prices as a commodity that was essentially a waste product associated with oil production gained significant value in its own right as the demand for it grew rapidly. Local gas distribution consumers and large end-use customers argued that federal regulation should be extended to the price of natural gas produced in the field in order to keep prices from rising and allowing gas producers to earn competitive market rents higher than they had ever dreamed. The Supreme Court agreed with the arguments for regulating the field price of natural gas in the *Phillips Case* in 1954 (347 U.S. 672). The FPC was then charged with

regulating the field price of natural gas as well as the prices for transporting it through the interstate pipeline system. It started to embark on this quest by trying to set cost-based regulated prices produced by thousands of producers located in many different production basins. The FPC did not get very far before concluding that producer by producer regulation was not feasible because there were too many producers and a lengthy cost-based regulatory process. The FPC then adopted what it thought would be a less burdensome and more sensible approach by setting cost-based prices for all of the gas produced in large production basins from reserves discovered in different time periods. That is, the FPC held "area rate proceedings" to establish regulated prices for gas discovered at different times in individual gas producing areas. These area rate proceedings also took many years. The price of gas delivered by pipelines would then involve the "rolling together" of the varying regulated prices determined through this process.

This regulatory scheme virtually assured that prices paid by pipeline for gas produced in the gas fields would be too low to clear supply and demand. And by the 1970s, serious natural gas shortages emerged both in the form of rationing of supplies to existing gas customers and denying hookups to new gas customers. The primary problem was that the regulation of the field prices of natural gas kept these prices from rising sufficiently to reflect supply and demand conditions. The shortage problems got even worse as oil prices rose in 1974 and again in 1979-81 as consumers sought to switch to low regulated priced gas whose supply was limited and could not match demand. It was cheap but lots of consumers couldn't get it at any price due to both price regulation and restrictions on resale of incumbent rights to regulated price natural gas.

The primary beneficiaries of natural gas price regulation at that time were Canadian producers who could sell into the U.S. market at high unregulated prices and customers with legacy gas contracts who paid prices well below market clearing levels. These contracts could not be resold and were slowly coming to an end.

The Natural Gas Policy Act of 1978 began the process of deregulating the field price of natural gas. This process was accelerated during the 1980s and by the early 1990s, natural gas field price regulation was completely gone. However, during a long transition period, the same molecules of natural gas were being sold in the field at many different prices depending upon when FERC-regulated gas supply contracts between producers and pipelines, between pipelines and distribution companies, and between pipelines and large industrial and electric utility customers were signed. These contracts were rolled together to give consumers a blended price that was initially lower than the then prevailing market price for deregulated "new" natural gas supplies available to clear the market. The shortages continued.

Then in the mid-1980s, the unregulated market price for "new" natural gas fell dramatically and stayed at much lower levels than those that prevailed during the early 1980s for many years. As unregulated natural gas prices fell dramatically, regulated contract prices were now often higher than unregulated market prices. Distribution companies and large direct pipeline service customers argued that FERC should reset the contract prices to reflect lower natural gas prices or, instead, pipeline customers should be permitted to reject these contracts, be permitted to buy gas directly from producers and arrange separately to have the gas shipped to them over the same pipelines using unbundled FERC regulated pipeline transportation charges. The producers with the high-

priced contracts and the pipelines with the obligations to take and pay for gas under these contracts were not impressed with the case for market-based pricing.

And so began a long process through which the FERC unwound the web of contracts linking producers, pipelines, and distribution contracts, unbundling transportation service from the production and marketing of natural gas, reforming the regulation of pipeline transport rates by setting generous price caps and encouraging negotiated transportation contracts. The states also began to require that local distribution companies use transparent competitive bidding programs to acquire gas supplies separately from pipeline services Some states followed by unbundling local distribution service for smaller retail customers as well.

After a very long process of "deregulation," regulatory reform and industry restructuring, we now have a reasonably well integrated North American market for natural gas supplies (Cuddington and Wang 2006), a pipeline system that has grown and adapted to changing supply and demand conditions, a more efficient end-use pricing system in which delivered gas prices are now more closely aligned with changes in supply and demand conditions for natural gas --- whose price has varied by a factor of three in the last year alone ---, growing competition in the pipeline sector as investors are free to seek to build new capacity to service new gas supply regions with few regulatory hurdles --- as they are doing as we speak to provide the transportation service for the growing supplies of natural gas in the Rockies and from gas shale deposits in Texas, the South and Appalachia which will reduce pipeline congestion and better integrate the far West market with the rest of Canada and the U.S. There has been innovation in gas exploration and production techniques, dramatically increasing North American gas

supplies above what was expected only a few years ago, as well as innovations in pipeline construction and operations, and natural gas storage. This mixture of deregulation, industry restructuring and light handed regulation of pipeline transportation and storage has been a great success.

I will turn very briefly to a few observations about the electric power sector. I have written a lot about deregulation, industry restructuring and network regulatory reform of electric power sectors so my views are well known (Joskow 2000, 2006, 2008). Accordingly, I will be brief. The electric power industry can be restructured and its regulation reformed by applying a model similar to the successful model that has been observed in the natural gas industry adapted to reflect the special attributes of electricity. This type of reform program was adopted in England and Wales in the 1990s and works very well. It began to be adopted in the U.S. in the late 1990s, but was slowed down considerably after the California electricity crisis in 2001. We now have some parts of the country with fully liberalized electricity systems --- New York, most of New England, Texas --- those with pretty much the traditional system of regulated vertically integrated monopoly, and those somewhere in between.

This bizarre mix of competition and regulation for suppliers using the same physical electric power network is inefficient and establishes a poor platform for new proposed energy and environmental policy initiatives targeted at the electric power sector. The problems here are not technical or economic. They are political, as incumbents resist restructuring, deregulation and regulatory reform, as states seek to protect their regulatory prerogatives, and as a consequence of eight years with an administration that has given little if any support for this kind of “deregulation” program

in the electric power sector, despite the fact that Texas has perhaps the most complete and successful electricity liberalization program in the country. President Bush brought an outstanding individual from Texas to lead FERC's deregulation program, that advanced significantly during the Clinton administration, but did not aggressively support his efforts. The one thing one can't accuse the Bush administration of is aggressive support for deregulation in the electric power sector.

Let me turn briefly to telecommunications. This has been a long and tedious process of introducing competition into what was an end-to-end regulated monopoly (including a monopoly over customer premises equipment and network switching equipment) that goes back to the 1970s (Crandall 1991). The conventional wisdom at that time was that that the old system worked well and was quite innovative. I will not repeat the telecommunications restructuring, deregulation and regulatory reform story here since, unlike the natural gas story, it is well documented in the literature (Crandall 1991, Joskow and Noll 1999, Crandall and Hausman 2000). There are some lessons to be learned, however:

a. The original reform model, and the model upon which the antitrust cases against AT&T and FCC policies to encourage competition were based, assumed that the local network was a natural monopoly and that promoting competition in other segments of the industry, required extensive regulation of the terms and conditions of access to the local network (Joskow and Noll 1999). Designing the terms and conditions of access to the local network was relatively straightforward when it was focused on giving consumers access to competing suppliers of intercity service, though it required unwinding a complicated web of cross-subsidies from intercity service to local service

and from urban consumers to rural consumers. In the end it was easier to do in theory than in practice, especially during the period when AT&T had both to compete with other suppliers of intercity service and provide them with access to their intercity network at regulated prices to facilitate their ability to compete. It was messy but that's what had to be done until competing intercity networks could expand.

The challenge of designing policies to promote competition at the local network level was more significant, more complicated, and plagued by more missteps (Crandall and Hausman 2000, Hausman 1999, Vogelsang 2003). At the very least we must admit that regulating the prices and terms and conditions of access to individual unbundled local network elements was both technically challenging and was implemented poorly. Indeed, the whole idea that there are likely to be social benefits from encouraging competitors to compete at the local network level largely by buying and reselling all of the elements of the incumbent's network is questionable, unless it were part of a rapid transition to facility-based competition. Getting the local network element prices right was almost impossible, and the disincentives to investment resulting from getting the prices wrong potentially very costly, discouraging innovation (Hausman 1997). At worst, the entire exercise was doomed to failure.

b. In fact, by and large, competition to provide local service came from real facility based innovations that were largely unanticipated when the original reform model was conceived, rather than through the implementation of unbundled network elements access pricing policies (Swan and Loomis 2005). The primary competition for local service now comes from cable companies and from wireless service. The unbundled network elements program led to little technological improvements in the local networks,

and may have retarded such innovation. In particular, it probably slowed down investments in local networks that would have enabled the local telephone companies to compete effectively with cable companies to provide high-speed broadband service and video services sooner than has been the case.

The lesson here is that any regulatory reform program must anticipate that there may be transforming innovations on the supply and demand sides and should be structured to adapt to them quickly. The difficulty of designing regulatory processes that have these attributes must be considered to be one of the potential dynamic costs of regulation. Regulatory mechanisms that restrict the development and diffusion of new and better products and services can be very costly. Facilitating technological innovations that reduce costs or bring new and better products to market convey "first order" efficiency benefits to the economy ("rectangles" in cost-benefit space), while static monopoly problems per se are "second order" efficiency losses ("triangles" in cost-benefit space).

I will conclude this section with a few observations about the regulation of Cable TV (Crawford 2000, FCC Fact Sheet 2000). This industry was started as an unregulated industry by entrepreneurs who sought to bring television service to rural areas where it was unavailable. For example, I am told that cable TV was brought to Ithaca, New York by the owner of a local appliance store who wanted to sell television sets to the people who lived there and could not get direct over-the-air TV reception. Because the cable companies had to cross public rights of way and use poles owned by the telephone or electric companies they needed a municipal franchise, though it did not have to be exclusive, and pole attachments rights from these other utilities, which were in turn

regulated by state public utility commissions. Initially, the interest in cable TV systems in large urban areas, where there were typically three or more local stations was quite limited because the cable companies had little to offer except to rebroadcast the signals of TV stations whose signals they could receive by putting a big antenna on a hill.

As local cable systems expanded in remote areas and the local populations bought television sets, concerns began to be raised about cable service prices. At the same time cable operators making substantial investments in new facilities were interested in having their franchises become exclusive. So, began to emerge a mutually beneficial local franchising process where municipalities gave cable operators exclusive franchises, sometimes through competitive bidding, in return for price guarantees, price adjustment procedures and other goodies for the municipalities (e.g. to wire government building for free and to offer a special municipal channel).

Technology marched on. Cable operators discovered that they could import more distant signals by using microwave technology, expand the quality of service, increase demand, and raise prices. The availability of television signals also expanded after the federal government opened up portions of the UHF spectrum to television. Cable operators also discovered that they could offer additional services --- movies --- for a separate fee. The innovation adopted by HBO to deliver its movie and sports service via satellite to cable systems that installed the necessary reception equipment greatly reduced the costs and expanded the diffusion of “premium” movie services. Ted Turner soon followed by putting his local independent broadcast station in Atlanta (WTBS) on the satellite as well, charging a fee to cable operators for retransmitting it. The additional programming made cable service of greater interest to viewers in cities which had

multiple free over-the-air broadcast service and new cable systems began to spread to more and more cities.

The use of microwave and satellite transmission and the rebroadcast of signals from broadcast stations got the federal government into the act. And eventually, the FCC (prodded by Congress) decided that a new technology was emerging that had both (real or imagined) natural monopoly characteristics and threatened the economic models of local "free" broadcast stations by creating more competition. While this competition was good for consumers it was not good for the local stations which were well-represented in Washington and used their political influence to thwart the rapid growth of competition from cable systems. So the FCC began to regulate the services that cable operators were permitted to offer and eventually was charged with regulating cable service prices.

In the mean time, new cable-only channels began to emerge as the technology for distributing many more channels on cable networks advanced and the number of subscribers to cable service increased as well. These new services were attractive to consumers, increased the demand for cable service, and further threatened the broadcast networks and local stations. Prices for cable service rose as the quality of services provided increased. Broadcast networks and local stations faced even more intense competition. The FCC first expanded regulation of cable television services and than began to relax these regulations. In 1984 Congress stepped into the act and passed the Cable Television Policy Act of 1984 which adopted a broad set of regulatory restrictions on subscriber prices, ownership arrangements, franchise provisions and renewals, channel usage, etc. with the goal of reducing the rate of increase in subscriber prices and promoting competition. However, subscriber prices continued to increase rapidly after

the 1984 Act was passed and the hoped for competition did not emerge. In 1992 Congress passed the Cable Television Consumer Protection and Competition Act with further tightened FCC regulation of cable TV prices (Crawford 2000). The expectation was that the new regulatory framework would lead to the average subscriber price falling by 10%. Instead the average cable bill rose. The FCC imposed a further reduction in per channel charges in 1994 with limited impact and then began to phase out the ineffective regulation. In 1996, the Telecommunications Policy Act phased on out subscriber rate regulation under the assumption that competition from telephone companies and wireless provided would emerge to constrain the market power of incumbent television companies. During this entire period of time cable system capacity grew rapidly along with the number of programs available to subscribers. The share of households subscribing to cable television continued to increase. Facility-based competition from local telephone companies and wireless technologies was slower to emerged than anticipated, but provisions in the 1996 Act that reduced barriers to entry ultimately helped to stimulate it.

There are a number of lessons here as well. First, regulating in the context of rapidly changing service quality availability is very difficult and often counterproductive. Second, incumbents will spend large amounts of money to retard competition. Third, imperfect competition is likely to yield superior results to price and entry regulation. Finally, the most important regulatory innovations were those that promoted competition rather than those that sought to control real or imagined market power problems.

b. Environmental Regulation

There are few economists who do not believe that environmental externality problems create a good case for government regulation of emissions into the air, water and land that harm the health and/or wellbeing of individuals or increase costs for businesses that must cope with emissions affecting the air, water, or land. I realize that some believe that it can all be left to common law enforcement of property rights and use of liability rules, but I think that is pretty much a fringe view.

The primary economic controversies regarding environmental regulations turn on questions of what emissions should be regulated (is the likely harm greater than the direct and indirect costs of regulation?), how stringently should emissions be controlled (what level of emissions balances the environmental harm and the costs of mitigation?), what mechanisms should be used to regulate (source specific standards, prices (emissions taxes), quantities (cap and trade), hybrid systems, etc.), and how should the rules be enforced? There are legitimate differences of opinion on these questions and this necessarily can lead to a lot of controversy. However, characterizing these controversies as "regulation" vs. "deregulation" rarely makes much sense (though there are certainly important cases such as greenhouse gasses and mercury where the "regulations" vs. "no regulation" bridge must be crossed first).

The first two questions are necessarily difficult to answer with precision because the measurement of environmental harm and mitigation costs are necessarily uncertain and subject to change over time. However, I think that it's fair to say that most economists believe that we should at least try to perform the best cost benefit analysis that we can given the information available and to leave room for policy adaptation as

more information is obtained. We must recognize, however, that there is a lot of disagreement over how these cost-benefit analyses can best be done and the values that should be placed on key variables (e.g. value of a human life, morbidity costs, recreational values, non-use values, revealed preferences vs. contingent valuation methods, etc.). Or look at the controversies between distinguished economists about the proper discount rate and utility function parameters to use for evaluating the trajectory of constraints on GHG emissions (Nordhaus 2007, Weitzman 2007, Stern 2007). New scientific and epidemiological evidence may lead to higher or lower estimates of the damages than originally thought as time passes. We also know from experience that with the right incentives the costs of mitigation have often turned out to be lower than was originally thought as innovative control responses are identified and utilized.

The one area where there is substantial agreement among economists is with regard to the best mechanisms for controlling emissions given targets for how tight the constraints should be. The regulatory mechanisms that has historically been favored by environmental regulators has been source-specific emissions standards and/or source-specific technology standards. These regulatory approaches fail to recognize that there is often significant diversity among sources in their costs of reducing emissions, that new and better technologies may be induced to be developed and deployed with the right incentives, that meeting aggregate emissions reduction targets and/or mitigation costs using this approach depend heavily on assumptions about industry developments over time (e.g. the rate of growth in demand for the product, domestic production vs. imports), and that this approach has tended to be litigation intensive, delaying achievement of environmental goals.

Instead, economists have come to favor the use of "market-based mechanisms" to control emissions where the implementation costs are not excessive: emissions charges, cap and trade systems, hybrid systems combining cap and trade with a backstop price for more emissions permits. These mechanisms all involve creating a price for emissions and then allowing those covered by the program to adapt to these prices in the most economical fashion available to them. There is a well developed theoretical literature on the factors that favor price, quantity or hybrid approaches (Weitzman 1974, Roberts and Spence 1992). The choice turns on the nature of the uncertainty about the benefits and costs of mitigation and the shapes of the benefit and cost functions. Despite the teachings of this literature, the choices between market-based approaches have turned in practice primarily on political considerations (Joskow and Schmalensee 1998). The public does not like direct taxes and market based approaches appear to be easier to get adopted if they are formulated as cap and trade systems (perhaps with a backstop price).

We now have a lot of experience with cap and trade systems in the U.S. drawn from programs for eliminating lead in gasoline, controlling sulfur dioxide emissions and NOx emissions from power plants (Ellerman et. al. 2000). We also are gaining experience with the application of a cap and trade system to control emissions of CO_2 is Europe (Joskow and Ellerman 2008). These systems work well in terms of reducing costs, encouraging diverse and innovative mitigation responses, and meeting environmental goals on schedule. They are also well-adapted to new information about the relevant costs and benefits since the government can buy allowances and retire them to tighten constraints or increase the supply of allowances to reduce the constraints.

The notion that there has been "deregulation" of emissions into the air, water, and land is nonsense. Nor is it the case that the quality of the environment has generally deteriorated in the last couple of decade. At least for the traditional air emissions covered by the Clean Air Act (i.e. excluding greenhouse gasses), the record is clear that emissions have declined and air quality has improved over the last 15 years, continuing a trend that goes back to 1970. And except for ozone (8-hour standard), micro-particulates and (now) mercury, virtually the entire population lives in areas that meet the national ambient air quality standards. Stratospheric ozone is recovering and concentrations of ozone depleting chemicals is declining. Reversing a long-term trend, wetland acreage increased in the last decade. Drinking water quality has improved. Hazardous waste generation has declined significantly. Forest cover has increased in the U.S. There are, no doubt, areas where environmental quality has deteriorated (e.g contamination of fish), though the EPA has been particularly bad at developing a wide range of useful environmental indicators and collecting the time series data to understand relevant trends, but, putting aside greenhouse gas emissions, the general trends are positive. Rather than arguing about "deregulation" the real issues are whether the constraints on emissions are too tight or too lenient and whether we are meeting environmental goal as efficiently as possible.

So, "deregulation" of emissions that harm human health and welfare must be a code word for something else. Perhaps it is the failure of the Bush administration to further tighten the national ambient air quality standards. Or its failure to embrace a more aggressive GHG mitigation program, though it's hard to call this deregulation since GHG were never regulated. It also probably reflects a reaction to what is perceived to be "stealth deregulation" through "lax" monitoring and enforcement and tighter cost-benefit

standards applied by OMB. "Stealth deregulation" is wrong and properly criticized if it involves a failure to enforce the law. The government should enforce the law faithfully and efficiently whether it likes it or not and go through the administrative procedures, court reviews, and seek legislative if it seeks to change the way it implements the law. However, difference in views on the relevant benefits and costs should be expected.

Most regulatory statutes give the executive branch and independent regulatory agencies substantial discretion in how they regulate, what they regulate, and the resources they devote to particular regulatory activities. Both Congress and the courts have oversight over these decisions and constraint this discretion. Nevertheless, different administration have different views on a wide range of regulatory policies, including environmental policies, and it should not be a surprise that the implementation of regulatory responsibilities will change over time with the broader policy and ideological views of different administrations. Characterizing the exercise of this discretion as "deregulation," is not productive. Better to call it inadequate, excessive, or ineffective regulation as the case may be.

c. Quality and Safety Regulation

Perhaps the most controversial areas of federal regulation are the statutes and agencies that have responsibility for regulating the quality and safety of products and services and the regulation and enforcement of workplace safety criteria. The continuing interaction between administrative regulation and tort litigation further complicates the situation. These are areas also the agencies whose behavior and performance have been studied least over the last decade (Viscusi 2006 and Sunstein 2002 are exceptions) and

where agencies have the most discretion, are most susceptible to wide variations in implementation strategies, as well as to stealth deregulation. While the federal government has been engaged in quality and safety regulation for many years (e.g. the FDA was created in 1906), its responsibilities increased significantly during the 1930s and again 1970s. We now have a long list of federal and complementary state regulatory agencies responsible for product quality and product and workplace safety issues. They include the consumer protection bureau of the FTC, the CPSC, FDA, NHTSA, OSHA, NRC, etc. Few of these agencies have ever received high marks for their efficiency or effectiveness in actually improving product quality and product and workplace safety (Joskow and Noll 1981, Viscusi 2006). Their role has been further complicated in some cases by controversies over the respective roles of administrative regulation and tort litigation.

While the statement of the missions of these agencies is sometimes broad and bold, it is often unclear exactly what metrics should be applied to measure their success in achieving them. Exactly how do we measure the effects of these agencies efforts to regulate quality and safety? It is not clear. Have reduced budgets, staffing , and the issuance of new standards by these agencies led to significant declines in safety? This is far from obvious. While the readily available evidence is limited, most of the available indicators are positive. For example, we know that commercial aircraft fatality rates have continued to decline from very low levels over the last 8 years, traffic fatality rates have been roughly constant since 2000 and roughly half of what they were in 1980 (motorcycle rider death rates have increased), mine fatalities have declined and citations and fines for mine safety violations have increased. Railroad-related injuries and

fatalities have declined since 2000. OSHA inspections have been roughly constant while mine inspections have decreased. However, early criticisms of the safety agencies indicated that they focused too much on inspections and not enough on safety standards that would make a difference, so perhaps this is not a good metric. Occupational deaths have declined by 62% and occupational injuries by 42% since 1971 (when OSHA was created), and fatality rates continued to decline in the last decade, but how much of this is due to the activities of OSHA and companion state regulatory agencies and how much to other factors (e.g. changes in the structure of the U.S. economy, automobile and truck safety standards, etc.) is not known. Moreover, fatality rates for self-employed workers who general fall under OSHA's radar, are much higher than for other workers and transportation-related injuries accounted for over 40% of the total work-related injuries in 2007.

The fundamental problem here is that it is hard to regulate product quality and product and workplace safety well. There are over 15,000 product categories subject to CPSC jurisdiction and millions of workplaces and thousands of job categories are covered by OSHA regulations. Consumers and workers have diverse preferences regarding risk, product quality, tradeoffs between cost and quality, tradeoffs between wages and safety, etc.,. Consumers and workers may easily mis-estimate the risks that they face and be more risk averse than is "rational." (Sunstein 2002). Regulators must naturally focus their attention on what they perceive to be the areas where product quality and safety issues are very serious and where regulatory requirements will be effective. Riding a bicycle, skiing, climbing a ladder, riding a motor cycle, etc. will inevitably lead to accidents. A safety standards regulator can set bicycle helmet standards but cannot

force bicycle riders to wear helmets Moreover, in making regulatory decisions, assumptions must be made about the information available to consumers, how they process it, and how it affects their behavior. There are lessons to be learned here from psychology and behavioral economics, but it is unclear that these agencies have ever made much of an effort to integrate these considerations into their regulatory procedures.

Regulation of product quality and safety can also be excessively costly to consumers, workers and producers. Delaying the availability of new products that meet safety and quality standards is costly to consumers. This criticism has been made in the past of the FDA and other safety regulatory agencies that must certify products before they are released. Regulatory costs and delays may also reduce incentives to develop new products. Another criticism of health and safety regulation is that regulators are too cautious in evaluating risk and impose costs on products and workplaces that well informed consumers and workers would not willingly bear (Viscusi 2006).

I do not think that the "regulation vs. deregulation" debate in the area of product quality and safety regulation and product and workplace safety regulation is particularly productive. Rather, I think that it's time to go back to square one. That means clearly identifying the relevant market imperfections, estimating their societal costs, examining alternative mechanisms for regulating (e.g. standards, information provision, disclosure requirements), integrating new learning from psychology and behavioral economics into the process of designing information and disclosure plans that are more likely to help consumers and workers to make wiser decisions, effectively balancing the costs and benefits of alternative regulatory procedures and mechanisms, and deciding on whether

we will rely on regulatory actions or litigation to provide safety and quality incentives to producers and employers, but not both.

5. Some Thoughts on Financial Market Regulation

I began this talk by observing that the ongoing financial market crisis was clearly caused by a combination of public policy failures reinforced by behavioral failures by private sector financial institutions, intermediaries, rating agencies and creditors. However, my own view is that we still do not fully understand the public policy and private sector failures and the interactions between them that caused the problems. We necessarily know even less about the appropriate public policies and private sector institutional reforms to keep these problems from emerging again.

I believe that the basic market failures vs. regulatory failures framework can and should be applied to fundamental reforms of financial market regulatory institutions. I also believe that characterizing the public policy challenge as "regulation vs. deregulation" is not particularly constructive. Finally, the lessons learned from applying this framework empirically to other areas of government regulation by microeconomists can usefully inform the evaluation of alternative potential reforms of financial market regulation. While I must leave it to others with more expertise in the structure, behavior and performance of contemporary financial market institutions, I offer the following observations based on our experience with regulatory reform in other industry contexts.

We must start by fully understanding what attributes of modern financial markets led to the recent meltdown and to identify the market and institutional imperfections that led to the problem. The problems here are unlikely to be the new financial instruments

that have been introduced in the last several years per se but rather the private and public governance arrangements in which they are traded. Many of these financial product innovations can help to diversify risks and reduce the cost of capital if they are traded within a suitable public regulatory and private financial firm governance framework in place. Mortgage-backed securities and other types of "simple" asset backed securities have been around for a long time and, in principle, can help to reduce risk by aggregating mortgages from many different asset owners and locations facing risks that are not highly correlated. Collateralized debt obligations which allow such securities to be sliced into tranches with different levels of risk can, in principle, also help to diversify risk and reduce risk-bearing costs. This is exactly the way corporations with "tranches" of secured bonds, unsecured bonds, preferred stock, and common equity have been financed for a very long time. Nor is it a bad idea in principle to offer insurance to holders of both private and public debt instruments. In short, many of these products appear to have attractive efficiency enhancing properties.

So, what is the problem? Some of these products are also complex, increasingly non-transparent, are traded in a way that may undermine incentives to properly evaluate risks, and complicate the challenges of dealing with systemic risks that can lead to the collapse of financial markets, which in turn leads to large adverse consequences for real economies. So, it is not the products themselves, but rather market and institutional imperfections that were created or enhanced by the proliferation of these products that are likely to be the source of the problem. These effects are exacerbated by the globalization of financial markets and the absence of much of an international regulatory framework.

The focus should be on the incentive and systemic risk issues associated with the institutions that create and trade these products, not simply on the products themselves.

Constructive analysis of what happened, how to bring the crisis to an end and how to keep it from happening again requires starting with the right analytical perspective. I argued earlier that credit markets are different from markets for ordinary goods and services and that regulatory reform based on analogies to ordinary goods and services could be very misleading. So, what are the attributes of financial markets that require that need to be better understood to formulate good policies? First, financial markets are characterized by systemic risks of collapse that have potentially serious negative implications for the performance of the larger economy. These risks are enhanced by the increased costs of liquidity resulting from systematic fear about the credibility of financial commitments. The societal costs of these systemic risks are not naturally internalized into private decisions. Concerns about bank runs, bank solvency, credit market collapses, etc., have always been the rationale for prudential regulation. The failure to integrate non-bank financial institutions, including money market funds, hedge funds, and other intermediaries into this prudential regulatory system is likely to prove to have been an important contributor to the problems we must now confront. Why is credit insurance any different from other types of insurance? We require insurance companies to hold reserves for the latter but not for the former and require insurers to adhere to strict and transparent accounting and disclosure rules. Why not so for credit default swaps?.

Second, illiquidity costs are another externality. Illiquidity costs arise when everyone tries to get out the door at the same time and drive the price that can be fetched for securities to levels below their intrinsic value if they were held to maturity. It is easy

for many money market funds to buy and sell 1% of their book of business each day. It is not possible for all of them to sell 20% of their book of business in one day for a positive price, no matter how secure are the securities they hold.

Third, the new financial products created new opportunities to quickly lay off risks on third parties who had only opaque insights into the risk attributes and potential liquidity costs of the underlying securities, relying on rating agencies rather than individual due diligence. These risks were both standard and systemic and were exacerbated by the costs of illiquidity which were largely ignored by the rating agencies. This created serious moral hazard problems, facilitated by the failure of the credit rating agencies to adequately assess risks and their incentives to underestimate risks arising from the ways that they were paid. These moral hazard problems created new challenges both for regulators and for the risk management, compensation, and governance arrangements relied upon by financial firms that trade these securities.

Fourth, there were governance imperfections at large complex financial institutions arising from the nature of managerial compensation arrangements which rewarded short term profits rather than long term returns

Fifth, sophisticated investors were not as sophisticated as the regulators, especially the SEC, had assumed. This in turn led to a failure in what was assumed to be largely a self-regulating system where the sophisticated investors effectively policed the integrity of the system, protecting unsophisticated investors. A lot of sophisticated investors appear to have been burned by Mr. Madoff, so one must question the basic assumption that sophisticated investors facilitate a sort of reverse Gresham's Law.

Sixth, the creation of large private mortgage banks which could securitize and sell complex mortgage backed securities with implicit government guarantees created additional moral hazard problem. Privatize or don't privatize. Don't privatize with implicit open ended government safety nets. It is the worst of both worlds.

Finally, financial markets are global markets while regulatory institutions are primarily national of subnational (e.g. state regulation of insurance in the United States).

New regulatory interventions should be targeted at costly market imperfections and should use the most efficient tools available to deal with them. The current regulatory framework for both prudential regulation and investor protection regulation has evolved haphazardly over many years. It involves a complex mix of federal and state regulation of banks, insurance companies, and other financial intermediaries, as well as self-regulating institutions. It has not adapted to the globalization of financial markets. Every time a new problem has emerged we have created a new regulatory agency (or a new law like Sarbanes-Oxley) to deal with it rather than carefully reevaluating the entire regulatory framework. We need to start with a clean slate, carefully articulate market imperfections, regulatory goals to deal with them and identify regulatory mechanisms and institutions that can deal with the problems most effectively. We don't want to throw away efficiency enhancing financial products and institutions. Rather we want private and public governance arrangements that ensure that they are used properly and do not increase systematic risks of financial market collapse.

6. Conclusions

The regulatory and structural reforms that have been implemented over the last thirty years have, on balance, been beneficial for the economy. There are certainly exceptions and there is always room for improvement. The ongoing problems in financial markets and with financial market regulation should not be an excuse for throwing the baby out with the bathwater. Moreover, as we consider reforms to financial market regulation and financial institutions, there is much to learn from the experience with analyzing and implementing regulatory reforms in other sectors. The market failures vs. regulatory failures framework is robust. Characterizing the issues as "regulation" vs. "deregulation" is not constructive. Given the attributes of financial products, markets, public and private governance alternatives, what is the best that we can do in an imperfect world.

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June 19, 2009

Honorable Dave Camp
Ranking Member
Committee on Ways and Means
U.S. House of Representatives
Washington, DC 20515

Dear Congressman:

At the request of your staff, the Congressional Budget Office (CBO) has analyzed the potential effects on households of the cap-and-trade program that would be implemented pursuant to H.R. 2454, the American Clean Energy and Security Act of 2009, as reported by the House Committee on Energy and Commerce on May 21.

The attached report summarizes the results of that analysis, indicating both the net overall cost per household nationwide and the net costs or benefits that would be realized by households in various income quintiles. CBO has estimated those amounts for the bill as it would be implemented in 2020 (but shown in 2010 dollars). This analysis does not address other provisions of the bill, nor does it encompass the potential benefits associated with any changes in the climate that would be avoided as a result of the legislation.

I hope this information is helpful to you. The CBO staff contacts are Frank Sammartino, who can be reached at (202) 226-2680, and Terry Dinan, who can be reached at (202) 226-2940.

Sincerely,

Douglas W. Elmendorf

Douglas W. Elmendorf

Attachment

cc: Honorable Charles B. Rangel
Chairman

Honorable Henry A. Waxman
Chairman
Committee on Energy and Commerce

Honorable Joe Barton
Ranking Member

Congressional Budget Office

The Estimated Costs to Households From the Cap-and-Trade Provisions of H.R. 2454

June 19, 2009

Global climate change is one of the nation's most significant long-term policy challenges: Reducing emissions of greenhouse gases (GHGs) would moderate the damage associated with climate change and, especially, the risk of significant damage, but doing so would also impose costs on the economy. In the case of carbon dioxide (CO_2)—which accounts for 85 percent of U.S. GHG emissions—higher costs would stem from the fact that most economic activity is based on fossil fuels, which contain carbon and, when burned, release it in the form of that gas.

H.R. 2454, the American Clean Energy and Security Act of 2009, as reported by the House Committee on Energy and Commerce on May 21, 2009, would create a cap-and-trade program for GHG emissions, an incentive-based approach for regulating the quantity of emissions. (The bill would also make a number of other significant changes in climate and energy policy.) The legislation would set a limit (the cap) on total emissions over the 2012–2050 period and would require regulated entities to hold rights, or allowances, to emit greenhouse gases. After allowances were initially distributed, entities would be free to buy and sell them (the trade part of the program).

This analysis examines the average cost per household that would result from implementing the GHG cap-and-trade program under H.R. 2454, as well as how that cost would be spread among households with different levels of income.[1] The analysis does not include the effects of other aspects of the bill, such as federal efforts to speed the development of new technologies and to increase energy efficiency by specifying standards or subsidizing energy-saving investments.

Reducing emissions to the level required by the cap would be accomplished mainly by stemming demand for carbon-based energy by increasing its price. Those higher prices, in turn, would reduce households' purchasing power. At the same time, the distribution of emission allowances would improve households' financial situation. The net financial impact of the program on households in different income brackets would depend in large part on how many allowances

[1] For information about the projected budgetary impact of the bill, see Congressional Budget Office, cost estimate for H.R. 2454, the American Clean Energy and Security Act of 2009 (June 5, 2009).

were sold (versus given away), how the free allowances were allocated, and how any proceeds from selling allowances were used. That net impact would reflect both the added costs that households experienced because of higher prices and the share of the allowance value that they received in the form of benefit payments, rebates, tax decreases or credits, wages, and returns on their investments.

The incidence of the gains and losses associated with the cap-and-trade program in H.R. 2454 would vary from year to year because the distribution of the allowance value would change over the life of the program. In the initial years of the program, the bulk of allowances would be distributed at no cost to various entities that would be affected by the constraint on emissions. Most of those free allocations would be phased out over time, and by 2035, roughly 70 percent of the allowances would be sold by the federal government, with a large share of revenues returned to households on a per capita basis. This analysis focuses on the effect of the legislation in the year 2020, a point at which the cap would have been in effect for eight years (giving the economy time to adjust) and at which the allocation of allowances would be representative of the situation prior to the phase-down of free allowances. The incidence of gains and losses would be considerably different once the free allocation of allowances had mostly ended. Although the analysis examines the effects of the bill as it would apply in 2020, those effects are described in the context of the current economy—that is, the costs that would result if the policies set for 2020 were in effect in 2010.

On that basis, the Congressional Budget Office (CBO) estimates that the net annual economywide cost of the cap-and-trade program in 2020 would be $22 billion—or about $175 per household. That figure includes the cost of restructuring the production and use of energy and of payments made to foreign entities under the program, but it does not include the economic benefits and other benefits of the reduction in GHG emissions and the associated slowing of climate change. CBO could not determine the incidence of certain pieces (including both costs and benefits) that represent, on net, about 8 percent of the total. For the remaining portion of the net cost, households in the lowest income quintile would see an average *net benefit* of about $40 in 2020, while households in the highest income quintile would see a *net cost* of $245. Added costs for households in the second lowest quintile would be about $40 that year; in the middle quintile, about $235; and in the fourth quintile, about $340. Overall net costs would average 0.2 percent of households' after-tax income.

How the GHG Cap-and-Trade Program Established Under H.R. 2454 Would Work

H.R. 2454 would establish two cap-and-trade programs, one for six GHGs (mostly CO_2) and one for a seventh GHG, hydrofluorocarbons (HFCs). The first program, the focus of this analysis, is generally referred to as the GHG cap-and-trade program.

H.R. 2454 would set limits on GHG emissions for each year. Regulated entities could comply with the policy in some combination of three ways:

- By reducing their emissions,
- By holding an allowance for each ton of GHGs that they emitted, or
- By acquiring an "offset credit" for their emissions.

Offset credits would be generated by firms that were not covered by the cap but that reduced their emissions or took actions to store emissions in trees and soil, using methods that would be approved by the Environmental Protection Agency. The bill would allow firms to use a significant quantity of offset credits—generated in the United States and overseas, with a maximum quantity for each specified in the legislation—toward compliance with the cap. Most of those offset credits would be generated by changes in agricultural and forestry practices. To the extent that acquiring offset credits was cheaper than undertaking more emission reductions, allowing firms to comply with offset credits would lower compliance costs overall.

CBO estimates that the price of an allowance, which would permit one ton of GHG emissions measured in CO_2 equivalents, in 2020 would be $28.[2] H.R. 2454 would require the federal government to sell a portion of the allowances and distribute the remainder to specified entities at no cost. The portions of allowances that were sold and distributed for free would vary from year to year. This analysis focuses on the year 2020, when 17 percent of the allowances would be sold by the government and the remaining 83 percent would be given away. Entities that received allowances could sell them or use them to meet their compliance obligations.

Estimated Costs per Household

The GHG cap-and-trade program established under H.R. 2454 would impose costs on U.S. households and provide some financial benefits, as well as the benefits associated with any changes in the climate that would be avoided as a result of the legislation. (This analysis addresses only those financial benefits.) The costs would be incurred through higher prices for the goods and services that households consumed, and the incidence of those costs would be determined primarily by households' consumption patterns. In the aggregate, most of those costs would be offset by income or other benefits provided to households as a result of the distribution of the value of the emission allowances. The legislation

[2] That price accounts for the effects of banking emission allowances as well as the ability of firms to comply with the cap by purchasing domestic and international offset credits. For more detail on how CBO estimated allowance prices, see the agency's cost estimate for H.R. 2454.

would influence how much of that value was conveyed to various households by specifying how to allocate the allowances. For example, H.R. 2454 would direct some of that value to low-income households by specifying that 15 percent of the allowance value be used to provide energy rebates and tax credits for such households.

Gross Compliance Costs

Gross compliance costs would consist of the cost of emission allowances, the cost of both domestic and international offset credits, and the resource costs incurred in order to reduce the use of fossil fuels:

- *The cost of the allowances.* The cost of acquiring allowances would become a cost of doing business. In most cases, the firms required to hold the allowances would not bear that cost; rather, they would pass it onto their customers in the form of higher prices.
- *The cost of both domestic and international offset credits.* Like the cost for allowances, the cost of acquiring offset credits would be passed on by firms to their customers in the form of higher prices.
- *The resource costs associated with reducing emissions.* The resource costs would include the value of the additional resources (including nonmonetized resources, such as time) required to reduce emissions—for example, by generating electricity from natural gas rather than from coal, by making improvements in energy efficiency, or by changing behavior to save energy (by carpooling, for example).[3]

According to CBO's estimates, the gross cost of complying with the GHG cap-and-trade program delineated in H.R. 2454 would be about $110 billion in 2020 (measured in terms of 2010 levels of consumption and income), or about $890 per household (see Table 1). Of that gross cost, 96 percent would be the cost of acquiring allowances or offset credits. The reminder would be the resource costs associated with reducing emissions.

As noted, firms would generally pass the cost of reducing their emissions—or of acquiring offset credits or emission allowances—on to their customers, and their customers' customers. (Indeed, assuming that higher costs are passed into prices is customary in distributional analyses.) Households and governments would bear those costs through their consumption of goods and services. Because households account for the bulk of spending, they would bear most of the costs. The federal

[3] The resource cost does not indicate the potential decrease in gross domestic product (GDP) that could result from the cap. The reduction in GDP would also include indirect general equilibrium effects, such as changes in the labor supply resulting from reductions in real wages and potential reductions in the productivity of capital and labor.

government and state and local governments would bear the remainder (an estimated 13 percent) through their spending on goods and services.

The distribution of the gross cost of complying with the policy would be quite different if the price level did not increase as a result of the cap—if, for example, the Federal Reserve adjusted monetary policy to prevent such an increase. In that case, the compliance costs would fall on workers and investors in the form of lower wages and profits. Under that alternative assumption, the gross cost of the program would fall more heavily on high-income households than is indicated in this analysis because the distribution of wages and profits is more tilted toward higher-income households than is the distribution of expenditures.

The Disposition of Allowance Value

Although households and governments would pay for the cost of the allowances—generally in the form of higher prices—those allowances would have value and would be a source of income. The ultimate effects of the cap-and-trade program on U.S. households would depend crucially on policymakers' decisions about how to allocate that value. Under H.R. 2454, allowances would be allocated among businesses, households, and governments, and the value of most of those allowances would ultimately be conveyed to households in various ways.

Under H.R. 2454, about 30 percent of the allowance value—$28 billion—would be allocated in a fairly direct manner to U.S. households to compensate them for their increased expenditures. That relief to households would include the 15 percent of the allowance value set aside for a low-income energy rebate and a tax credit for households receiving benefits through the Supplemental Nutrition Assistance Program or through the Medicare Part D low-income subsidy, and for households not participating in those programs but with income below certain thresholds. It would also include about $14 billion in allowances given to companies that distribute electricity and natural gas, with instructions to pass those benefits on to residential customers.

Roughly 50 percent of the allowance value—$47 billion—would be directed to U.S. businesses to offset their increased costs. That amount includes about $14 billion provided to what are termed emission-intensive trade-exposed industries (which would be less able to pass their compliance costs on to their customers than would other industries facing less international competition) and oil refiners. It also includes $27 billion worth of allowances that would be given to local distributers of electricity and natural gas, with instructions to pass those savings on to commercial and industrial customers (as distinct from the amount passed on to residential customers noted in the previous paragraph). The value of the allowances received by businesses would ultimately accrue to households in the form of increased returns on their investments.[4]

[4] The cost of obtaining allowances would be passed into prices in most cases because that cost would raise firms' variable production costs (that is, the costs to produce additional units of

About 10 percent of the allowance value would be allocated to the federal government and to state governments to spend within the United States (not accounting for the amount used to fund the energy rebate and tax credit). For example, the bill would direct a portion of the allowance value to be spent encouraging the development of particular technologies (such as electricity generation that includes carbon capture and storage) and improvements in energy efficiency. The value of those allowances allocated to governments would ultimately be passed on to households in the form of higher wages, increased returns on their investments, or lower energy costs.

Finally, H.R. 2454 would direct the federal government to spend 7 percent of the allowance value overseas, funding efforts to prevent deforestation in developing countries, to encourage the adoption of more efficient technologies, and to assist developing countries in adapting to climate change. The value the allowances spent overseas would impose a net cost on U.S. households: They would bear the cost of the allowances but would not receive the value (apart from the benefits of slowing climate change). In contrast, the other allowance allocations would not impose a net cost on U.S. households taken as a whole: Households would bear costs but ultimately would receive equivalent benefits.

Additional Benefits and Costs

Some additional transfers of income and additional costs would result from the GHG cap-and-trade program under H.R. 2454 but are not reflected in the gross compliance costs and the disposition of the allowance value discussed above. Those additional transfers would total about $14 billion, but they would also add close to $12 billion to the government's costs, which ultimately would be borne by households through higher taxes or reduced government spending. They would include the following:

- *The value of the rebates and tax credits for low-income households that exceeded the 15 percent of the allowance value that the bill would set aside to pay for them.* The cost of the rebates and credits would exceed that allowance value by $2.8 billion, CBO and the Joint Committee on Taxation (JCT) estimate. That amount would add to the sums received by households but would also increase the cost to the government.

- *Increases in government benefit payments that are pegged to the consumer price index, such as Social Security benefits.* Under the assumption that the

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output). In contrast, the receipt of allowances that is not linked to the quantity of output would represent a reduction in firms' fixed production costs. Businesses generally do not change prices in response to changes in fixed costs as they do in response to changes in variable costs. Therefore, the value of the allowances received would generally accrue to shareholders (or perhaps workers in some cases).

costs of compliance are passed through to consumers in higher prices and that the Federal Reserve does not take action to offset those price increases, the rise in the consumer price index would trigger increased cost-of-living benefits in indexed programs.[5] The increase in those transfer payments would help offset the increased expenditures for the households that received them. At the same time, increasing those payments would impose a cost on the federal government.

- *Reduced federal income taxes.* Because the federal income tax system is largely indexed to the consumer price index, an increase in consumer prices with no increase in nominal incomes would also reduce federal income taxes. That effect would increase households' after-tax income but would also add to the federal deficit. In combination, the effect of price changes on the government's indexed benefit payments and income tax receipts would convey an estimated $8.7 billion to households.

- *The net income received by providers of domestic offset credits.* Covered entities would spend an estimated $5.5 billion purchasing domestic offset credits to comply with the cap. Suppliers of offset credits would receive that amount in gross income but would incur costs to generate them. The additional net income of suppliers of domestic offset credits would be an estimated $2.7 billion.

Net Economywide Cost

Taking into the account the gross cost associated with complying with the cap ($110 billion); the allowance value that would flow back to U.S. households ($85 billion), both in the form of direct relief and indirectly through allocations to businesses and governments (all of which would eventually benefit households in people's various roles as consumers, workers, shareholders, and taxpayers); and the additional transfers and costs discussed above (providing net benefits of $2.7 billion), the net economywide cost of the GHG cap-and-trade program would be about $22 billion—or about $175 per household. Four factors account for that net cost:

- The purchase of international offset credits (about $8 billion),

- The cost of producing domestic offset credits (about $3 billion),

- The resource costs associated with reducing emissions (about $5 billion), and

- The allowance value that would be directed overseas (about $6 billion).

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[5] CBO estimates that, if the relative price increases triggered by the cap-and-trade program were passed through to customers and not offset by actions by the Federal Reserve, the price level would be 0.7 percent higher in 2020 than it would otherwise be.

Each of those components represents costs that would be incurred by U.S. households as a result of the cap-and-trade program but would not be offset by income resulting from the value of the allowances or from additional payments (such as increases in Social Security benefits) that would be triggered by the program.

Transitional Costs

The measure of costs described above reflects the costs that would occur once the economy had adjusted to the change in the relative prices of goods and services. It does not include the costs that some current investors and workers in sectors of the economy that produce energy and energy-intensive goods and services would incur as the economy moved away from the use of fossil fuels. To be sure, increased production of energy from non-fossil-fuel sources (such as wind or solar) and a shift to more energy-efficient production processes would create jobs and profit opportunities as well. However, those jobs might be in different regions of the country or require different skills than the jobs being lost, and the profit opportunities might arise from different types of capital; their availability would mute but not eliminate the costs of the transition. Thus, investors would see the value of some stocks decline, and workers would face higher risk of unemployment as jobs in some sectors were eliminated. Stock losses would tend to be widely dispersed among investors because shareholders typically diversify their portfolios. In contrast, the costs of unemployment would probably be concentrated among relatively few households and, by extension, their communities. The magnitude of those transitional costs would depend on the pace of emission reductions, with more rapid reductions leading to larger costs.

The magnitude of transitional costs would also be affected by international trade, especially for goods or services that embody large amounts of GHG emissions. The cost of producing such goods in the United States would rise under the cap-and-trade program, thereby disadvantaging producers of those goods relative to foreign competitors that did not face a similarly stringent program for reducing emissions. Although large segments of the U.S. economy either do not face significant foreign competition (for example, the electricity and transportation sectors) or involve trade with countries that have a cap-and-trade program (the European Union, for example), some important manufacturing industries, such as steel, face competition from countries that do not face the costs of such a system.

At the same time, as already noted, the prices of stocks in industries that would be expanding under a cap-and-trade program—such as renewable energy—could rise, as would job openings in those industries. CBO expects total employment to be only modestly affected by a cap-and-trade program to reduce GHG emissions. Except during cyclical downturns such as the current recession, most individuals who seek employment are able to find jobs, and a cap-and-trade program would not greatly diminish that ability. Some regions and industries would experience substantially higher rates of unemployment and job turnover as the program

became increasingly stringent. That transition could be particularly difficult for individuals employed in those industries (such as the coal industry) or living in those regions (such as Appalachia). However, any aggregate change in unemployment would be small compared with the normal rate of job turnover in the economy.

Distribution of Costs Across Households in Different Income Brackets

Estimates of the average net cost to households under H.R. 2454 do not reveal the wide range of effects that the cap-and-trade program would have on households in different income brackets, different sectors of the economy, and different regions of the country. In order to provide greater insight into some of those variations, CBO estimated the effect of the GHG cap-and-trade program on the average household in each fifth (quintile) of the population arrayed by income.[6]

Net Costs and Benefits

Taking account of households' share of the gross compliance cost and resource costs and the relief that would flow to households either through direct rebates and transfers or indirectly through the allocation of allowances, CBO estimates that households in the lowest income quintile would see an average *net benefit* of about $40, while households in the highest income quintile would see a *net cost* of approximately $245 (see Table 2). Households in the second lowest quintile would see added costs of about $40 on average, those in the middle quintile would see an increase in costs of about $235, and those in the fourth quintile would pay about an additional $340 per year. Overall, costs for households would average 0.2 percent of their average after-tax income.

Data and Methodology

The database for the analysis was constructed by statistically matching income information from the Statistics of Income data from the Internal Revenue Service, households' characteristics from the Current Population Survey reported by the Bureau of the Census, and data on households' expenditures from the Consumer Expenditure Survey by the Bureau of Labor Statistics. The data are from 2006, the latest year for which information from all three sources was available, and thus reflect the patterns of income and consumption in that year. The data were adjusted to 2010 levels by the estimated overall growth in population and income.

The estimated price increases for specific goods and services come from a model of the U.S. economy that relates final prices of goods to the costs of production

[6] CBO ranks households on the basis of household income adjusted for differences in household size. Each quintile contains an equal number of people.

inputs. Gross costs have been distributed to households on the basis of their consumption of those goods and services.[7]

CBO allocated households to quintiles on the basis of a comprehensive measure of household income that accounts for cash and noncash income and adjusts for household size. After-tax household income reflects the impact of federal income, payroll, and excise taxes.

As discussed below, for this analysis, CBO did not allocate to households in various income categories $7.2 billion of net costs incurred by federal, state, and local governments and $5.5 billion of the value of allowances allocated to businesses because there is no clear basis for identifying which households would either bear those costs or benefit from the value of those allowances. With those items excluded, the gross cost would come to approximately $770 per household, compared with the total gross cost of $890 per household (as reported in Table 1); the net cost used in this distributional analysis would come to $165 per household, compared with the overall net cost of $175 (as reported in Table 1).

The Distribution of Gross Compliance Costs

The largest part of the gross cost of the program would stem from holding allowances and purchasing offsets. Those costs would become a cost of additional production for firms subject to the cap on emissions, which they would generally pass on to their customers in the form of higher prices. The prices of goods and services throughout the economy would rise on the basis of the CO_2 emissions associated with their production and consumption. Goods and services resulting in greater emissions would have larger price increases; for example, the price of electricity would increase more than the price of food.

Another portion of the gross cost is the resource costs of implementing the legislation. Those resource costs would include expenditures that firms and households made to reduce their emissions (for example, by generating electricity from natural gas rather than from coal or by installing insulation) as well as inconvenience costs (from driving less, for instance). CBO reports all of those costs in dollar values and has assumed that households would bear those costs in proportion to their consumption of goods and services that result in CO_2 emissions. Thus, households that consumed relatively large shares of fossil-fuel-intensive goods and services prior to the policy would bear the cost of either reducing those emissions or purchasing allowances and offset credits. The

[7] For the purposes of this analysis, CBO allocated the cost of reducing all of the gases covered in the GHG cap-and-trade program across households and governments on the basis of their contributions to carbon dioxide emissions, which constitute more than 85 percent of those gases.

average resource cost accounts for only about $35 of the average gross cost increase of $770 per household.[8]

The gross cost would be largest in absolute terms for the average household in the highest income quintile. High-income households consume more goods and services than do lower-income households; consequently, they would experience a greater increase in expenditures as those prices rose as a result of the cap on emissions. In total, households in the highest income quintile would bear an estimated 36 percent of the gross cost associated with the cap, and their annual expenditures would increase by about $1,380, on average. In contrast, expenditures would increase by an estimated $425 for households in the bottom quintile, without any offsetting cost decreases or income transfers taken into account.

Although the increase in out-of-pocket expenditures because of the higher prices would be substantially larger for high-income households than for low-income households, they would impose a larger burden—measured as a share of income—on low-income households. That increased cost would account for 2.5 percent of after-tax income for the average household in the lowest income quintile, compared with 0.7 percent of after-tax income for the average household in the highest quintile. That difference occurs for two reasons: Lower-income households consume a larger fraction of their income, and energy-intensive goods and services make up a larger share of lower-income households' expenditures.

The Distribution of Direct Relief to Households

About 31 percent of the allowance value would be allocated in a fairly direct manner to U. S. households to compensate them for their increased expenditures (see Table 1). Some of that relief is expected to be allocated across most households in the form of a rebate on their bills for heating and cooling their homes. Other relief would be directed at low-income households in the form of an energy rebate or a tax credit. By CBO's estimates, 25 percent of the direct relief to households would go to households in the lowest income quintile and 50 percent to households in the two lowest quintiles combined. On average, the amount of direct relief would offset 94 percent of the additional expenses that households in the lowest quintile incurred. In contrast, the direct relief received by households in the highest quintile would offset only 18 percent of their added costs.

The Distribution of Allowance Value to Households via Businesses

H.R. 2454 would direct about 51 percent of the allowance value to businesses. In addition, net income would accrue to producers of domestic offsets. CBO

[8] That $35 figure is the household portion of the $40 average resource cost for the economy as a whole, shown in Table 1. The remaining $5 is the government portion of the resource cost (discussed later).

assumes that transfers to businesses (either in the form of allowances or cash) would lead to higher profits.[9] That result would be likely to occur in cases in which the transfers reduced the fixed costs associated with producing a good or providing a service. In general, businesses change prices in response to changes in their variable production costs (costs that increase in proportion to the quantity of goods or services provided) but not in response to changes in their fixed costs. That assumption was also used by CBO and JCT in estimating of the amount of the energy rebate and tax credit that would be provided to low-income households.[10] Increased profits, net of taxes, were allocated to households according to their holdings of equities, which were estimated from the Federal Reserve's Survey of Consumer Finances. Those holdings include equity held through mutual funds and private pension accounts.

CBO estimates that about 63 percent of the allowance value conveyed to businesses would ultimately flow to households in the highest income quintile.[11] On average, that relief would offset $885 of the additional expenses of those households resulting from the higher prices. In contrast, households in the lowest income quintile would receive only an estimated 5 percent of the relief targeted to businesses—an average of $65 per household.

The Costs and Allowance Value Not Included in CBO's Distributional Analysis

In total, federal, state and local governments account for roughly 14 percent of CO_2 emissions through the goods and services that they purchase. As a result, governments would incur roughly 14 percent of the gross compliance costs (the costs of purchasing allowances and offsets and of reducing emissions), amounting to about $15 billion. The federal government would also incur additional costs of about $12 billion to pay for the rebate for low-income households and the energy tax credit in excess of the allowance value allocated for those benefits, and to

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[9] Trade-exposed industries might not be able to increase their prices to reflect the higher costs that they would face as a result of the cap. As a result, the cost of the cap might fall on workers and shareholders in those industries rather than on their customers. Correspondingly, the relief aimed at those industries (which would be linked to their level of production) would tend to offset costs that workers and shareholders in those industries would otherwise incur. CBO assumed for this analysis that the cost of complying with the cap would lead to price increases for those industries. Correspondingly, CBO reflected the value of allowances allocated to those industries as offsetting price decreases.

[10] CBO assumed that allowances that were given to local distributers of electricity and natural gas would be passed on to commercial and industrial customers as a fixed rebate on their bill. As a result, that rebate would be retained as profits by the businesses that received them. An alternative assumption would alter the distributional results, in part, by altering the estimated size of the energy rebate and tax credit that low-income households received.

[11] Under an alternative assumption that transfers to businesses result in lower prices, a larger share of the benefits would flow to households in other income quintiles.

account for the costs of higher benefits and lower taxes because of increases in the consumer price index. The incidence of these costs would depend on the manner in which governments chose to cover them. For example, if governments chose to increase taxes, the cost would fall on households on the basis of their share of federal, state, and local taxes. In contrast, if governments chose to cover the additional expenses by cutting back on the services that they provide, the cost would fall on households that no longer received those services. As a result of the uncertainty about the incidence of governments' gross compliance costs and certain other costs, CBO did not distribute those costs across households.

On the other side of the ledger are a nearly equivalent amount of allowances and other benefits that were not allocated to households in this analysis. Those include about 11 percent of the allowance value that is directed to be spent by federal and state governments in a manner that does not have a clear incidence. For example, $5 billion would be given to state governments to fund increases in energy efficiency and the use of renewable energy. The federal government would also receive additional taxes from the allowances allocated to businesses and the income received by producers of domestic offsets. Because there is no clear basis for estimating how that value would ultimately be distributed across households in different income quintiles, CBO did not allocate those additional government receipts for this analysis. CBO also did not allocate the estimated $5.5 billion of the allowance value provided to businesses through subsidies for capturing and storing CO_2 emissions from electricity generation and developing advanced auto technologies because of similar uncertainty about the incidence of those benefits across households.

Altogether, CBO did not distribute across household income quintiles costs and benefits with a net contribution of $1.7 billion of the total $22 billion net economywide cost of the cap-and-trade program (as reported in Table 1). The undistributed costs and benefits account for about $10 of the total per-household net cost of $175 (as reported in Table 1).

While the net cost that CBO did not distribute was relatively small, the distributional effects of the omitted costs and benefits could be significant. For example, if most of the omitted costs were to fall on lower-income households while most of the omitted benefits were to fall on higher-income households, the distributional outcomes could be significantly different than those reported in Table 2.

Table 1. Total Cost and Average Cost of the Greenhouse-Gas Cap-and-Trade Program in H.R. 2454

`	Total Cost (Billions of dollars)	Share of Allowance Value (Percent)	Average Cost per Household (Dollars)
Gross Costs of Complying with the Cap			
Cost of Allowances and Offsets			
Market Value of Allowances	91.4	100.0	740
Domestic and International Offsets	13.3	n.a.	110
Resource Costs	4.9	n.a.	40
Total Gross Cost	109.6	n.a.	890
Disposition of Allowance Value to Domestic Entities			
Allocation of Allowances to Households			
Low-income rebate and tax credit	-13.7	15.0	-110
LDC residential customers	-14.5	15.8	-115
Allocation of Allowances to Businesses			
Trade-exposed industries	-14.1	15.4	-115
LDC nonresidential customers	-27.1	29.7	-220
Other	-5.5	6.0	-45
Allocation of Allowances to Government			
Deficit reduction	-1.0	1.1	-10
Energy efficiency and clean energy technology	-6.9	7.5	-55
Other public purposes	-2.3	2.5	-20
Total	-85.0	93.0	-690
Other Transfers			
Low-Income Rebate and Tax Credit Not Covered by Allowance Allocation	-2.8	n.a.	-25
Automatic Indexing of Taxes and Transfers	-8.7	n.a.	-70
Net Income to Providers of Domestic Offsets	-2.7	n.a.	-20
Total	-14.3	n.a.	-115
Additional Government Costs			
Low-Income Rebate and Tax Credit Not Covered by Allowance Allocation	2.8	n.a.	25
Automatic Indexing of Taxes and Transfers	8.7	n.a.	70
Total	11.6	n.a.	95
Net Economywide Cost	21.9		175
Memorandum: Source of Net Economywide Cost			
International offsets	7.8	n.a.	65
Production cost of domestic offsets	2.7	n.a.	20
Resource costs	4.9	n.a.	40
Allowance value going overseas	6.4	7.0	50
Total	21.9	n.a.	175

Source: Congressional Budget Office.

Notes: n.a. = not applicable; LDC = local distribution companies.
The figures in the table show the effects of the program in 2020 applied to levels of income in 2010.

Table 2. Distribution of the Costs and Financial Benefits of the Greenhouse-Gas Cap-and-Trade Program in H.R. 2454 Among Households, by Level of Income

	Gross Costs	Direct Relief to Households	Allocation to Businesses and Net Income to Domestic Offset Producers[a]	Net Cost
		Average Dollar Cost per Household		
Lowest Quintile	425	-400	-65	-40
Second Quintile	555	-420	-90	40
Middle Quintile	675	-300	-140	235
Fourth Quintile	815	-245	-230	340
Highest Quintile	1,380	-250	-885	245
All Households	770	-320	-285	165
		Cost as a Percentage of After-Tax Income		
Lowest Quintile	2.5	-2.3	-0.4	-0.2
Second Quintile	1.5	-1.1	-0.2	0.1
Middle Quintile	1.2	-0.6	-0.3	0.4
Fourth Quintile	1.1	-0.3	-0.3	0.4
Highest Quintile	0.7	-0.1	-0.5	0.1
All Households	1.0	-0.4	-0.4	0.2
		Percentage Shares of Costs and Value		
Lowest Quintile	11	25	5	-5
Second Quintile	14	25	6	5
Middle Quintile	17	19	10	28
Fourth Quintile	21	15	16	41
Highest Quintile	36	16	63	31
All Households	100	100	100	100

Source: Congressional Budget Office.

Notes: The figures are 2010 levels based on 2006 distribution of income and expenditures.
Households are ranked by adjusted household income. Each quintile contains an equal number of people.
Households with negative income are excluded from the bottom quintile but included in the total.

a. Includes allowance allocations for nonresidential customers of local distribution companies and trade-exposed industries.

Backgrounder

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The True Costs of EPA Global Warming Regulation

Ben Lieberman

Legislation designed to address global warming failed in Congress this year, largely due to concerns about its high costs and adverse impact on an already weakening economy. The congressional debate will likely resume in 2009, as legislators try again to balance the environmental and economic considerations on this complex issue. Meanwhile, the Environmental Protection Agency (EPA), pursuant to a 2007 Supreme Court decision, has initiated steps toward bypassing the legislative process and regulating greenhouse gas emissions under the Clean Air Act.

The EPA's Advance Notice of Proposed Rulemaking (ANPR) is nothing less than the most costly, complicated, and unworkable regulatory scheme ever proposed. Under ANPR, nearly every product, business, and building that uses fossil fuels could face requirements that border on the impossible. The overall cost of this agenda would likely exceed that of the legislation rejected by Congress, reaching well into the trillions of dollars while destroying millions of jobs in the manufacturing sector.[1] The ANPR is clearly not in the best interests of Americans, and the EPA should not proceed to a Notice of Proposed Rulemaking and final rule based upon it.

Climate Legislation

Concern that carbon dioxide and other greenhouse gases are gradually warming the planet has emerged as the major environmental issue of the day, and certainly the most hyped one. Carbon dioxide is a naturally occurring component of the air, but is also the ubiquitous and unavoidable by-product of

Talking Points

- Congress has thus far rejected legislation that seeks to curb global warming, in large part due to the prohibitive costs of reducing the carbon dioxide emissions from the fossil fuels that currently comprise 85 percent of the nation's energy supply.
- The Environmental Protection Agency's attempt to enact such measures through regulations under the Clean Air Act, pursuant to a 2007 Supreme Court decision, would be at least as costly, and probably more so, than the legislation rejected by Congress.
- The Clean Air Act is ill suited to address global warming. Attempts to do so would almost certainly unleash a costly and impractical regulatory scheme that would ensnare all manner of vehicles as well as a million or more businesses, buildings, and farms.
- Heritage's economic analysis estimates a nearly $7 trillion cumulative decline in GDP by 2029 from such regulations, and up to 3 million lost manufacturing jobs.

This paper, in its entirety, can be found at:
www.heritage.org/Research/EnergyandEnvironment/bg2213.cfm

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fossil fuel combustion, which currently provides 85 percent of America's energy. Thus, any effort to substantially curtail such emissions would have extremely costly and disruptive impacts on the economy and on living standards.

For this reason, the federal government has been cautious about embarking on mandatory carbon reductions. In 1997, the U.S. Senate unanimously resolved to reject any international climate change treaty that unduly burdened the U.S. economy or failed to engage all major emitting nations, such as China and India. Although the Kyoto Protocol was signed by the U.S. later that year, neither President Bill Clinton nor President George W. Bush ever submitted the treaty to the Senate for the required ratification. This has shown itself to be a wise move: Many, if not most, of the European and other developed nations that ratified the treaty are failing to reduce their emissions due to the prohibitive costs in doing so.

Legislatively, Congress has thus far rejected every attempt to control carbon dioxide emissions. Chief among the legislative proposals in 2008 was S. 2191, the America's Climate Security Act of 2007, originally sponsored by Senators Joe Lieberman (I–CT) and John Warner (R–VA). This was a so-called cap-and-trade bill that would set a limit on the emissions of greenhouse gases, especially carbon dioxide from the combustion of coal, oil, and natural gas. Each power plant, factory, refinery, or other regulated entity would have been allocated rights to emit limited amounts of carbon dioxide and other greenhouse gases. Those entities that reduced their emissions below their annual allotment could sell their excess allowances to those that did not—the trade part of cap and trade. The bill would start with a mandated emissions freeze at 2005 levels in 2012, and end with a 70 percent reduction by 2050.

In effect, this bill would have acted like a tax on energy, driving up its cost so that businesses and consumers are forced to use less.

Last June, America's Climate Security Act was withdrawn by its Senate supporters after only three days of debate. A Heritage Foundation analysis detailed the costs of the bill, which included a 29 percent increase in the price of gasoline, net job losses well into the hundreds of thousands, and an overall reduction in gross domestic product of $1.7 to $4.8 trillion by 2030.[2] At the time of the debate, gasoline was approaching $4 per gallon for the first time in history, and signs of a slowing economy were beginning to emerge. Economically speaking, the bill was one of the last items on the agenda that Americans wanted, and its Senate sponsors recognized that. Beyond the costs, the bill would have—even assuming the worst case scenarios of future warming—likely reduced the earth's future temperature by an amount too small to verify.[3]

The debate is sure to resume in 2009, but the economic concerns about such measures remain. Though gasoline prices may be lower next year than the last time climate legislation came to a vote, unemployment will likely be higher as will unease about the overall state of the economy. Thus, the legislative effort to place costly restrictions on energy still faces an economic headwind. Notwithstanding the state of the economy, such measures will always fail any reasonable cost-benefit test given their high costs and environmental benefits that are marginal at best.

Regulation as an Alternative to Legislation

While proponents of greenhouse gas restrictions have lobbied for additional legislation, they have also tried to force the EPA to regulate carbon dioxide as a pollutant under existing law. In 1999, an

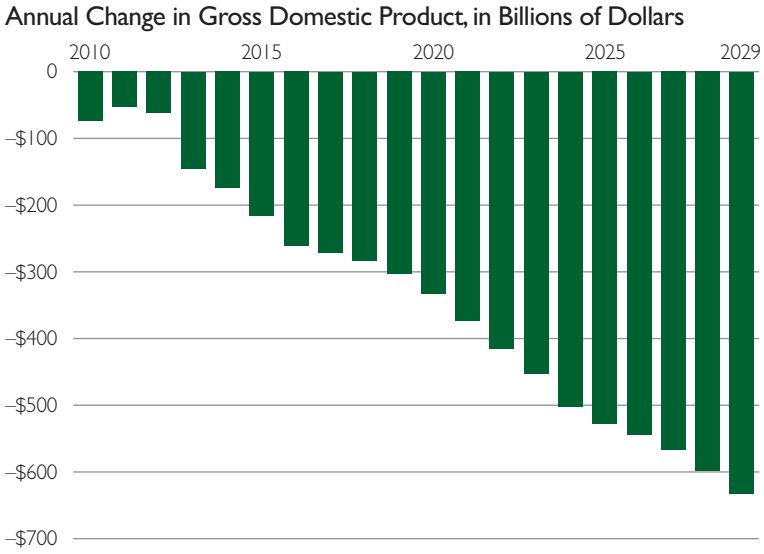
1. This *Backgrounder* is a companion to: David W. Kreutzer and Karen A. Campbell, "CO_2-Emission Cuts: The Economic Costs of the EPA's ANPR Regulations," Heritage Foundation *Center for Data Analysis Report* No. 08-10, October 29, 2008, at *http://www.heritage.org/Research/EnergyandEnvironment/cda08-10.cfm*.
2. William W. Beach et *al.*, "The Economic Costs of the Lieberman-Warner Climate Change Legislation," Heritage Foundation *Center for Data Analysis Report* No. 08-02, May 12, 2008, at *http://www.heritage.org/Research/EnergyandEnvironment/cda08-02.cfm.*
3. Ben Lieberman, "The Lieberman–Warner Climate Change Act: A Solution Worse Than the Problem," Heritage Foundation *Backgrounder* No. 2140, June 2, 2008, pp. 6–9, at *http://www.heritage.org/Research/EnergyandEnvironment/bg2140.cfm.*

environmental activist group sued the EPA over its refusal to restrict such emissions from motor vehicles under the Clean Air Act. The case eventually reached the Supreme Court, which in April 2007 ruled in a five-to-four decision against the EPA.

The decision did not require the EPA to change its position and begin regulating carbon dioxide from vehicle exhaust; it only required the agency to demonstrate that whatever it chooses to do complies with the requirements of the Clean Air Act. Nonetheless, the agency's detailed ANPR, published on July 30, 2008, appears to treat such regulation as a foregone conclusion. Although the ANPR is preliminary in nature, the level of detail (the ANPR and supporting documentation exceed 18,000 pages) suggests that the EPA has already decided to impose regulations that are unprecedented in their cost, complexity, and reach.

Lost Gross Domestic Product Due to Clean Air Act Regulation of CO_2

By restricting CO_2 emissions, the Clean Air Act will create higher energy costs and decrease the U.S. economy by an average of $339 billion every year through 2029.



Source: Center for Data Analysis, Heritage Foundation calculations from the Global Insight macroeconomic model.

Chart 1 • B 2213 heritage.org

The reasons for Congress's reluctance to enact global warming legislation are every bit as relevant to the debate over whether or not the EPA should achieve the same results through regulations. This is especially true given the many shortcomings of the Clean Air Act as an instrument for regulating carbon dioxide emissions—for which the statute was not intended. In effect, the measures detailed in the ANPR would require action at least as costly as comparable cap-and-trade bills, and likely more so given the added difficulty of doing it in a much more convoluted fashion.

Regulating Vehicles—and Almost Everything Else

Because no technology exists to date that offers the possibility to filter out carbon dioxide emissions from motor vehicle exhaust, the only way to reduce emissions is to use less fuel. In the ANPR, the EPA contemplates higher gas mileage standards for motor vehicles beyond those already scheduled to be imposed in accordance with the 2007 Energy Independence and Security Act. The EPA also discusses strict requirements for everything from airplanes to ships to trains to lawnmowers, all of which could be subject to new design specifications and usage limitations as well as fuel economy standards, as described in painstaking detail in the ANPR.

Beyond regulating anything that is mobile and uses energy, the ANPR also contemplates targeting anything that is immobile and uses energy—commercial and non-commercial buildings, large and small businesses, and farms. Under the Clean Air Act, once carbon dioxide emissions from motor vehicles are regulated, emissions from stationary sources must also be controlled under the New Source Review (NSR) and other Clean Air Act programs because they apply to all pollutants subject to regulation anywhere else in the statute. Even if the agency tries to rein in the reach of its regulation,

it will almost certainly face litigation by environmentalists opposing such restraint.

Given that the existing threshold for regulation under the Clean Air Act—250 tons of emissions per year, and in some cases as little as 100 tons per year—is easily met in the case of carbon dioxide emissions, the agency could impose new and onerous NSR requirements heretofore limited to major industrial facilities. Other Clean Air Act programs, such as the Title V permitting program and the hazardous-air-pollutants program, have even lower thresholds, creating a regulatory maze both restrictive and redundant.

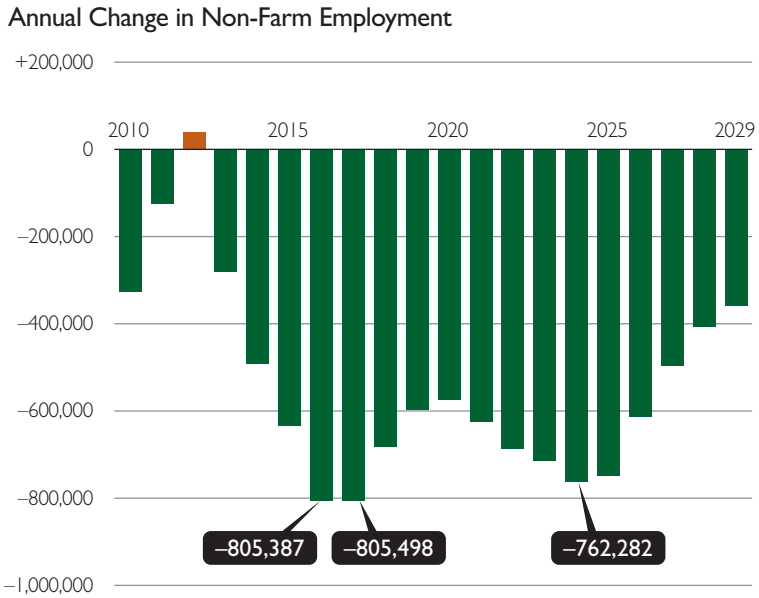
Most pollutants regulated under the Clean Air Act are trace compounds like ozone or mercury that are typically measured in parts per billion, so these threshold levels are sensible to distinguish *de minimis* contributors from significant ones. But carbon dioxide is not a trace compound, thus, existing Clean Air Act thresholds are ill suited. Background levels alone account for 275 parts per million, and even relatively small usage of fossil fuels could reach these thresholds. Thus, even the kitchen in a restaurant, the heating system in an apartment or office building, or the activities associated with running a farm could cause these and other entities—potentially more than a million buildings, 200,000 manufacturing operations, and 20,000 farms[4]—to face substantial and unprecedented requirements. Churches, hospitals, schools, and government buildings could also be subjected to these requirements.

This type of industrial-strength EPA red tape that imposes an average of $125,000 in costs and takes 866 hours to complete[5] could now be imposed, for the first time, on a million or more entities beyond the large power plants and factories that have traditionally already been regulated in this manner. Even more significant than the administrative costs is that all of these entities would be required to install costly technologies and operate under certain restrictions, as determined by EPA bureaucrats.

In sum, a host of complicated and redundant regulations could be applied to nearly every product, nearly every business, and nearly every building in America that uses fossil fuels. The ANPR, if finalized in anything near its current form, would create an environmental regulatory scheme more costly and intrusive than all the others combined.

Clean Air Act Regulations Will Cost Millions of Jobs

The U.S. will lose 10.7 million jobs cumulatively through 2029.



Source: Center for Data Analysis, Heritage Foundation calculations from the Global Insight macroeconomic model.

Chart 2 • B 2213 heritage.org

4. Portia M. E. Mills, Mark P. Mills, "A Regulatory Burden: The Compliance Dimension of Regulation CO_2 as a Pollutant," U.S. Chamber of Commerce, September 2008, p. 3.
5. Carrie Wheeler, "Information Collection Request for Prevention of Significant Deterioration and Nonattainment New Source Review," U.S. Environmental Protection Agency, no date.

The Costs of the ANPR

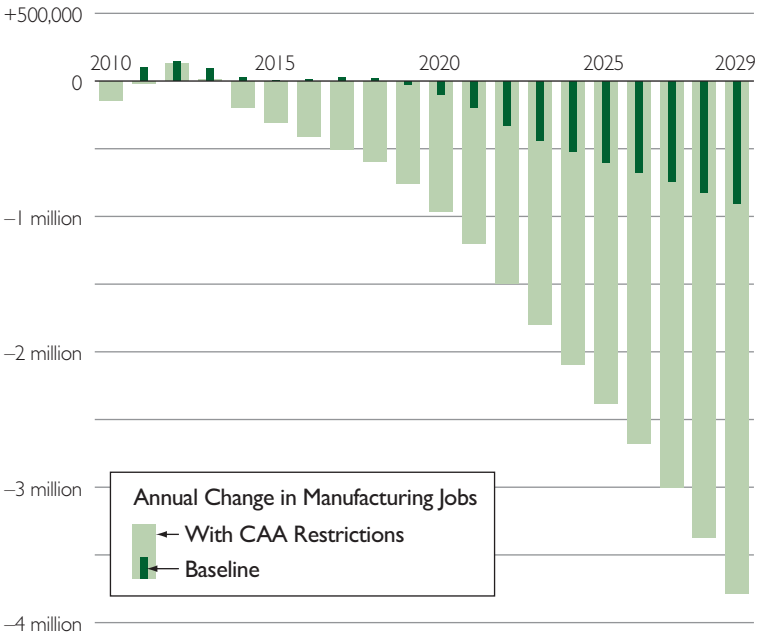
Either through legislation or regulation, efforts to reduce fossil fuel emissions will impose costs throughout the economy. For purposes of this analysis of the ANPR, the Heritage Foundation ignores the up-front administrative and compliance costs of imposing such an unprecedented crackdown both for regulated entities and for federal and state regulators. Heritage analysts instead assume the unlikely scenario of successful ANPR implementation and focus only on the cost of the rules in the form of higher energy costs.

The impact on the overall economy, as measured by gross domestic product (GDP), is substantial. The cumulative GDP losses for 2010 to 2029 approach $7 trillion. Single-year losses exceed $600 billion in 2029, more than $5,000 per household. (See Chart 1.) Job losses are expected to exceed 800,000 in some years, and exceed at least 500,000 from 2015 through 2026. (See Chart 2). Note that these are net job losses, after any jobs created by compliance with the regulations—so-called green jobs—are taken into account. Hardest-hit are manufacturing jobs, with losses approaching 3 million. (See Chart 3). Particularly vulnerable are jobs in durable manufacturing (28 percent job losses), machinery manufacturing (57 percent), textiles (27.6 percent), electrical equipment and appliances (22 percent), paper (36 percent), and plastics and rubber products (54 percent). It should be noted that since the EPA rule is unilateral and few other nations are likely to follow the U.S. lead, many of these manufacturing jobs will be outsourced overseas.

The job losses or shifts to lower paying jobs are substantial, leading to declines in disposable income of $145 billion by 2015—more than $1,000 per household.

Manufacturing Jobs Will Take Significant Hit

Primarily due to increasing productivity, manufacturing can expect to see employment losses approaching 1 million jobs even without restrictions on CO_2 emissions. This is the baseline case. Higher energy costs from CO_2 restrictions under the Clean Air Act will lead to nearly 3 million more lost jobs in addition to the baseline losses.



Source: Center for Data Analysis, Heritage Foundation calculations from the Global Insight macroeconomic model.

Chart 3 • B 2213 heritage.org

Conclusion

Virtually every concern heightened by the economic downturn, especially job losses, would be exacerbated under the ANPR. As with cap-and-trade legislation, the EPA's suggested rulemaking would be poison to an already sick economy. But even in the best of economic times, this policy would likely end them. The estimated costs—close to $7 trillion dollars and 3 million manufacturing jobs lost—are staggering. So is the sweep of regulations that could severely affect nearly every major energy-using product from cars to lawnmowers, and a million or more businesses and buildings of all types. And all of this sacrifice is in order to make, at best, a minuscule contribution to an overstated environmental threat. Congress has wisely resisted

implementing anything this costly and impractical. The fact that unelected and unaccountable EPA bureaucrats are trying to do the opposite is all the more objectionable.

—Ben Lieberman is Senior Policy Analyst in Energy and the Environment in the Thomas A. Roe Institute for Economic Policy Studies at The Heritage Foundation.

BusinessWeek

Viewpoint June 17, 2009, 11:04AM EST text size: TT

Innovation Economics Can Fight Global Warming

Going beyond carbon emissions caps, innovation economists are calling for bold public-private partnerships to spur energy research

By Rob Atkinson

The U.S. House of Representatives may be on the verge of passing the most significant environmental measure since 1990. The bill, named for its sponsors, representatives Howard A. Waxman (D-Calif.) and Edward J. Markey (D-Mass.), would for the first time impose caps on carbon dioxide emissions, which contribute to global warming. It also would allow companies to buy credits from each other, permitting them to exceed their greenhouse gas limits.

While the so-called cap-and-trade mechanism (or some kind of carbon pricing) is needed, it isn't enough. To really avert climate change, the government needs to adopt an explicitly green innovation policy. Unfortunately, green innovation is getting short shrift in this bill and in Washington generally.

Four prevailing doctrines shape U.S. economic policy today: Keynesian economics; two versions of neoclassical economics (conservative supply-side economics and liberal "Rubinomics"); and the new kid on the block, "innovation economics," about which *BusinessWeek* Chief Economist Michael Mandel wrote a cover story last September.

Both conservative and liberal neoclassicists oppose any government allocation of scarce goods and services. They prefer a market tool such as emissions trading that would set a price for carbon pollution, believing—incorrectly—that companies seeing potential profits would then develop needed technologies. The two camps differ slightly in how to determine a carbon price. In line with their faith in markets, most supply siders who worry about global warming favor carbon taxes, while liberal neoclassicists favor cap and trade.

profit motive requires real choices

Latter-day Keynesians, true to the principals of Keynes himself, also back cap and trade, though they regard it as a form of necessary regulation—government sets limits and companies have no

choice but to comply. They also don't give much thought to explicitly spurring green innovation because they believe that strict caps in and of themselves would fix things.

Innovation economists see efforts to reduce emissions of carbon dioxide and other greenhouse gases as fundamentally an innovation challenge. They are less sanguine than neoclassicists about the power of price signals alone to bring about a solution, believing that the profit motive works only when there are adequate alternatives to shift to. Without viable electric cars, for example, people will still drive gasoline-powered cars, no matter how much fuel costs, although they might switch to more fuel-efficient models.

Moreover, they believe that even if the price signal is "correct," the innovation that's needed is often delayed because of market failures such as externalities—situations where innovators can't get the full reward from their innovations. Consequently, adherents of innovation economics say that the government must spend more on research and development to develop cost-effective noncarbon or low-carbon energy alternatives.

So who is right? Putting a price on carbon emissions would certainly help. But it's wishful thinking to believe that raising the price by $20 to $40 a ton would make a big difference. A case in point is the Netherlands. Gasoline there costs approximately $8 a gallon today—$5 of which comes from various taxes, amounting to a de facto carbon tax. This is equivalent to $400 per ton for carbon, vastly higher than the price that the Waxman-Markey proposal would bring about.

Keynesians ignore political realities

Yet while the Dutch drive less than Americans and do so in smaller cars, they still drive conventional vehicles. In fact, there are virtually no electric cars in the Netherlands. If a price of $400 per ton doesn't inspire consumers to embrace electric cars, why would a modest U.S. cap-and- trade system produce the kinds of innovation we need? Pricing carbon is not sufficient to change behavior or investments.

There's a fundamental problem with the Keynesian take on carbon reduction, too. Without systemic and radical innovation, meeting emission caps might become extremely costly in later years as limits become tougher. If the cost of regulation jumps, politicians would undoubtedly be pressured to weaken the caps. Any compromise would send the wrong signal to developing nations, which also must lower their output of greenhouse gases to slow or halt climate change.

If we are to halve global carbon emissions by 2050—the minimum reduction needed, according to many scientists—we will need radically cleaner technologies such as fully electric cars, affordable solar cells, and large-scale electricity storage devices.

To make this happen, the federal government should develop a broader approach, including spending more money on clean energy R&D. The government can afford it. In 1980, about 10% of federal research went to energy—down to less than 2% today. Getting back to 1980 levels would lift energy R&D expenditures by $11.4 billion a year.

Needed: Clean energy research funding

To encourage private-sector investment, Congress should also significantly increase the tax credit for R&D related to carbon emissions. Recent energy legislation created a 20% credit for corporate research conducted in collaboration with such public entities as federal labs and universities. That tax break should be 40%, and Congress should raise other energy R&D credits to 30%.

In addition, the government should establish new clean energy research centers that could discover and test new technology. Congress took a step in this direction with the 2007 creation of the Advanced Research Project Agency in the Energy Dept. Now lawmakers need to fully fund it.

The Waxman-Markey bill would establish eight "Clean Energy Innovation Centers" around the country to do R&D and accelerate the commercialization of clean energy technologies. But according to the Breakthrough Institute, the bill would allocate less than $1 billion to clean energy R&D. Much more is needed if we are serious about solving global warming.

In the end, differences over climate change go to the heart of most economic policy debates in Washington. Neoclassicists give short shrift to innovation (and innovation policy), and believe innovation is best left to the invisible hand of the marketplace. Likewise, neo-Keynesians don't give innovation its due, arguing that government can simply mandate the results it needs. In contrast, innovation economists put innovation at the center and argue that advances require bold public-private partnerships. We can't afford to do less.

Rob Atkinson is Founder and President of The Information Technology and Innovation Foundation, a Washington, DC-based think tank. He is also author of The Past and Future of America's Economy: Long Waves of Innovation that Drive Cycles of Growth. *His focus is on IT and innovation and policy to support them.*

Backgrounder

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Red Tape Rising: Regulatory Trends in the Bush Years

James L. Gattuso

In this election year, Americans will hear a lot about taxes. Candidates for everything from President to village alderman will present their plans on who should pay and how much. Yet in the political frenzy, one type of tax will almost certainly be overlooked: the hidden tax of regulation. The federal government alone enforces thousands of pages of regulations that impose a burden of some $1.1 trillion—an amount that is comparable to total federal income tax receipts.

And the cost of regulation is getting higher. Despite the claims of critics—and some supporters—of the Bush Administration, net regulatory burdens have increased in the years since George W. Bush assumed the presidency. Since 2001, the federal government has imposed almost $30 billion in new regulatory costs on Americans. About $11 billion was imposed in fiscal year (FY) 2007 alone.

Even more are on the way. Historically, the amount of regulatory activity surges dramatically in the last year of a presidential Administration, whether Republican or Democrat, as regulators, freed from normal political constraints, clean off their desks. A similar surge looks likely for the final year of the Bush Administration unless the President and other policymakers keep a tight hand on the regulatory leash.

Background

Over 50 agencies ranging from the Animal and Plant Health Inspection Service to the Bureau of Customs and Border Protection have a hand in federal regulatory policy. Together, they enforce over 145,000

Talking Points

- The regulatory burden has increased during the Bush Administration.
- Since 2001, the annual regulatory cost of federal regulation has increased by nearly $30 billion. Over $11 billion was added in FY 2007 alone.
- By contrast, actions to lessen regulatory burdens have been rare. In FY 2007, savings from significant actions reducing regulation totaled some $684 million, or about 1/17th of the cost of new burdens imposed that year.
- Regulatory burdens may increase even more in 2008, with a bevy of costly new regulations already in the pipeline. Historically, regulatory activity surges during the final year of a presidential Administration.
- Policymakers should consider a number of reforms, including strengthening the OMB's Office of Information and Regulatory Affairs, establishing a Congressional Regulation Office, establishing a sunset date for all new regulations, and requiring independent agencies to submit benefit-cost analyses for review by the OMB.

This paper, in its entirety, can be found at:
www.heritage.org/Research/Regulation/bg2116.cfm

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pages of rules, with purposes and impacts as varied as the agencies themselves. Some rules are meant to protect health and safety, some to protect (or suppress) economic competition, and others to protect the environment.

Certainly, many of these regulations are justified—and even necessary. For instance, most would agree on the need for security rules to protect citizens against terrorism, although the extent and scope of those rules may be subject to debate. Moreover, imposition of a regulation is not *per se* inconsistent with market principles. Some in fact reinforce property rights and market mechanisms.

Nevertheless, all rules come at a cost: a "regulatory tax" imposed on all Americans. Of course, Americans do not file regulatory tax forms on April 15, and there is no bottom line indicating how much they pay for these regulations. Hidden or not, however, the tax is large. According to a 2005 study for the Small Business Administration, the cost of all rules on the books is $1.1 trillion,[1] about the same amount that Americans paid in federal income taxes in 2007.

Even this staggeringly large number may underestimate the cost of regulation, since many costs are by their nature unknowable. For many economic regulations, the primary cost may not be any direct burden placed on consumers or businesses, but constraints on innovation. Assessing such losses is impossible because inventions that never existed cannot be measured.

Moreover, regulations can also reduce Americans' health and safety. Delays in new drug approvals by the Food and Drug Administration have led to thousands of unnecessary deaths.[2] By encouraging the purchase of smaller cars, automobile fuel efficiency standards have contributed to thousands of deaths in car accidents.[3] Rules banning health claims on wine bottles have denied Americans information about the beneficial effects of the moderate consumption of wine on heart health.[4]

Regulation in the Bush Years: Still Going Up

To its credit, the Bush Administration during its seven years in office has made significant efforts to rein in regulation, mostly through enhanced review of regulatory proposals to ensure that any new restrictions are necessary and impose as little burden as possible. The White House agency responsible for reviewing proposed new rules—the Office of Information and Regulatory Affairs (OIRA), part of the Office of Management and Budget (OMB)—has taken an active role as a gatekeeper.[5] It has established strict criteria for agencies' "regulatory impact analyses" of their rules and for peer review of those analyses. In early 2007, President Bush further strengthened the system by, among other things, increasing the role of designated "regulatory policy officers" within agencies.[6]

Some have argued that regulatory reforms have gone too far and that regulations have been dangerously weakened. Such criticism has been especially

1. W. Mark Crain, "The Impact of Regulatory Costs on Small Firms," Small Business Administration, Office of Advocacy, September 2005, at *www.sba.gov/ADVO/research/rs264tot.pdf* (March 10, 2008).
2. See David R. Henderson, "End the FDA's Monopoly," Hoover Institution *Weekly Essay*, February 23, 2004, at *www-hoover.stanford.edu/pubaffairs/we/2004/henderson02.html* (September 13, 2004).
3. See National Research Council, Transportation Research Board, *Effectiveness and Impact of Corporate Average Fuel Economy (CAFE) Standards* (Washington, D.C.: National Academy Press, 2002), at *http://books.nap.edu/openbook.php?record_id=10172&page=R1* (March 10, 2008).
4. See Ben Lieberman, "The Power of Positive Drinking: Are Alcoholic Beverage Health Claims Constitutionally Protected?" *Food and Drug Law Journal*, Vol. 58, Issue 3 (2003).
5. See James L. Gattuso, "Regulating the Regulators: OIRA's Comeback," Heritage Foundation *Executive Memorandum* No. 813, May 9, 2002, at *www.heritage.org/Research/Regulation/EM813.cfm*, and "Who Will Regulate the Regulators? The Battle over Susan Dudley and OIRA," November 9, 2006, Heritage Foundation *WebMemo* No. 1250, at *www.heritage.org/Research/Regulation/wm1250.cfm*.
6. See Curtis W. Copeland, "Changes to the OMB Regulatory Review Process by Executive Order 13422," Congressional Research Service *Report for Congress*, February 5, 2007, at *www.fas.org/sgp/crs/misc/RL33862.pdf* (March 10, 2008).

frequent over the past year in the wake of fatal mine accidents in West Virginia and Utah and widespread recalls of toys made in China. For instance, these incidents led *USA Today* to charge that Bush has let "[r]egulators slumber."[7]

Others go even farther. OMB Watch, a pro-regulation advocacy group, charged that Bush has "left the public uncertain about whether we can count on our government to provide adequate safeguards."[8] The Center for American Progress charged that "[i]nstead of protecting the public, the administration has weakened or thrown out a host of protective standards."[9]

Regulation by the Numbers

The rhetoric is alarming, but it does not fit the facts. Far from shrinking to dangerously low levels, regulation has actually grown substantially during the Bush years. By almost every measure, regulatory burdens are up.[10]

Tracking year-to-year changes in regulatory burdens is no easy task. Unlike on-budget expenditures, there is no single bottom line figure to report. Yet a number of measures together can provide a fair picture of what is happening in the regulatory world.[11]

Regulatory Budget and Staffing Levels. Critics of Bush Administration regulatory policy have argued that budget cuts are evidence that restrictions are being loosened. Yet according to an analysis by George Mason University's Mercatus Center and Washington University's Weidenbaum Center, appropriations for federal regulatory agencies have increased during the Bush years from $27 billion in FY 2001 to $44.9 billion in FY 2007—a 44 percent increase in inflation-adjusted dollars.[12] The total staffing of regulatory agencies went up nearly as much, from 172,000 employees to over 244,000—a 41 percent increase.

To a significant degree, these increases are due to the federal takeover of airport screening operations by the Transportation Security Administration (TSA). But even with the TSA excluded, the increases were still sizeable, with regulatory budgets still increasing by 30 percent and non-TSA staff levels rising almost 11 percent.

While homeland security functions garnered the largest increases, expansion has not been limited to that area. Agencies responsible for consumer safety and health have received budget increases of 33 percent in real terms since 2000[13] and staff increases of over 9 percent. Other areas with increases include transportation, energy, and general business regulation. Environmental regulation declined in real (although not nominal) terms, from about $6 billion to $5.6 billion. However, because environmental spending increased during the 1990s by about one-third, today's funding is still well above its 1990 level.

7. Editorial, "Our View on Protecting the Public: Regulators Slumber, Letting Health and Safety Suffer," *USA Today*, November 1, 2007, at *http://blogs.usatoday.com/oped/2007/11/our-view-on-pro.html* (March 10, 2008).
8. OMB Watch, "A Year for Failure: Regulatory Policy News in 2007," December 18, 2007, at *www.ombwatch.org/article/blogs/entry/4416/18* (March 10, 2008).
9. Reece Rushing, "Safeguarding the American People: The Progressive Vision vs. the Bush Record," Center for American Progress, August 23, 2007, at *www.americanprogress.org/issues/2007/08/safeguarding_report.html* (March 13, 2008).
10. For an earlier assessment of regulatory trends in the Bush years, see James L. Gattuso, "Reining in the Regulators: How Does President Bush Measure Up?" Heritage Foundation *Backgrounder* No. 1801, September 28, 2004, at *www.heritage.org/Research/Regulation/bg1801.cfm*.
11. The discussion and analysis in this paper focus primarily on regulation as imposed by rules promulgated by agencies, as opposed to regulation imposed by Congress through legislation. Regulation by legislation, while certainly important, is largely outside the scope of this paper.
12. Jerry Brito and Melinda Warren, "Growth in Regulation Slows: An Analysis of the U.S. Budget for Fiscal Years 2007 and 2008," George Mason University, Mercatus Center, and Washington University at St. Louis, Weidenbaum Center on the Economy, Government, and Public Policy, *Regulator's Budget Report* No. 39, June 2007, at *www.mercatus.org/repository/docLib/20070619_2008_Regulators_Budget.pdf* (March 10, 2008).
13. The Mercatus–Weidenbaum report does not provide agency-specific details for 2001.

Regulatory Page Counts. What are regulators actually doing with their resources? Perhaps the most commonly cited yardstick of regulatory activity is the size of the *Federal Register*. Before any new federal rule can be proposed or finalized, the agency involved must publish it in this daily publication. In 2007, the *Federal Register* declined slightly in size, weighing in at 72,090 pages. That figure is less than its all-time record of over 75,000 pages but still higher than any year before 2000.[14]

Unlike the *Federal Register*, which is in effect a posting board for all sorts of agency actions, the Code of Federal Regulations (CFR) is the regulatory equivalent of a statute book that includes only the text of existing regulations. In number of pages, the CFR makes the *Federal Register* look Lilliputian, with the 2007 edition totaling 145,816 pages, more than 4,500 pages longer than in 2001, when Bush took office,[15] and almost 8,000 pages longer than in 2000.

However, the *Federal Register* and CFR page counts have significant drawbacks as measures of regulation. The *Federal Register* contains more than regulations, including discussions of rules, determinations under rules, requests for public comment, and more. In addition, agencies must publish all rule changes in the *Federal Register*, both actions to eliminate or reduce regulatory burdens and actions to increase them.

CFR page counts have similar limitations. Most notably, the number of pages in a regulation does not necessarily indicate a heavier burden. A 500-page regulation could impose a lesser burden than a simple one-line prohibition of an activity.

The Number and Cost of Major Rules. More important than the mere number of pages in the *Federal Register* or the CFR is the content of those pages: How many rules are being adopted, and what do they cost Americans?

Many thousands of regulatory actions are taken each year: 3,595 rules were printed in the *Federal Register* in 2007 alone.[16] However, a large number of these are not "regulatory" in the commonly understood sense of the word because they do not limit or impose mandates on private activities. Many rules each year are fiscal in nature, such as those that establish rules and conditions for federal spending programs.[17] Others are annual determinations, such as the number of birds that can be hunted in certain areas, based on preexisting regulatory schemes.

Excluding these "non-regulatory" rules still leaves many thousand agency actions each year that increase or decrease regulatory burdens. Each has a real cost, but the size of their impact varies widely. Perhaps as much as 90 percent of regulatory costs comes from "major" or "economically significant" regulations—regulations that have economic impacts of more than $100 million.[18] While costly, relatively few regulations reach this threshold, making it feasible to examine them individually.

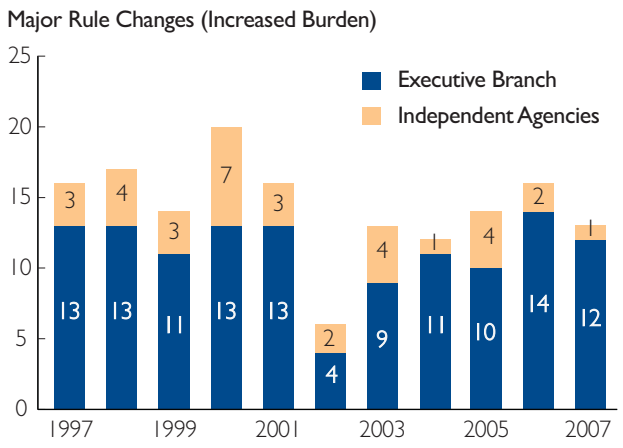
During the first seven years of the Bush presidency, 98 such major rules were promulgated by federal agencies. Of those, 75 (more than 10 per year) increased regulatory burdens on Americans. This is significantly less than the rate during the Clinton Administration, which adopted major increases in regulation at a rate of some 19 times per year from 1997 to early 2001.[19]

Although the Bush Administration imposed fewer new burdens on Americans, the total regulatory bur-

14. U.S. National Archives and Records Administration, Office of the Federal Register, "Chart 7: Federal Register Pages Published, 1936–2008." This total excludes blank pages.
15. U.S. National Archives and Records Administration, Office of the Federal Register, "Chart 12: Code of Federal Regulations—Total Pages 1938 Through 1949, and Total Volumes and Pages 1950 through 2006."
16. .US. National Archives and Records Administration, Office of the Federal Register, "Chart 10: Federal Register Documents, 1976–2008."
17. Such rules can burden the private sector. For instance, Medicare rules are a major burden on doctors and hospitals. While these rules pose substantial problems, they are outside the scope of this paper.
18. Office of Management and Budget, Office of Information and Regulatory Affairs, *Progress in Regulatory Reform: 2004 Report to Congress on the Costs and Benefits of Federal Regulations and Unfunded Mandates on State, Local, and Tribal Entities*, pp. 26–27, at *www.whitehouse.gov/omb/inforeg/2004_cb_final.pdf* (March 10, 2008).

Chart 1 B 2116

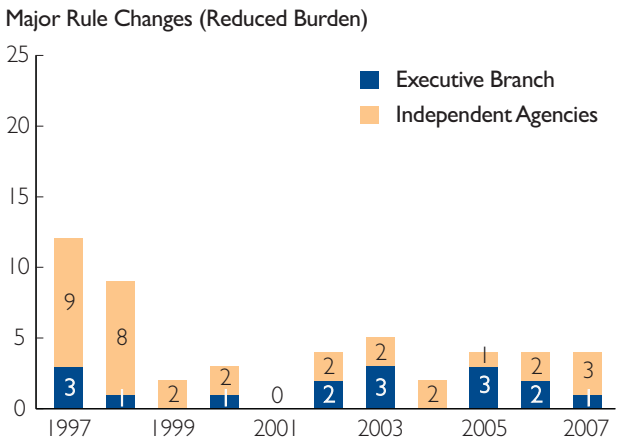
Major Increases in Regulatory Burdens, 1997–2007



Source: U.S. Government Accountability Office, Federal Rules Database, at *www.gao.gov/fedrules.html* (March 10, 2008).

Chart 2 B 2116

Major Decreases in Regulatory Burdens, 1997–2007



Source: U.S. Government Accountability Office, Federal Rules Database, at *www.gao.gov/fedrules.html* (March 10, 2008).

den continued to increase in absolute terms. Compared to the 74 rule changes that increased regulatory costs, only 23 rule changes reduced burdens. In other words, for every case in which regulators reduced a burden, they increased burdens over three times.

Interestingly, independent agencies such as the Federal Communications Commission (FCC) and Securities and Exchange Commission (SEC), which are not under the President's direct control and are not subject to White House regulatory review procedures, have accounted for more than half of all deregulatory actions.

The reason for the higher percentage of deregulatory actions at these independent agencies is unclear. One factor may be that both the FCC and the SEC administer 1930s-era economic regulations that have been undergoing significant change. The FCC's deregulatory record was due largely to proceedings liberalizing radio spectrum rules. However, regardless of the deregulatory actions of the independent agencies, they are still a major source of new regulation, accounting for about a quarter of all rules that increased burdens.[20]

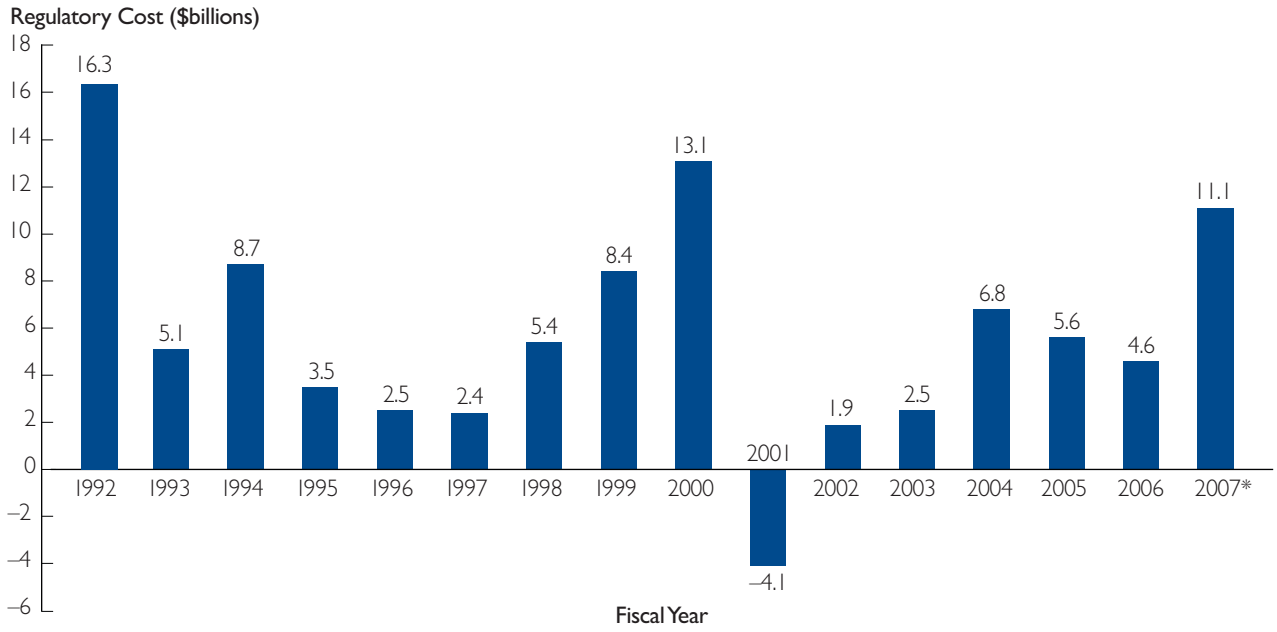
Cost Estimates. The costs and number of regulations are increasing substantially. Based on regulatory impact analyses prepared by agencies, over $28 billion in new regulatory costs has been imposed on Americans since the beginning of the Bush Administration.[21]

Regulatory costs went down only in one year (2001) due to the repeal of an ergonomics rule promulgated by the Department of Labor under the Clinton Administration. After remaining relatively low for the next couple of years, average new costs for 2004 through 2006 ranged between $4 billion and $6 billion.

19. Based on major rules reported to Congress by the Government Accountability Office (GAO) pursuant to the Congressional Review Act of 1996. U.S. Government Accountability Office, Federal Rules Database, at *www.gao.gov/legal/congress.html* (March 10, 2008). For the purposes of this analysis, only rules reported by the GAO after March 2001 are attributed to the Bush Administration. Rules before 1997, the first full year of GAO reports, are not included. Fifteen of the rules attributed to the Clinton Administration were "midnight regulations," finalized in early 2001.
20. Because of a quirk in the law, the GAO data do not include FCC decisions implementing the Telecommunications Act of 1996.

Chart 3 B 2116

Cost of Major New Regulations, FY 1992–2007



* Estimate based on reports from individual agencies.
Sources: Office of Management and Budget and Heritage Foundation calculations based on reports from individual agencies.

In 2007, costs shot up to their highest level yet in the Bush Administration. OIRA has not yet released figures for FY 2007, but some $11.8 billion in new costs was imposed, based on estimates from individual agencies. Most of this cost ($6.7 billion) comes from a single regulation: the fine particle implementation rule from the Environmental Protection Agency (EPA). Almost $1.4 billion comes from the Department of Homeland Security's anti-terrorism standards for chemical facilities. The Department of Transportation's rules on electronic stability control systems for automobiles cost $985 million per year, and new side-impact collision rules cost about $764 million per year.[22]

While substantial, these numbers likely underestimate the total cost of the new regulations. Costs for many rules, including those by most independent agencies, are not quantified. Moreover, the estimates are drawn from analyses produced by the regulators themselves, who have an incentive to minimize the reported costs.[23]

Whatever the exact number, the cost of new restrictions dwarfs the savings to Americans from actions reducing regulatory burdens. In FY 2007, federal regulators completed eight major proceedings that reduced burdens: five from the SEC, two from the Department of Agriculture, and one from the EPA.[24] Of these, cost savings were quantified for

21. Totals are net of savings from deregulation but not of claimed benefits from regulatory actions. Calculations are by OIRA through FY 2006. FY 2007 totals are based on regulatory impact analyses by individual agencies for rules finalized in FY 2007. In its estimate, OIRA adjusted the numbers to a standard inflation-adjusted level and made other changes for consistency. For FY 2007, such modifications were not made. Where agencies provided a range of numbers, the midpoint was used unless another figure was indicated. For 2007, the cost of the EPA's particulate matter rule adopted in October 2006 was not included because this was redundant with the EPA's implementation rule for particulate matter adopted in April 2007.

three, totaling just under $684 million, or about 1/17th of the new costs imposed.[25]

In both number and cost, the trend is clear: Rather than shrinking, the burden of regulation expanded during the Bush years. That growth was relatively slow during the first several years but has accelerated during the President's second term. Contrary to much popular rhetoric, significant deregulation has been virtually nonexistent.

The Expected Regulatory Surge

Looking ahead, the growth of regulatory burdens is likely to accelerate further. Historically, regulatory activity surges at the end of a presidential Administration. In the months before (and for several months after) President Bill Clinton left office, a rush of "midnight regulations" were adopted, pushing the total for 2000 to $13.1 billion—over one-third higher than for any other year of his Administration.

Yet the pattern is not limited to Democrats. In 1992, the last year of President George H. W. Bush's Administration, regulatory costs hit $12.5 billion. Regulatory costs even surged in 1988, at the end of the Reagan Administration.

These surges are not random. The most likely explanation is that regulators have an institutional incentive to clear their desks before turning over the office keys to new occupants. In the process, the normal review procedure may be overwhelmed, with more costly rules slipping through the screens.

There are already signs that such a regulatory surge is on the way for 2008. Reams of new rules are in the pipeline for 2008, ranging from Department of Agriculture rules on genetically modified food to Food and Drug Administration rules on dietary supplements to Americans with Disabilities Act rules for airlines.

The EPA looks to be particularly busy, with rules being adopted or nearing completion on everything from ozone to electric generator emissions. However, the most costly EPA agenda item could be regulation of carbon dioxide and other greenhouse gases from motor vehicles. In April 2007, the U.S. Supreme Court ordered the EPA to determine whether or not such gases endanger the public health and must be regulated under the Clean Air Act.[26] The EPA had argued (unsuccessfully) that ubiquitous substances such as carbon dioxide should not be considered "pollutants" and that the agency was therefore not directly required to regulate. If it does regulate greenhouse gas emissions, the costs could be immense.[27]

22. Other rules finalized during FY 2007 and their estimated annual costs include Food and Drug Administration rules on blood transfusions ($10.3 million) and dietary supplements ($153 million); Department of Homeland Security rules on electronic transmission of manifests ($123 million), hazardous materials transport ($247.5 million), and documents for Western Hemisphere travelers ($649 million); SEC rules on proxy materials ($24.8 million); Department of Agriculture rules on the use of stunning devices ($171.2 million); Department of Energy rules on reliability of bulk-power systems ($131.76 million); EPA rules on air pollution from mobile sources ($359.4 million) and drinking water ($62.05 million); Treasury and Health and Human Services rules on the "wellness market" ($11.5 million); and Department of Labor rules on mine evacuations ($42.6 million).
23. Independent agencies are not required to prepare regulatory impact analyses. For instance, the FCC almost never calculates the costs of its rules, but the SEC routinely does so, although it is not required.
24. The cost savings from the rule changes were as follows: SEC rules on termination of a foreign private issuer's registration ($200 million), management reports on internal controls (no estimate), Internet availability of proxy materials ($144.85 million), periodic reports (no estimate), and mutual fund redemption fees ($175.4 million); Department of Agriculture rules on bovine importation ($37.1 million) and milk marketing orders (no clear estimate); and EPA rules on oil spill prevention ($126.5 million).
25. The totals in Chart 3 are costs of new regulations minus cost savings from reductions of regulation. They are not net of quantified benefits of regulations. While estimates of benefits are critical to the consideration of a particular regulation, the purpose of this paper is to examine the total burden of regulations imposed. Just as the federal budget includes the full cost of each spending program, not just the net cost of presumed benefits, these figures are meant to reflect the full costs of regulation.
26. *Massachusetts et al. v. Environmental Protection Agency et al.*, No. 05–1120 (U.S. April 2, 2007).

The Federal Communications Commission is also considering new regulation. Most notably, FCC Chairman Kevin Martin has proposed a variety of new restrictions and mandates on the cable television industry and rules on how network managers manage traffic on their networks. The cost of such regulation is unknown—the FCC does not produce cost-benefit analyses—but it would likely be significant.

What Is to Be Done?

No single magic bullet will stop the growth of regulation, but policymakers can take steps to increase scrutiny of new and existing rules, both to ensure that each is necessary and to minimize costs. Specifically, they should:

- **Continue to strengthen the Office of Information and Regulatory Affairs.** OIRA has long played a key role in ensuring that proposed new rules are well scrutinized before adoption. During the Bush Administration, it has played a particularly significant role, strengthening and systematizing regulatory review procedures so that they are more consistent, transparent, and effective. However, OIRA is still badly outgunned in regulatory battles, with almost 5,000 regulatory agency staffers per OIRA staffer. OIRA should be provided with additional resources to regulate the regulators.[28]
- **Establish a Congressional Regulation Office.** While Congress receives detailed information from the Congressional Budget Office on the state of the budget and on proposals that would affect the budget, it has no similar source of information on regulatory programs. A Congressional Regulation Office would help to fill this gap. Such an office could review the regulatory impact of legislative proposals and report on the cost and effectiveness of rules adopted by agencies. In this way, it would act as both a complement to and a check on OIRA.
- **Establish a sunset date for all new federal regulations.** While every new regulation promulgated by executive branch agencies undergoes a detailed review, no similar process is in place for reviewing regulations that are already on the books.[29] Old rules tend to be left in place even though they may no longer be necessary.[30] Policymakers should create a process under which the regulatory closet is regularly cleaned by establishing a sunset date on all new regulations, after which they would expire unless they are explicitly renewed by regulators. Ideally, such a sunset date should apply to all regulations, but given the vast number of regulations in place, such a requirement would not be feasible. By limiting review to new regulations—perhaps on the 10th anniversary of a rule—agencies could adequately review the merits of and need for each regulation.
- **Require independent agencies to submit cost-benefit analyses to OIRA.** Independent agencies (e.g., the FCC and SEC) produce a substantial share of the major new rules that are finalized

27. See Ben Lieberman, "EPA Should Avoid Regulating Carbon Dioxide Emissions," Heritage Foundation *WebMemo* No. 1822, February 21, 2008, at *www.heritage.org/Research/EnergyandEnvironment/wm1822.cfm*.
28. This can be done without additional budget expenditures by shifting a small portion of the approximately $45 billion that is spent on regulatory agencies to OIRA.
29. Under Section 610 of the Regulatory Flexibility Act, agencies are now required to review rules that have a "significant economic effect on a substantial number of small entities" 10 years after adoption to determine whether the rules should be changed. However, this does not require agencies to make an affirmative determination that the rule is necessary. See Small Business Administration, Office of Advocacy, "Section 610 of the Regulatory Flexibility Act: Best Practices for Federal Agencies," October 2007, at *www.sba.gov/advo/r3/r3_section610.pdf* (March 10, 2008). If an agency does nothing, the rule continues. The proposal above would reverse that presumption.
30. On several occasions, OIRA has solicited comment from the public on rules that should be reformed. However, the recommendations received are only suggestive. Although OIRA encouraged agencies to consider the changes, it has little or no ability to initiate action on any such reforms. In 2007, the Small Business Administration launched a similar effort called the Small Business Regulatory Review and Reform Initiative. This initiative solicited ideas from small businesses regarding regulations that should be modified and has garnered a substantial number of recommendations. However, like OIRA, the Small Business Administration has no power to force agency action.

each year. The overall impact of these agencies is even greater because they cover some of the economy's most dynamic and vital sectors. Yet their rules are not reviewed by OIRA before they are promulgated, and often their costs and benefits are never formally analyzed. This problem could be resolved by subjecting independent agency rules to the OIRA review process. If that cannot be done, agencies should at least be required to prepare cost-benefit analyses of all planned significant rules and forward these analyses to OIRA for non-binding review.

Conclusion

Contrary to much popular rhetoric about massive regulatory rollbacks, the regulatory burden on Americans has grown, not shrunk, during President George W. Bush's tenure. This growth was relatively slow during the first few years of the Administration, but it has been accelerating. Consistent with past trends, a surge in regulation may be in the cards for the President's final year.

Policymakers should be on guard to prevent this surge in the short run. In the longer run, they should adopt sensible reforms to ensure that both new and old rules are thoroughly vetted to ease the burden of this regulatory tax on Americans.

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J O I N T C E N T E R
AEI-BROOKINGS JOINT CENTER FOR REGULATORY STUDIES

Has Economic Analysis Improved Regulatory Decisions?

Robert W. Hahn and Paul C. Tetlock*

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J O I N T C E N T E R

AEI-BROOKINGS JOINT CENTER FOR REGULATORY STUDIES

In order to promote public understanding of the impact of regulations on consumers, business, and government, the American Enterprise Institute and the Brookings Institution established the AEI-Brookings Joint Center for Regulatory Studies. The Joint Center's primary purpose is to hold lawmakers and regulators more accountable by providing thoughtful, objective analysis of relevant laws and regulations. Over the past three decades, AEI and Brookings have generated an impressive body of research on regulation. The Joint Center builds on this solid foundation, evaluating the economic impact of laws and regulations and offering constructive suggestions for reforms to enhance productivity and welfare. The views expressed in Joint Center publications are those of the authors and do not necessarily reflect the views of the Joint Center.

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Executive Summary

In response to the increasing impact of regulation, several governments have introduced economic analysis as a way of trying to improve regulatory policy. This paper provides a comprehensive assessment of government-supported economic analysis of regulation. We find that there is growing interest in the use of economic tools, such as benefit-cost analysis; however, the quality of analysis in the U.S. and European Union frequently fails to meet widely accepted guidelines. Furthermore, the relationship between analysis and policy decisions is tenuous. To address this situation, we recommend pursuing an agenda that allows economics to play a more central role in regulatory decision making. In addition, we suggest that prediction markets could help improve regulatory policy and improve measurement of the impact of regulation.

Has Economic Analysis Improved Regulatory Decisions?

Robert W. Hahn and Paul C. Tetlock

1. Introduction

Most citizens are familiar with regulation in their everyday lives. The government requires that you obtain a license to drive a vehicle; that you get a permit if you want to expand your home; and that you and your belongings are inspected before traveling on an airplane.

Businesses, too, are quite familiar with regulation. Pharmaceutical companies need to get approval for drugs and medical devices; toy manufacturers need to comply with safety standards; and automobile manufacturers need to comply with safety and environmental standards. In some cases, the government restricts entry into businesses. For example, there are tight restrictions on foreign ownership of airlines, and there are limitations on who can practice medicine and law. In addition, government regulators place constraints on what utilities can charge for energy and electricity.

Work on the costs and economic impact of U.S. regulation suggests that costs, and sometimes benefits, can be sizable. The U.S. Office of Management and Budget (OMB) provides a rich source of information on the costs of federal regulation. In its 2006 summary, OMB examines regulations that generate over $100 million in costs or benefits annually and which monetize a substantial portion of the costs and benefits. The annualized costs of these major U.S. federal regulations from 1995-2005 are estimated to range from $37 billion to $44 billion (2001 dollars).[2] The corresponding benefits were estimated to be in the range of $94 billion to $449 billion (OMB, 2006b). In addition, because regulations are often in place for many years, the cumulative effects can be staggering. In the U.S. it is estimated that the cost of complying with environmental protection alone is more than $170 billion (1990 dollars) annually (Environmental Protection Agency, 1990).

All this regulation has not escaped the notice of politicians. Some elected officials blame regulation for slowing down the pace of economic progress, while others point to

[2] All dollar numbers are converted to 2005 dollars using the Consumer Price Index from the Bureau of Labor Statistics to adjust for inflation, unless otherwise noted.

the benefits that can result from regulations aimed at improving workplace safety and the environment.

Less widely recognized, perhaps, is that economics has played and will continue to play an important role in how governments understand and implement regulations. In 1981, President Reagan set up an office within the OMB whose primary aim was to improve the quality of regulations using economic analysis. More recently, Prime Minister Tony Blair (2005) gave a speech in which he argued that risk cannot be eliminated, that it should be managed wisely, and that impact assessments were needed to help set priorities.

The interest in managing regulation by using economic analysis extends far beyond Washington and London. Economic analysis, such as benefit-cost analysis, is becoming more widely used as a tool for informing regulatory decisions in developed and developing countries. Indeed, the European Union and Mexico have embraced this idea, as have many states in the U.S.

Formal regulatory evaluation typically includes a requirement that regulatory agencies perform some kind of economic analysis, usually benefit-cost analysis, before promulgating a regulation. A key reason for such regulatory evaluation is to guide agencies to more efficient decisions in regulatory proceedings.

Regulatory evaluation is sometimes done by the agency implementing a regulation, but it can also be done by a government agency or department whose primary task is to help improve regulations by using economic analysis. In the U.S., the regulatory agency typically does a benefit-cost analysis of a proposed regulation and its alternatives. This is then sent, along with the proposed regulation, to analysts at the president's Office of Management and Budget, who review the proposal. The OMB either offers suggestions for improving the regulation or accepts the regulatory proposal as is. Such centralized oversight can help with interagency coordination, setting priorities, and implementing more cost-effective and economically efficient regulation.

Using economic analysis to inform regulatory decisions is interesting and important for at least two reasons. First, because regulation uses a sizable amount of resources, it is reasonable to ask whether the benefits of regulation are worth the costs. As we document later, there is evidence to suggest that existing regulations leave

substantial room for improvement. Many regulations would not pass a benefit-cost test; others could yield much higher net benefits with appropriate modifications.

Second, the efficiency of the regulatory evaluation process itself is a key determinant of whether policy makers implement efficient regulations. For governments to make informed choices, it is essential that economic analyses of proposed regulations properly identify, quantify, and monetize benefits and costs of these proposals. At the same time, the limitations of benefit-cost analysis, such as difficulties in monetizing key benefit and costs, need to be appreciated. An efficient regulatory process will generally use benefit-cost analysis as an input into important regulatory decisions, but will not allow such analysis to dictate decisions.

This paper starts by explaining how such benefit-cost analyses are done. It will then bring some news that may be welcome to economists seeking research topics, but unwelcome to economists in their role as citizens. Despite the considerable costs and potential benefits of regulation, the quality of government analyses of regulation falls far short of basic standards of economic research, and it does not appear to be getting any better over time. Thus, although there is some evidence economic analysis *can* improve the benefit-cost ratio of regulations, there is insufficient evidence that economic analysis of regulatory decisions has actually had any substantial impact. Indeed, we do not even have answers to basic questions like whether benefit-cost analyses tend to overstate benefits, perhaps out of regulatory zeal, or whether they overstate costs, perhaps because they fail to recognize how innovation will reduce the costs after regulations are imposed.

2. Connecting Regulation, Economic Analysis and Efficiency

The precise definition of regulation is the subject of some dispute. At the broadest level, regulation could include any attempt by the government to affect human behavior. Economists typically analyze regulatory policies designed to address various market failures, such as externalities, asymmetric information, and market power (Bator, 1958; Joskow and Noll, 1981; Lave, 1981). Examples include price controls or entry restrictions, regulation of pollution and safety in the workplace, and information disclosure requirements.

Benefit-cost analysis is a tool that is frequently used by economists who analyze regulation. An example of a benefit-cost analysis that played an important, if not pivotal role in improving the efficiency of regulation was the economic analysis of the regulation phasing lead out of gasoline. Upon entering office in 1981, the Reagan administration had targeted that regulation for elimination. The regulation would have required refiners to reduce lead in gasoline more quickly because of the health hazards it posed when released into the air. According to Christopher DeMuth, who was the OMB official in charge of reviewing the regulation: "A very fine piece of analysis persuaded everyone that the health harms of leaded gasoline were far greater than we had thought, and we ended up adopting a much tighter program than the one we had inherited. At the same time, the introduction of marketable lead permits saved many hundreds of millions of dollars from the cost of that regulation" (DeMuth, 1994).

Both the initial analysis and final analysis had an impact on the shaping of this rule. The initial analysis found the benefits to so greatly outweigh the costs that more detailed analysis was quickly organized. The final analysis found that tightening the lead standard more than had been proposed could result in net benefits between $4 and $20 billion (1983 dollars) over 4 years (Nichols, 1997).

The benefits, totaling over $20 billion, came from reduced vehicle maintenance, reduced emissions, and reduced lead-related health damages. Lead caused the premature wear of exhaust systems and spark plugs and made more frequent oil changes necessary. Analysts found that the benefits of reducing the otherwise necessary maintenance totaled about $3 billion (Nichols, 1997).

The analysis also considered the frequency of "misfueling," or using leaded gasoline in vehicles built to use unleaded gasoline. Misfueling caused damage to catalysts, which increased air pollution emissions of hydrocarbons, carbon monoxide, and nitrogen oxides. The benefits of reducing harmful emissions from misfueling were estimated to be about $600 million. In addition, the analysis found that the reduction in lead in gasoline would result in benefits of almost $2 billion for children. This figure was based on the sum of the avoided costs of medical treatment and remedial education from the decrease in the number of children with hazardous levels of lead in their blood. (Nichols, 1997)

Another sizable benefit included in the analysis was the reduction in problems associated with high blood pressure due to lower blood lead levels in adults. The estimated reduction in medical costs, lost wages, and the value of reduced mortality risk exceeded $18 billion (Nichols, 1997).

Analysts monetized costs using a complicated linear programming model of the refinery sector, which produced estimates of total costs of less than $2 billion. In addition, they estimated that a provision in the marketable lead permit system that allowed banking of early lead reduction credits for future use would save an additional $200 million in costs. (Nichols, 1997)

The preceding example demonstrates how economic analysis can improve regulation. Unfortunately, governments implement many regulations where the costs probably exceed the benefits. For example, Morrison, Winston, and Watson (1999) did an analysis of Airport Noise and Capacity Act of 1990, which specified noise limits around airports. They found the costs were likely to exceed benefits by $5 billion (1995 dollars). The Act called for the elimination of a large amount of aircraft from U.S. airports that did not meet new noise level limits. This meant that about 27 percent of the value of the industry fleet would have to be replaced earlier than planned. The authors found that the costs of this premature replacement would be about $10 billion.

The benefits of noise regulation—quieter residential environments around airports—were found to be about $5 billion. Morrison, Winston, and Watson (1999) determined the noise reduction in decibels and valued it based on estimates of homeowners' willingness to pay, assuming that a one decibel reduction in noise level raised the present value of homes by one percent. They found that the costs exceeded the benefits by roughly $5 billion. The authors then used the results of their analysis to propose an alternative solution to the noise problem that could have resulted in net benefits of $200 million.

These examples suggest that it is not always straightforward to estimate the benefits and costs of individual regulations. Estimating benefits can involve a long chain of reasoning that links basic science to health effects to the monetization of those effects. Costs are also difficult to estimate because it is hard to gauge how firms will respond and how technology will evolve. Furthermore, it can be quite difficult to estimate how a

regulatory policy will affect different segments of the population. Such distributional concerns, while important, have not been a primary focus of benefit-cost analysis.

Scholars have, however, used benefit-cost analysis and related tools to suggest how regulations might be improved—*e.g.*, Morrall (1986), Tengs and Graham (1996), and Winston (2006). Less widely appreciated is that research reveals that a significant number of regulations would be likely to fail a benefit-cost test based on benefits and costs that were actually monetized. For example, using OMB's (2006b) numbers on the 95 major rules from 1995 to 2005 for which substantial benefits and costs were monetized, we find that 14 of 95 are likely to fail a benefit-cost test.[3] These analyses suggest that some regulations would have benefited from redesign while others should not have been implemented in the first place. For these regulations, annualized costs exceeded annualized benefits by roughly $2.8 billion.

Furthermore, research based on government analyses suggests that some health, safety, and environmental regulations that primarily address cancer may end up costing more lives than they save. An extreme, hypothetical example can help illustrate how this can happen. Suppose a regulation aimed at improving safety in the workplace really does nothing, but forces firms to incur a billion dollars in compliance costs. Assuming that some of this spending would be diverted from expenditures on health care, the regulation would have the net effect of harming the health of workers and consumers and shortening life expectancy. Hahn, Lutter, and Viscusi (2000) found that just over half of the 24 regulations they examined are likely to bring about an unintended increase in the risk of dying. At the same time, they note that aggregate mortality risk declines for the entire set of regulations, primarily because a few regulations in their sample yield large reductions in risk.

3. The Impact of Economic Analysis in the Regulatory Process

Many countries and states have a requirement to do some kind of economic analysis before implementing a regulation. President Reagan signed an executive order in 1981 that required a benefit-cost analysis for each new major regulation for agencies in

[3] When the agency did not provide a best estimate, we used the midpoint of its range as our point estimate.

the executive branch. All presidents since that time have continued this practice. There are similar initiatives in many OECD countries and the EU, but the U.S. is probably the world's leader in implementing some form of government sponsored benefit-cost analysis to inform significant regulatory decisions.

This section reviews attempts to measure the impact of economic analysis of regulations on outcomes and also summarizes information on the quality of regulatory impact analyses (RIAs) – which are required to include an evaluation of the costs and benefits of regulations. A key issue is whether the use of economic analysis in the regulatory process has made a big difference. Research to date suggests two findings: economic analysis probably has had an impact in particular cases, and there is little evidence that such analysis has had a large overall impact, though we cannot rule out this possibility.

Observation 1: *The quality of government-sponsored economic analysis of regulations appears to fall far short of economic guidelines.*

Regulatory scholars and the U.S. Office of Management and Budget have offered a number of guidelines for applying benefit-cost analysis to regulatory issues. These include quantification of costs, benefits, and net benefits to the extent feasible, and consideration of alternatives. OMB also advises on the treatment of inflation, discount rates, and uncertainty (OMB, 1992; Arrow *et al.*, 1996). Based on evidence from 48 RIAs done during the Clinton administration, Hahn *et al.* (2000) argue that agencies often fail to comply with the analytical requirements in OMB guidelines.

A more comprehensive study by Hahn and Dudley (2004) finds that economic analyses prepared for environmental regulations typically do not provide enough information to make decisions that will maximize the efficiency or effectiveness of a rule. A summary of their results, based on a sample of 74 regulations, spanning three administrations, is shown in Figure 1. They find that a significant percentage of the analyses in all three administrations do not provide some very basic economic information, such as information on net benefits and policy alternatives. For example, 69 percent of the analyses in the sample failed to provide any quantitative information on net benefits. A little over half of the analyses quantified at least some benefits of policy

alternatives. RIAs tended to calculate either cost effectiveness or net benefits, but rarely both. The absence of these RIA components illustrates how difficult it would be for a decision maker to use basic quantitative information on net benefits or cost effectiveness.

Impact assessment (IA) is the European counterpart of a U.S. RIA. An impact assessment is required for all major European Commission initiatives and should contain an evaluation of the social, economic, and environmental impacts of various policy options associated with a proposal. The Commission encourages estimates to be expressed in qualitative, quantitative, and, where appropriate, monetary terms (Commission of the European Communities, 2002).

Researchers are beginning to evaluate the European system, and the results appear to have some similarities with the United States. Using a "scorecard" approach that assesses whether an analysis included particular items, they find that IAs fail to discuss many important categories of information.

Renda (2006) provides the most comprehensive European study to date. All 70 Impact assessments of major proposed initiatives completed by the European Commission by June 2005 are evaluated using a scorecard similar to that used by Hahn and Dudley (2004). Renda finds that many important IA components are frequently missing. For example, the IAs seldom estimated costs, almost never quantified costs to businesses, did not specify specific benefits, and virtually never compared the costs and benefits. In addition, alternatives were seldom compared and discount rates were almost never specified.

It is possible to do a comparison of Renda's results with those of Hahn and Dudley; however, it is important to recognize that the studies involve different scorers, different samples, and different time periods. For example, Renda focuses on 95 recent IAs, while Hahn and Dudley focus on 74 environmental RIAs from the Reagan presidency through the Clinton presidency.

Table 1 shows 6 categories measuring whether a particular analysis provided point or range estimates for costs, benefits and net benefits. The U.S. scorecards were better in 5 of 6 categories. The sole exception was one where they were both poor – the provision of a best estimate of net benefits. For that case, the overall percentages differed by about a percentage point.

The frequent failure of analyses to quantify and monetize benefits need not reflect a weakness in agency practice or oversight. For example, science may not exist to inform quantification and monetization. Moreover, the degree to which benefits and costs can be monetized will vary across regulations. There is at least some evidence, however, that suggests that there are weaknesses in both agency practice and evaluation in the U.S. and Europe. Though it is nearly impossible to test whether EPA did everything it could have done, Hahn and Dudley (2004) examine whether the agency utilized the available information it developed in its benefit-cost analysis. Of the 60 RIAs that monetized at least some costs and considered at least one alternative, 11 did not monetize at least some costs of alternatives. In addition, two RIAs quantified lives saved, but did not monetize any benefits, even though the Value of Statistical Life has been studied extensively.

Observation 2: *The quality of regulatory analysis in the U.S. does not appear to have changed much over time.*

If a regulatory oversight agency were in place for a period of time, one might think that the quality of analysis would improve. Unfortunately, Hahn and Dudley (2004) found no clear trend in the quality of benefit-cost analysis across administrations or across time. They note, for example, that there is some improvement in the calculation of net benefits and cost effectiveness, but also some decline in the consideration of alternatives. Furthermore, using their data, we find that the quality of regulatory analysis, as measured by the total number of items included in their scorecard, did not significantly differ across time periods. Of the 76 yes or no items in their scorecard, regulations before the end of 1990 include an average of 30.0 items, whereas regulations after 1990 include 30.5 items.

Interestingly, Renda (2006) suggests regulatory oversight in the European Union may be getting worse. His study finds that almost all scorecard items decline over the three years for which he has data. For example, the percentage of IAs quantifying or monetizing at least some costs, quantifying or monetizing at least some benefits, and the percentage quantifying costs and benefits of alternatives all declined each year from 2003 to 2005.

Graham, Noe, and Branch (2006) claim that things may have improved under the George W. Bush Administration. They argue that the overall rate of net benefits is larger and that the average benefit to cost ratio for major rules was about thirteen in the first forty-four months of the Bush Administration, as compared to about five during the previous nine years.

The calculation may be misleading for two reasons. First, comparisons of benefit-cost ratios exclude many costly regulations without monetized benefits—*e.g.*, homeland security and environmental regulations with benefits that are difficult to monetize (OMB, 2005). In 2003-2004 alone, costs summing to over $3 billion had no monetized benefits. Second, even if these average benefit-to-cost ratios accurately represent the true average benefit-cost ratios over these two periods, it does not necessarily follow that the improvement is due to more effective oversight.

Observation 3: *Economic analysis can improve regulation, but it is not clear whether economic analysis used in regulatory decisions has had a substantial impact.*

There have been a number of case studies of regulatory analyses and regulations. Morgenstern (1997) asked economic analysts to describe their experience with benefit-cost analysis of a particular environmental regulation during the review period at EPA. His basic finding was that all authors agreed that economic analysis improved the quality of the rule being considered. Although the authors were all economists involved with the rule rather than disinterested observers, we think that their unanimous view is instructive. They identified reductions in cost in all twelve cases and increases in benefits in five of the twelve, implying at least some increase in net benefits in each case.

A key issue is the kind of improvement that actually resulted from a particular analysis. A sentiment expressed by some of the authors who argued that analysis made a big difference in the rule was that such analysis did not typically change how the problem was framed in any dramatic way. In other words, benefit-cost analysis was helpful in hashing out the details of a rule, such as choosing a level of stringency, but it often did not consider whether there may be an entirely different solution to the problem.

Other research on regulatory analyses reveals some deeper economic problems with environmental, health and safety regulation. Figure 2 plots data on the cost per

statistical life saved--a measure of how effective a regulation is at extending the life-span of the affected population (Morrall 2003).[4] The figure consists of 79 final regulations, broken down into three categories: regulations aimed at improving safety ("safety"); regulations aimed primarily at reducing cancer ("toxin control"); and a miscellaneous category labeled "other."

Two key trends are evident from the data. First, the toxin control regulations appear to cost more at the margin than do safety regulations for each statistical life saved (Tengs *et al*., 1995). Second, there is substantial variation within and across both the safety and the toxin control categories (Morrall, 2003; Tengs *et al*., 1995). The cost per statistical life saved ranges from $100,000 to $100 billion (2002 dollars). In addition, the variation in the cost per statistical life saved increases significantly in the 19 years after 1986 than in the 19 years before 1986, suggesting that there may now be greater potential gains in reallocating resources across life-saving investments. This research on cost effectiveness suggests that we are probably allocating resources aimed at saving lives inefficiently. For example, there appear to be ample opportunities for increasing the number of statistical lives saved and lowering the expenditures for toxin control regulations. At the very least, the data strongly suggest that society could save more statistical lives and reduce expenditures on life-saving regulations.

There have been very few attempts to estimate systematically the impact of economic analysis of regulation on actual decisions. One study by Farrow (2000) provides a statistical analysis of regulatory oversight using U.S. data. Farrow uses the decision to reject or accept a proposed regulation as his dependent variable. He then examines whether rules that are rejected have a higher cost per statistical life saved, after controlling for other variables. He considers sixty-nine proposed regulations over the period 1967 to 1991. Farrow's main findings are that regulatory oversight had at best a slight effect on the cost per statistical life saved. Rejected rules were only slightly more expensive than rules that were adopted. Additionally, the cost per statistical life saved of

[4] Morrall (2003), p. 230, uses the term "opportunity costs of statistical lives saved" (OCSLS), but we use cost per statistical life saved in the interest of simplicity. Although we present the data as point estimates, we note that there is substantial uncertainty in these estimates. To update the data through 2005, we have added three recent data points to Figure 2 that are not in Morrall (2003).

final regulations was not better than it was for proposed regulations; and there was no evidence that the cost per statistical life saved decreased over time (Farrow, 2000).

Observation 4: *Thus far, comparisons of ex ante and ex post estimates of regulatory impacts do not tell us much about systematic biases.*

If policy makers had a crystal ball about the impacts of policy, it would be much easier to design more efficient regulations. Typically, though, they only have access to some crude *ex ante* estimates of economic impacts, which are made before a policy is implemented. In recent years, there has been considerable interest in ascertaining whether there are systematic biases in these *ex ante* estimates when compared with *ex post* estimates, which are made after a policy is implemented.

A number of researchers have highlighted the possibility of such biases. Some suggest that costs may be understated due to errors of omission, such as the time spent by high-level management on regulatory issues and the possible adverse consequences for innovation. Others claim that costs are systematically overestimated by industry, academic and government analysts alike, sometimes because firms naturally find cheaper ways to achieve regulatory objectives when the regulation is actually in force. Harrington, Morgenstern, and Nelson (2000) investigate the issue of validity of estimates by comparing *ex ante* and *ex post* estimates of costs and benefits of 28 rules. They conclude that costs are often overestimated prior to rule implementation and suggest that benefits are also overestimated. Seong and Mendeloff (2004) suggest that benefits can be overestimated when agencies assume that firms will fully comply with regulations.

OMB (2005) did a more comprehensive analysis of 47 rules for which *ex ante-ex post* comparisons were available. The OMB analysis suggests that benefits are much more likely to be overestimated than underestimated, costs are slightly more likely to be overestimated than underestimated, and the benefits-cost ratio is more likely to be overestimated than underestimated. OMB points out that the sample is not random. In fact, Harrington (2006) finds that even small changes in the rules included in the OMB study can drastically change its conclusion.

Evaluating the actual impact of regulations once they are enacted and comparing them with earlier predictions has theoretical appeal. However, in practice, there are three

significant limitations of these kinds of comparisons, particularly in regard to their usefulness in improving future regulations.

The first limitation is simply the infrequency with which careful, comprehensive *ex post* studies are conducted because of data and funding limitations, and little interest on the part of most governmental agencies. A second problem is that academics may select biased samples of regulations—*e.g.*, inefficient regulations where there is likely to be a publishable finding or applications that have a novel element, such as the performance of market-based approaches for environmental control. A third issue is that results from regulatory analyses could differ for several reasons including the author, data, model, key assumptions, and source of funding (Thompson, Segui-Gomez, and Graham, 2002). Until we resolve some of the substantial uncertainties in comparisons of regulatory analyses, it is premature to assume that biases go in a particular direction. Notwithstanding these limitations, we think *ex ante-ex post* comparisons of regulations by scholars and practitioners could be useful for enhancing our understanding of biases in economic analysis.

4. Learning from Experience

The preceding analysis suggests that the use of economic analysis in improving regulations has hardly been an overwhelming success. There is no evidence it has had a significant general impact, the economic analysis supporting it is frequently done poorly (if at all), and there is only anecdotal evidence to suggest that it made a difference.

There are several explanations for this rather dismal state of affairs. One is political: some interests groups see value in using economic analysis to inform regulatory decisions while others do not. Presidents clearly value using such analysis, but Congress may believe that regulatory evaluation done within the executive branch unduly limits its authority. Similarly, a regulatory agency may not want to have such analysis when it conflicts with its narrow agenda. Another explanation for the poor quality of economic analysis is that it is simply hard to do. It may be quite difficult, for example, to develop a reasonable estimate of the benefits of a particular homeland security regulation or a rule that calls for increased financial disclosure. A third explanation is that civil servants may

not be equipped to do the kind of analyses that are being required. We are not persuaded by this explanation because there are many good economists in the federal government, and the government can also hire consultants to help with such analysis. A fourth explanation is that it takes time for these economic tools to gain acceptance. We believe there is some truth in this, as ideas like benefit-cost analysis move from the classroom to the real world.

The failure of scholars to demonstrate a clear impact of economic analysis on policy raises the question of whether some form of regulatory evaluation is still worth supporting. To answer that question, we need to articulate the benefits and costs of reviewing regulation in a static and dynamic context. In a static setting, one would compare the expected present values of net benefits from the policy refined by the regulatory evaluation process with the status quo policy. Factors that influence these net benefits include a change in the policy goal, the date at which a regulation is announced, the implementation schedule and the enforcement mechanism. The impact of possible delay, which some critics point to as a significant cost of regulatory evaluation, would also be considered in such a calculation. The impact of delay could be negative or positive, depending on the net benefits of the policy that was selected.

While we will assess some of the static costs and benefits of reviewing regulation below, we do not attempt to quantify the dynamic costs and benefits because the necessary data do not exist. In a dynamic context, legislators could change laws and bureaucrats could change regulations and analysis in response to regulatory evaluation. For example, it is possible that lawmakers would attempt to bypass the regulatory evaluation process.

Notwithstanding the limitations on data on the benefits and costs of regulatory evaluation, we provide three arguments why several economists, including ourselves, still support introducing economic tools and improving their use throughout the world—*e.g.*, Arrow *et al.* (1996). First, it is difficult to measure the impact of doing economic analysis on policy outcomes. Therefore, the fact that we do not find much evidence should not be cause for alarm. Moreover, the evidence may come primarily from specific cases in which analysis has been helpful in affecting policy decisions. For example, Schultze

(1996) notes that the Council of Economic Advisers played a key role in stopping the supersonic transport during the Nixon years.

Second, our personal observations are consistent with the spirit of scholars and practitioners such as Schultze (1996). One of the authors was closely involved with the drafting of the White House version of the 1990 Clean Air Act Amendments, and saw firsthand how analysis helped inform decisions about shaping various aspects of that bill. For example, early draft proposals to regulate toxic air emissions would have required pollution controls that were either infeasible or extremely costly relative to the benefits. The final law contained less draconian measures, partly as a result of the economic analysis. While it is true that politics mattered, we think analysis helped at the margins. Moreover, these margins frequently had efficiency implications in the billions of dollars.

Third, the direct costs of regulatory evaluation in the U.S. appear to be small compared with the likely benefits, though we cannot prove it. Our best estimate, admittedly crude, is that the costs of reviewing regulations are on the order of $100 million annually. The cost estimate consists of two parts: the cost of doing the analysis and the cost of conducting the review process that uses the analysis. The average economic analysis of a major regulation costs about $700,000 (Congressional Budget Office, 1997). This figure includes resources spent directly by the regulatory agency and consulting expenses used to produce an economic analysis. The cost of OIRA staff resources used reviewing a major regulation is on the order of $20,000, which pales in comparison to the resources spent on the analysis itself.[5] This leads to a total cost of analysis for a major regulation of roughly $720,000. It also leads to the observation that the costs of review are typically small relative to the costs of initial analysis for major federal regulations that are subject to OMB review.

[5] We make the following calculation: 0.5 x (% of FTEs working on reviews)(OIRA budget)/ (economically significant rule reviews), or, 0.5 x (0.40)($7 million)/ (82) = $17,000. For the percentage of OIRA staff working on reviews, see GAO (2003), which gives the number of full-time employees primarily responsible for reviews in 2003. We assume this ratio still holds. For the current OIRA budget, see OMB (2006a). For the number of economically significant regulations, we use the number reviewed in 2005; see RegInfo.gov. Because the full-time employees responsible for economically significant regulatory reviews also review hundreds of non-significant regulations and paperwork under the Paperwork Reduction Act, we multiply the estimate by 0.5 to approximate the time actually spent on economically significant regulatory review. Over the period 2000-2005, this estimate ranges from $20,000 (2004) to $12,000 (2001) with a mean of $16,000 because of differences in the OIRA budget and the number of economically significant rules year each.

The preceding analysis raises the question of whether the benefits of reviewing regulation are likely to exceed the costs. There are about 100 major regulations reviewed each year, leading to a total cost of regulatory review of roughly $72 million annually (about 100 times $720,000).[6] We think, but cannot show definitively, there are many regulatory proposals for which net benefits are increased by at least a billion dollars annually as a result of analysis and evaluation—the removal of lead from gasoline being one example and the market-based approach for cutting sulfur dioxide emissions being another.[7] Thus, we think the current system is likely to have benefits in excess of costs if we make two key assumptions: all proposed policies would have been implemented without regulatory review; and the costs of policy delay from reviewing regulations are small.[8] Also, if one assumes that the economic analysis of a major regulation would be done for other reasons (i.e., the cost of doing the analysis can be treated as sunk), then the additional cost of $20,000 per major regulation is probably trivial compared with the potential benefits of reviewing regulations.

The potential benefits of effective regulatory evaluation could easily exceed the benefits attained by the current system. If more effective regulatory reviews would have eliminated just the major regulations with negative monetized net benefits from 1995 to 2005, the incremental net benefits of improved review would have exceeded $250 million per year.[9]

Finally, there is no obvious attractive alternative to doing some kind of analysis for key regulatory decisions, assuming that one objective of reviewing regulations is to increase economic efficiency. As Stigler (1982b) argues, “it takes a theory to beat a theory.”

Government analysis can and does make a positive difference in a variety of settings. Some analysis is better than no analysis in identifying potential problems in the

[6] From 2001 to 2005, the annual number of economically significant rule reviews ranges between 82 and 111, according to RegInfo.gov.
[7] See the discussion, for example, in Morgenstern and Landy (1997), pp. 457-459; 463.
[8] To our knowledge, there has not been a systematic empirical study of how the introduction of a regulatory review mechanism could change the nature of the policy proposals that are considered.
[9] For the 14 out of 95 major rules with negative net benefits, we divide the total annualized negative net benefits of $2.8 billion by 11 years to obtain $250 million per year. If regulations with negative net benefits remain in place for more than one year, $250 million per year represents a substantial underestimate of the total costs to society that could have been avoided with better regulatory review.

regulatory process. Viscusi (1996), for example, has argued that "regulatory reforms that improve the assessment of regulation and incorporate unbiased risk assessment procedures can potentially enhance the performance of regulatory policies." Under the right circumstances, good regulatory analysis can do even more to promote social welfare, provided that decision makers have an incentive to listen. As Stigler (1982a) notes, however, it is also important to have an understanding of why political outcomes deviate from those that might be preferred by economists. Such an understanding can lead to a more realistic assessment of the impacts of changes in rules, procedures, and institutions (*e.g.*, Shleifer, 2005).

The preceding arguments generally support some kind of economic analysis being used in regulatory decisions. Even though current review of regulations is likely to be justified on economic grounds, the process can be improved. There are two basic ways of improving the process. The first is to explore ways of doing better analysis. The second is to examine institutional and political changes that would make better use of the analysis. We consider both of these briefly.

There are a host of mechanisms that could improve analysis, including peer review, improving data quality, attracting better analysts, and following standard procedures for doing good analysis. Peer review poses problems because it is difficult to get good reviewers for this kind of work. Improving data and getting better analysts has potential if the government is willing to allocate the resources and do more outsourcing of analyses. Issuing guidelines for good analysis is problematic unless there is a mechanism to ensure that those guidelines will be followed. Because these kinds of ideas have been addressed elsewhere, we will not dwell on them here. Rather, we wish to offer one alternative that could represent a methodological breakthrough.

Recall that there are analytical challenges in assessing the overall impact of regulatory evaluation as well as the likely impact of specific regulations. One potentially constructive approach for addressing both problems is the introduction of prediction markets. Prediction markets are markets for contracts that yield payments based on the outcome of an uncertain future event, such as next year's GDP. These markets frequently outperform both experts and opinion polls (Berg *et al.*, 2003; Wolfers and Zitzewitz, 2004).

One way of learning about the impact of regulatory evaluation would be to set up a market for contracts based on key indicators, such as GDP or an overall price index (Hanson, 2003). While these indicators are imperfect measures of economic welfare, they may be better measures than we currently have. For example, the government could issue one contract that paid off an amount proportional to future GDP if a particular legislative measure were implemented; and a second that paid off an amount proportional to future GDP if the measure were not implemented. The difference between the prices of the two contracts could, in principle, capture the overall impact of regulatory evaluation on future GDP.

The same kind of prediction market contracts also could be introduced for estimated the expected costs and benefits of individual regulations. Examples of proxies for costs and benefits could include pollution levels, deaths from disease, and key price or quantity indices, such as energy or housing. These prediction markets could also provide information on how the expected net benefits of regulation change over time. Thus, they offer a radically different approach to measuring the impact of the regulatory process.

Prediction markets are not without problems, however. For example, it may be difficult to define reasonable proxies for costs and benefits. In addition, such markets measure correlation between policies and outcomes, whereas a decision maker is typically interested in causality.

We offer the preceding applications of prediction markets to suggest that there may be ways of dramatically improving the information available to decision makers in the future. At the same time, we recognize that better analysis is not, by itself, enough. There need to be institutional and political changes if regulatory evaluation is to be more effective.

One promising institutional change in the U.S. would be for Congress to create a Congressional Office of Regulatory Analysis that would complement the regulatory evaluation mechanism within OMB. Such an office is likely to be a cost-effective investment because it does not need to improve regulation much to pay for itself. Among other things, it could stimulate healthy competition between two government institutions with analytical responsibility for regulation, in much the same way that the two agencies that work on budget issues (OMB and the Congressional Budget Office) help keep each

other honest. Furthermore, Congress may want to ask this office not only to consider regulations, but laws that give rise to regulations. If it is true that laws drive regulation, it may be quite beneficial to do economic analysis of proposed laws. Europe, for example, does not solely focus on regulations, but allows for analysis of a wide range of instruments that correspond roughly to guidelines, laws, and regulations. It is an open question as to whether Congress would support such an office, but it may choose to do so simply to get a better understanding of the likely impact of regulation on different constituencies.

Another change that could improve regulatory evaluation in other countries and the European Union is for governments to issue an annual report, similar to OMB's report on the costs and benefits of federal regulation. That report should contain, among other things, the number and percentage of final regulations that pass a benefit-cost test based on factors that can be quantified and monetized, something that OMB's report does not currently contain. We believe such a report has the potential to add to our knowledge as well as promote greater transparency and accountability.

In the U.S., there are at least three ways of elevating benefit-cost balancing in decision making. All would involve a greater degree of political commitment than seems likely at present. One is for the president to require benefit-cost analysis for *all* major regulatory decisions made by the federal government, to the extent permitted by law. A second is for Congress to pass statutes that allow or mandate benefit-cost analysis. Finally, Congress could also allow the courts to strike down regulations that clearly fail a benefit-cost test.

5. Conclusions and Future Research

This paper has assessed what we know about the use of economic analysis in informing regulatory decisions. In specific cases, scholars have suggested that analysis does matter at the margins. However, there is not strong support for the view that economic analysis has had a significant general impact. Furthermore, there is evidence to suggest that the quality of regulatory analysis for a significant fraction of regulations does

not meet widely accepted guidelines. This is true both in the U.S. and in the European Union.

Given these unimpressive results, where should we go from here? Perhaps what is needed is a more disciplined and formal commitment to benefit-cost balancing, led by the president and Congress, along with comparable officials abroad. As noted above, such a commitment could entail mandating benefit-cost analysis of important regulations in statutes. Congress could also codify a version of the current executive order requiring benefit-cost analysis. It may also want to consider subjecting some proposed laws to at least a crude benefit-cost analysis prior to voting on them. Already, Congress often asks for estimates of the budgetary impacts of laws and proposed laws.

There are several ways in which social scientists could contribute to our understanding of the role of economic analysis in regulatory decisions. First, scholars could help identify the conditions under which particular forms of analysis, and particular expenditures on economic analysis, might yield more or less efficient policies. For example, cost-effectiveness analysis may be most useful in eliminating the most inefficient projects, such as a very wasteful chronic toxin regulation or a bridge to nowhere. Second, researchers could help contribute to the development of analytical tools that could improve evaluation. Possibilities include the prediction markets discussed above and new approaches for valuing the benefits from regulation. Third, researchers could contribute to the development and improvement of data sets that are used as inputs for statistical models that inform regulatory decisions, such as government inventories on private expenditures on pollution control.

Economists may also consider affecting the regulatory process more directly by doing timely benefit-cost analyses of important regulations and programs. In the past, economic studies of key sectors of the economy, such as transportation and energy, have been important factors in the decision to deregulate, or partially deregulate, those industries (Noll, 2006). Thus, academic economists can induce change by adding to our understanding of the impact of regulation.

While we have suggested that the government's economic analysis of regulatory decisions can be useful, we want to end on what we think is a realistic note. More widespread use of economic analysis can affect both the supply and demand for

regulation. On the supply side, such analysis has the potential to yield alternatives that increase the net benefits of achieving regulatory goals. On the demand side, such analysis can change the demand for regulation by making the positive and negative effects of regulation more widely known. In some instances, one might expect that politicians and bureaucrats would see little value in changing demand in that way. Politicians, in particular, tend to be more concerned with distributional issues than efficiency. Without significant support from key elected officials, we suspect that most attempts at introducing or strengthening the role of economic analysis will have a modest impact at best. That is, economic analysis cannot be expected to drive the political process.

Nonetheless, in a world where the number of trillion dollar economies is increasing and regulatory impacts are frequently measured in the billions, margins matter. Thus, economists should pay more attention to how economic analysis can contribute to improving such margins, insofar as that is possible.

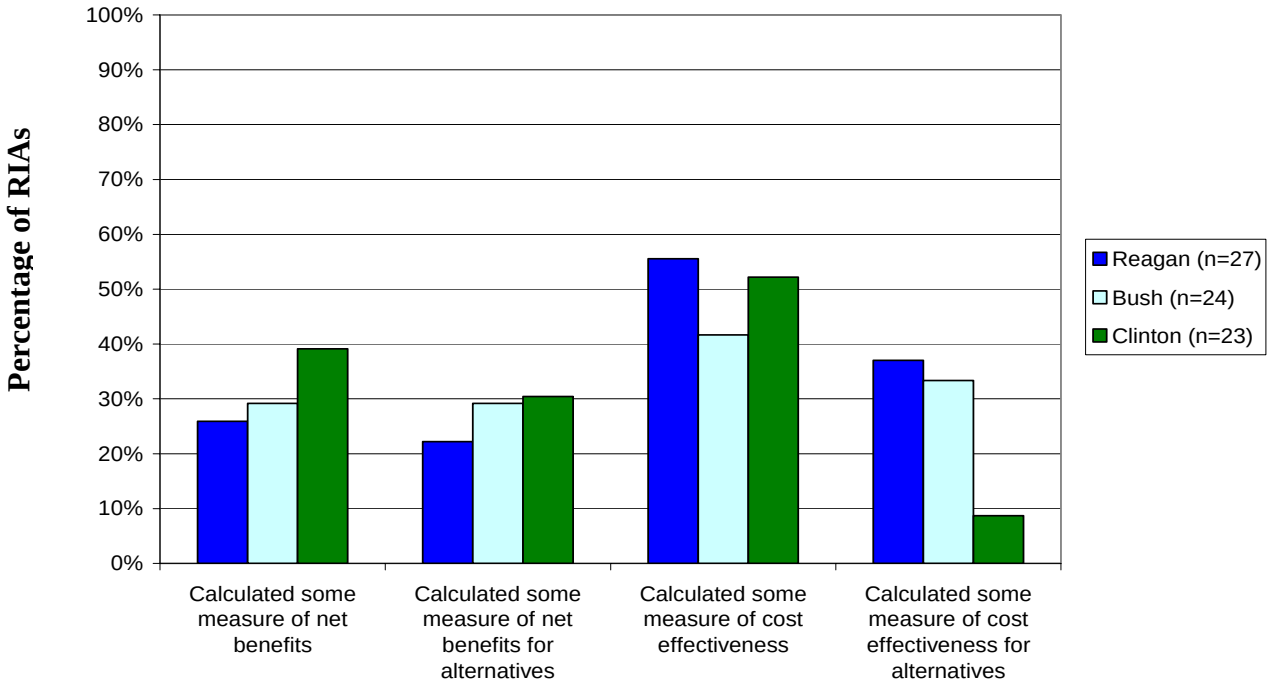
Table 1

Summary of U.S. Regulatory Impact Analyses and EU Impact Assessments

	Percent of Analyses in U.S. Study Including Scorecard Item (n=74)	Percent of Analyses in European Study Including Scorecard Item (n=70)
Estimation of Total Costs		
Provided best estimate of total costs	65%	19%
Provided range of total costs	34%	13%
Estimation of Total Benefits		
Provided best estimate of total benefits	22%	13%
Provided range of total benefits	26%	3%
Estimation of Net Benefits		
Provided a best estimate of net benefits	12%	13%
Provided a range of net benefits	20%	4%

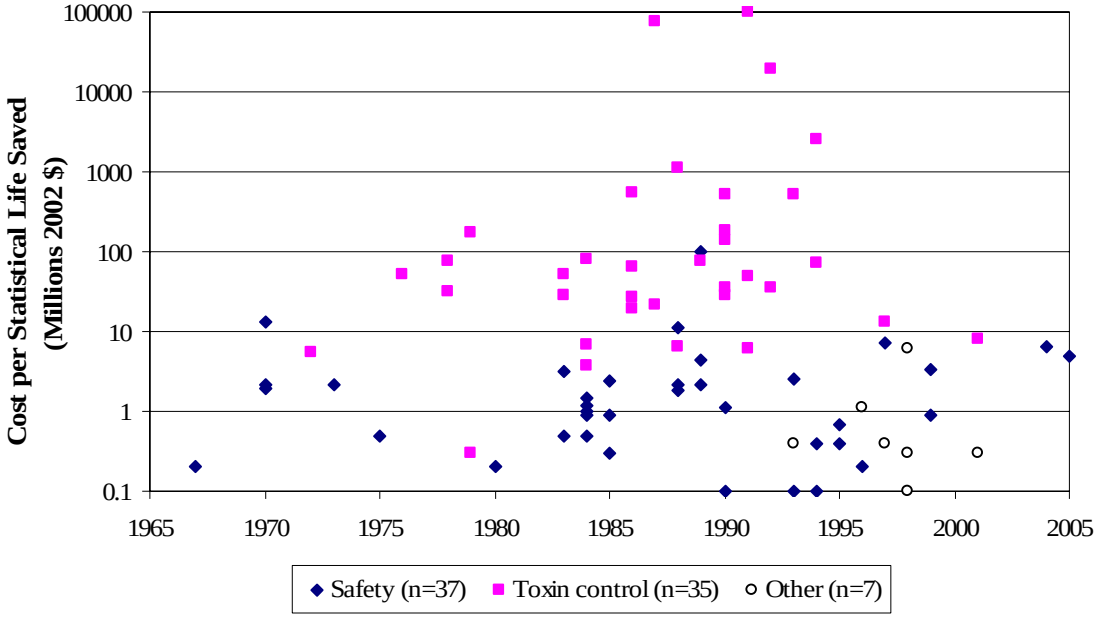
Notes: U.S. Study figures taken from Hahn and Dudley (2004), based on regulatory impact analyses. European Study figures taken from Renda (2006), based on impact assessments. See text for details. Numbers are rounded to nearest percent.

Figure 1
Analysis of Net Benefits and Cost Effectiveness of Regulatory Impact Analyses (n=74)



Source: Hahn and Dudley (2004).

Figure 2
Cost Effectiveness of Safety, Toxin Control, and Other Regulations (n=79)



Notes: Based on Morrall (2003), pp. 230-231, with 3 regulations added to update the dataset through 2006. "Safety" denotes that a regulation was aimed at reducing safety risk. "Toxin control" denotes that the regulation was aimed at controlling toxins associated with cancer. "Other" denotes that a regulation fell into a category other than safety or cancer. While Morrall (2003) uses the term "Opportunity Cost of Statistical Life Saved," we use the term "Cost per Statistical Life Saved."

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Contents

Introduction

Regulation is nearly as old as law itself. Like law in general, regulation consists of rules backed up with consequences, but it is law specifically aimed at preventing misconduct by businesses and other organizations, and enforced primarily by specialized government agencies. Although governments have regulated economic activity since ancient times, the regulatory state grew enormously in most economically advanced democracies in the twentieth century, spurred by rapid technological and economic change and political demands for protection against monopolistic power and the risks of industrial activity.

Over the past 50 years, regulatory agencies and the rules they promulgate have become prominent components of contemporary legal systems, often eclipsing legislative and judicial rules in their economic and social effects. In most countries, regulatory inspectors now constitute a vast white-collar police force, enforcing regulations that address risks from nearly every facet of economic activity, including rules on workplace safety, financial security, air and water pollution, fire and accident prevention, earthquake protection, health and elder care delivery, food and drug quality, and proper maintenance of airplanes, elevators, school buses and railroad tracks.

Appropriately, sociolegal scholars have increasingly turned their attention to regulatory processes in an attempt to discern how regulations actually operate and what impact they have on business and society. The study of regulation by sociologists, political scientists, economists, and others has tended to focus on four main areas. First, social scientists have sought to understand and explain the process by which regulations are created, scrutinizing the political and institutional variables affecting policymaking decisions within regulatory agencies. Second, researchers have studied the behaviour of government inspectors and the processes of regulatory enforcement. Third, social scientists have studied the effects of regulations and their enforcement on business behaviour – both the positive and negative, intended and unintended responses. Finally, researchers have theorized about and, increasingly, have empirically analysed new models of regulation, such as market-based, performance-based, and management-based regulation.

The essays in this volume have been selected to showcase the key issues addressed within the scholarly literature in each of these four areas, as well as to convey the research methods they have employed and the findings and generalizations they have produced. In this Introduction, we highlight the major themes and findings from the broader research literature represented by the work reprinted in this volume.

Regulatory Policy Making

Even as it has become widely accepted that it is socially beneficial to allow private businesses to make their own economic decisions in light of competitive and customer pressures, it is also widely accepted that certain types of business behaviour can be detrimental to society.

Government intervention is needed when high transaction costs prevent markets from adhering to the underlying assumptions of perfect competition (Coase, 1960; Zerbe and McCurdy, 1999). Society needs regulation specifically to correct for failures of the private marketplace, such as the accumulation of market power in the form of monopolies, the lack of information needed by market actors to make fully informed decisions, and the frequent negative side-effects or externalities of business activity (Stokey and Zeckhauser, 1980; Breyer, 1982; Sunstein, 1990; Viscusi *et al*., 2000).

Although the standard theory of market failure provides a well-accepted normative justification for regulation, it only goes so far in providing a positive or empirical account of how and why regulations get made. Social scientists have shown that policy making and implementation generally fails to follow a rational order that accords with how we might think policy *should* be made and implemented (Lindblom, 1959; Kingdon, 1984; Pressman and Wildavsky, 1984). The same can be said of regulatory policymaking. Despite the occasional exception (Levine and Forrence, 1990), for at least the last half-century scholars have argued that regulatory policymaking often departs from the normative logic of market failure and instead reflects the push and pull of interest group politics (Wilson, 1980, 1989).

Perhaps the clearest example of this kind of departure arises when regulatory authorities have been captured by the industries they are supposed to regulate, serving business interests rather than the overall interests of society (Huntington, 1952; Bernstein, 1955; Lowi, 1969). Some scholars have argued that regulatory programs respond to organized business interests by using the coercive power of government to impose barriers to entry on low-cost or foreign competitors (Stigler, 1971; Peltzman 1976). Examples of regulatory regimes that serve as barriers to entry, or otherwise advance the interests of regulated industry, include professional licensing, certain ratemaking regulatory regimes, and regulations that privilege existing firms over newer ones (Kolko, 1965; Ackerman and Hassler, 1981; Abbott, 1988; Stavins, 2006).

Furthermore, governments do not automatically enact new regulations in response to public problems, such as oil spills, industrial accidents, or financial scandals (Kingdon, 1984). A problem may be a necessary condition for the enactment of new regulation, but its existence is by no means sufficient to explain the adoption of new rules (Elliott *et al*., 1985). When the benefits of new regulations are spread out over thousands or millions of individuals, affected individuals face challenges in organizing to advance their interests (Olson, 1968). Since the costs of new regulatory programs are usually concentrated on a relatively small number of business enterprises that can bring political pressure to bear to thwart or modify regulatory proposals, industry's interests are likely to be better reflected in regulatory policy at the margin than are the greater aggregate interests of diffuse and unorganized social beneficiaries of regulation (Wilson, 1980).

Not all regulatory developments, though, can be explained as advancing the interests of regulated industry (Schneiberg and Bartley, 2001). The movement to deregulate major industries in the 1970s and 1980s clearly draws regulatory capture into question, for this never would have occurred if legacy firms possessed an iron grip on the policy process and used regulation to restrict entry to competitors (Derthick and Quirk, 1985). Similarly, the great expanse of consumer protection, environmental, worker safety and civil rights regulation enacted in the latter part of the twentieth century belies any simplistic belief in unwavering industry power (Kamieniecki, 2006). Much regulation today imposes extensive costs on

industry, often precisely to deliver broad and diffuse benefits to individuals across society (Vogel, 1989).

In the last half century, policy entrepreneurs have prodded governments around the world to enact scores of regulatory laws that do not appear to be primarily driven by industry's rent-seeking behaviour. Even if rent-seeking remains an important aspect of regulatory politics, the degree to which the rent-seekers succeed clearly varies. The explosive growth of regulation has been the product of intensifying political *demands* for regulation together with governmental *responsiveness* to those demands (Kagan, 1994; Braithwaite and Drahos, 2000). On the demand side, powerful political movements, such as the labour, environmental, and civil rights movements, have certainly been instrumental in the growth of regulation (McCann, 1986; Coglianese, 2001). In addition, better-educated and more affluent publics have simply become increasingly intolerant of risks and injustices that less affluent publics tend more readily to accept (Friedman, 1985; Inglehart, 1997).

On the responsiveness side, the increasing competitiveness of electoral democracy may result in a more ready supply of policy proposals from political candidates and parties eager to satisfy voters' desire for greater protection from harm, mistreatment and economic insecurity (Bardach and Kagan, 1982). Even competition across regulatory jurisdictions, which might be expected to lead jurisdictions consistently to race to the bottom in terms of regulatory stringency, has been found sometimes to prompt nations with less stringent regulations to emulate the laws of nations with tougher regulations (Revesz, 1992; Vogel, 1995; Vogel and Kagan, 2004). The ease of exchanging information in an increasingly global economy, as well as the trend towards greater integration of the world's economic and financial systems, also contributes to tendencies towards diffusion and convergence of regulatory policies (Shapiro, 1993; Lazer, 2005; but see Haines, 2005).

The ascendancy of the regulatory state over the past half-century has led social scientists to investigate how governments make regulatory policy. In doing so, they have explored both political and institutional factors that affect the decisions of regulatory officials. For example, in advanced economies like that of the United States, responsibility for regulatory policy making often rests with the bureaucracy, within which unelected officials in hundreds of regulatory agencies make key decisions affecting business and society. The delegation of authority to the bureaucracy creates a well-known principal-agent problem because agencies may generate policies that differ from the preferences of the elected officials that established them (Niskanen, 1971). As a legal matter, of course, bureaucratic agencies do make regulatory policy under the authority of legislation, which has sometimes been said to serve as a 'transmission belt' connecting bureaucracies to the legislature (Stewart, 1975). However, as an empirical matter, the concept of a legislative 'transmission belt' does not adequately explain agency policymaking. Regulatory agencies do still retain considerable discretion and autonomy (Eisner and Meier, 1990; Spence, 1997), if for no other reason than that statutory language is itself often vague and gives agencies a considerable degree of discretion (Lowi, 1969).

Scholars have focused much attention on efforts by the electoral branches of government in the United States to influence, if not control, bureaucratic behaviour. Two major schools of thought have developed, one that emphasizes 'presidential dominance', the other 'congressional dominance'. Presidents can seek to control agency policymaking by appointing the heads of the agencies and approving the submission of agency budgets to Congress (Moe,

1987; E. Kagan, 2001). Congress can call hearings and conduct investigations, but still more significantly the legislature can use appropriations to reward or punish agencies (McCubbins and Schwartz, 1984; Weingast, 1984). Over the years, researchers in the United States have found evidence that both presidents and Congress do influence the work of regulatory agencies (for example, Moe, 1982; Weingast and Moran, 1983; Wood, 1988; Wood and Waterman, 1991; Ringquist, 1995), although most of these studies focus on agencies' adjudication or enforcement decisions rather than on decisions about making new policies (Spence, 1997).

The essay by Mathew D. McCubbins, Roger G. Noll and Barry R. Weingast reprinted as Chapter 1 in this volume, turns attention to what has become known as the procedural control of agency policy making. McCubbins, Noll and Weingast theorize that Congress designs administrative procedures pre-emptively in an attempt to solve the principal-agent problem. Although the field of administrative law has long acknowledged the importance of regulatory procedures (for example, Breyer, 1982; Strauss, 1992), social scientists have more recently adopted a 'new institutionalist' orientation according to which they view policymaking and organizational structures as important variables in explaining policy outcomes (Moe, 1990). McCubbins, Noll and Weingast's contribution has been to show how the transparency required by congressionally imposed procedures helps political principals in the legislature keep tabs on regulatory agencies. They argue that the requirements for public comment mandated by the Administrative Procedure Act of 1946 help ensure ongoing participation by the same interest group coalition that supported Congress's legislative delegation to the agency in the first place. In this way, administrative procedure allows the coalition in the legislature to rely on interest groups as monitors and proxies, thereby overcoming the legislature's informational disadvantage and helping to 'stack the deck' in administrative proceedings in favour of the preferences of the winning legislative coalition (McCubbins, Noll and Weingast, Chapter 1, and 1989).

The path charted by McCubbins', Noll's and Weingast has been influential, with other scholars seeking to model the effects of administrative procedure on regulatory decision-making (Bawn, 1995; de Figueiredo *et al*., 1999; Epstein and O'Halloran, 1999). Efforts to test empirically the procedural control thesis have found some support in that procedural requirements for specified types of policy analysis may tilt the policy balance towards the values advanced by the analysis (Potoski and Woods, 2001). However, researchers have so far found relatively little support for the prediction that procedures 'stack the deck' in favour of the beneficiaries of new regulation (Balla, 1998; Spence, 1999; Potoski and Woods, 2001). For example, in a study of the implementation of legislation designed to increase Medicare reimbursement fees for primary care physicians, Balla (1998) found that the health care financing administration was more responsive in its rule-making to comments submitted by medical specialists than to those submitted by primary care doctors, the legislature's intended beneficiaries.

Even if rule-making procedures for public participation do not always 'stack the deck', this does not mean that these or other procedures make no difference whatsoever. An abundant research literature, both from the domain of administrative law and new institutionalism, continues to examine the importance of regulatory procedure and oversight mechanisms (Morgan, 1999; Kerwin, 2003). Increasingly, scholars have attempted to scrutinize empirically the effects of administrative procedures, asking whether specific procedures improve the regulatory process in the manner intended by institutional designers. As reviewed by Coglianese

(2002), the emerging literature that evaluates administrative procedures include studies of mandates for economic analysis of new rules (for example, Hahn, 1996; Morgenstern, 1997; Croley, 2003), opportunities for judicial oversight (for example, Mashaw, 1994; Schuck and Elliott, 1990), and experiments with consensus-based decision-making such as negotiated rule-making (for example, Harrington, 1994; Coglianese, 1997; Balla and Wright, 2003).

Of course, regulatory procedures may also sometimes have unintended or undesirable effects. Procedures that provide for oversight, for example, may contribute to an unwanted 'ossification' of the regulatory process (Mendeloff, 1988; McGarity, 1992). Whether oversight is performed by the courts or by a centralized review body such as the Office of Management and Budget, it adds another procedural layer and may prompt regulatory officials to act defensively, taking more time to build a case that will withstand the review process (R.A. Kagan, 2001). Facing additional burdens imposed by review procedures, some agencies have allegedly retreated from rule-making altogether (Mashaw and Harfst, 1991) or found alternative ways accomplishing regulatory goals without developing new rules (Hamilton and Schroeder, 1994).

Stuart Shapiro, in an essay reprinted here as Chapter 2, set out to test the extent to which regulatory procedures impede regulators from adopting regulations. To determine whether procedural stringency affects either substantive stringency or the frequency of regulatory change, Shapiro examined a carefully matched set of eight state systems of day care regulation – a regulatory domain largely unaffected by federal control. Exploiting the natural experiment made possible by a comparison of states with intricate rule-making procedures with otherwise similar states that have more streamlined procedures (Teske, 1994), Shapiro found no systematic difference in the pace or stringency of regulation across the two groups. What he did find, though, was that the key factor affecting regulatory policy was the overall political climate within the state, such as whether the legislature or governorship was controlled by Democrats versus Republicans.

Studying regulatory outcomes cross-nationally, other social scientists have similarly considered the extent to which policy structures or styles affect regulatory policy outcomes, especially compared with the effect of political factors, such as interests, ideologies and party control. National governments vary considerably in the way they incorporate affected interests into policy decision-making. As Robert A. Kagan (2001) and others have observed, the United States exhibits a more pluralistic policy structure than found in other countries, with competing interest groups vying for influence in an open and adversarial process (Lundqvist, 1980; Kelman, 1981; Badaracco, 1985; Brickman *et al.*, 1985; Rose-Ackerman, 1995). In contrast with American pluralism, corporatist policymaking in European countries, especially in Scandinavia, has often taken the form of formal and structured collaboration between peak industry associations, labour and government (Schmitter and Lehmbruch, 1979; Williamson, 1989).

Do these differences in policy structures lead to differences in regulatory outcomes? This question has been most widely studied in the context of environmental regulation (Crepaz, 1995; Jahn, 1998; Scruggs, this volume, Chapter 3, 2001; Neumayer, 2003). Lyle A. Scruggs, in an essay reprinted here as Chapter 3, found that OECD nations that have employed such 'corporatist' regulatory structures tended to achieve larger relative environmental improvements in the 1980s and 1990s, based on an index of several indicators. Scruggs failed to observe any explanatory power from electoral variables or political party control.

In contrast, a subsequent analysis of a similar group of countries by Neumayer (2003) found the opposite: namely that corporatist structures do not explain variation in air pollution levels across countries, but that lower pollution levels are associated with the strength of green and left-libertarian political parties.

Whatever effect corporatist policy structures have on environmental and other types of regulatory policy, these policy structures themselves can change over time. Some have suggested that the corporatist structures in Scandinavia and the Netherlands, for example, have begun to become more conflict-ridden and pluralistic (Christiansen and Rommetvedt, 1999). Furthermore, policies and policy outcomes themselves can change, even if basic differences in policy structures remain. In Chapter 4, David Vogel argues that the substantive differences between European and American environmental regulation have started to disappear over the past 15 years, as European regulatory policy has grown increasingly precautionary in its approach to risk. A subsequent analysis of a random sample of risks by Hammitt *et al*. (2005) confirms a slight degree of movement towards greater precaution in Europe; however, Hammitt *et al*. (2005) also show that the treatment of risk is highly diverse in both jurisdictions – with the US still more precautionary than Europe in its policies about some risks, but with Europe more precautionary for others.

Regulatory Enforcement

The ultimate impact of any regulatory policy depends not only on how that policy has been drafted and designed, but also on how enforcement officials take actions to implement those policies at the 'street-level' (Lipsky, 1980; Pressman and Wildavsky, 1984). The style and strategy of regulatory enforcement has attracted considerable attention from social scientists seeking to explain the behaviour of regulatory enforcement personnel.

Two contrasting models shape discussion of the enforcement or implementation of regulation (Bardach and Kagan, 1982; Hawkins, 1984; Reiss, 1984). One model treats regulatory enforcement mainly as a *legal process* and, according to it, regulations are viewed as authoritative legal norms whose violation demands punishment. The other model treats enforcement more as a *social process*, one aimed at stimulating cooperative government-business problem-solving and which calls for remedial responses to violations. In countries throughout the world, some advocacy groups and politicians insist that governments should zealously pursue a legalistic approach, while business groups and many regulatory officials insist that a more cooperative approach is more desirable and effective overall.

The legalistic model reflects the historical weight of criminal law in shaping society's response to deviant behaviour, even though the task of enforcing regulatory statutes is usually given to specialized administrative agencies rather than to traditional criminal law enforcement bodies. That is because regulatory programs are designed primarily to prevent rather than to punish harm, and prevention often demands specialized technical knowledge. Also, unlike most criminal laws, regulations tend not to seek to prohibit all harmful outcomes (say, pollution or worker risks) but only harm that rises above levels that are demonstrably and unacceptably high. In other words, regulations do not usually seek to eliminate all sources of pollution or all dangers in a workplace, but only 'unreasonable' pollution or hazards. Determining exactly which behaviours are likely to result in *unreasonable* hazards, or precisely what should be

done to prevent them, can require case-by-case administrative judgments based on particular technical factors.

Philip Selznick (1969, pp. 14–16) once wrote that the primary purpose of administration is not to determine 'the legal coordinates of a situation' in light of pre-established legal rules, but rather 'to get the work of society done', to refashion 'human or other resources so that a particular outcome will be achieved'. Effective regulatory enforcement, in this perspective, requires dialogue between regulators and officials in each regulatory facility. It requires whatever blend of rules and exhortation, threat and education, toughness and compromise will best induce particular regulated enterprises to cooperate. Even offering rewards may be effective at securing compliance (Grabosky, 1995; Braithwaite, 2002b). According to this view, in order to induce change in businesses' behaviour, regulatory officials must be granted considerable discretion in implementing general regulatory standards.

On the other hand, some regulatory violations – such as intentional fraud, lying to law enforcement and other governmental officials, and reckless disregard for the health and safety of others – are clearly criminal in nature. There are also always a considerable number of regulated entities, or harried sub-unit supervisors, who are inclined to cut corners on compliance to save time and money. Thus, in the hands of gullible, overly-busy, or politically-influenced regulatory officials, a regulatory agency too wedded to a cooperative enforcement style can degenerate into dangerous laxity (Gunningham, 1987) or unfairness (Yeung, 2004), or can overlook the root causes of regulatory problems in their zeal to mediate disputes in a way that satisfies all the affected parties (Silbey, 1984). Regulatory advocacy groups and many enforcement officials therefore argue that, in order to deter opportunism or heedlessness on the part of regulated businesses, regulatory field offices should have little discretion to use their own, potentially corruptible judgment. Effective regulation, on this view, requires specific legal rules, strictly enforced.

Both legalistic and cooperative enforcement styles are reflected in actual regulatory practice. As Peter J. May and Søren Winter make clear in their essay reprinted here as Chapter 6, regulatory practices are arrayed between the poles of legalistic enforcement and discretionary judgement, between inspectors who are quick to use the threat of legal sanctions and those who are more inclined to emphasize education and persuasion. Much sociolegal research on regulatory enforcement seeks to understand the causes and consequences of this variation between these two major enforcement styles, as well as to understand how these styles may interact with, or even complement, each other.

Although some agencies continue to approach enforcement legalistically, sociolegal research finds that *criminal* prosecution of regulatory violations is relatively infrequent (Hawkins, 1984; Spence, 2001). Many regulatory violations involve failure to file timely and fully accurate reports, or failure to take certain precautionary measures, and hence, unlike most traditional crimes, do not result in any immediate, tangible harm to others. Moreover, due to the complexity of regulatory rule-systems, many violations stem not from wilful disregard or reckless behaviour, but from ignorance of a particular requirement or from disregard of company compliance policy by lower-level employees (Kagan and Scholz, 1984; Vandenbergh, 2003). In both kinds of case, plus others in which violations do not lead to significant harms, prosecutors and judges are often reluctant to subject a businessperson or firm to the moral obloquy and harsh sanctions of the criminal law (Hawkins, 2002). Moreover, in practical terms, criminal prosecution, with its high burden of proof, can tie up agency

officials in extended, labour-intensive investigations and court hearings, while risking a legal defeat (Coffee, 1981, pp. 400–407; Hawkins, 1989).

Consequently, many regulatory agencies claim that they strive for a flexible enforcement style: legalistic and punitive when needed, but accommodative and helpful in others, depending on the reliability of the regulated enterprise and the seriousness of the risks or harms created by particular violations (Hawkins, 1984; May and Winter, Chapter 6). Academic analyses generally support this approach. In his essay reprinted as Chapter 5 in this volume, John T. Scholz models the regulatory enforcement as an iterative prisoner's dilemma. If the regulator seeks punitive legal sanctions for every detected violation, the regulated company might be expected to mount as strong a legal defence as possible – frustrating the goal of immediate reduction of the risks that the rules were designed to minimize. On the other hand, if the regulator withholds prosecution in return for the regulated firm's promise to cure the violation promptly, the firm might just keep stalling, especially since the legal threat has diminished. With these tradeoffs confronting regulators, Scholz concludes that the best outcome for society, over time, will result from a dynamic enforcement strategy, according to which regulators withhold penal action and even agree to accept 'substantial compliance' rather than demand literal compliance with all legal rules – as long as the regulated firm provides credible commitments to remedy the most serious violations quickly. At the same time, however, the regulator must develop a reputation for imposing prompt and costly legal sanctions whenever the regulated entity prevaricates or delays. Scholz labels this the 'tit for tat' enforcement strategy since the regulator meets a regulated entity's non-cooperation with punishment, while responding with forbearance to cooperation, accepting something short of full compliance in some cases (see also Bardach and Kagan, 1982; Hawkins, 1984).

John Braithwaite, drawing on extensive empirical research on regulation, agrees that cooperation is cheaper and better than punishment, as long as the threat of punishment lies behind the invitation to cooperate (Ayres and Braithwaite, 1992; Braithwaite, 2002a). Yet he also emphasizes that, in order to make that threat credible, regulators must have at their disposal legal sanctions that are less severe, quicker and cheaper than criminal prosecution, and hence more likely to be used. The most effective regulators can plausibly threaten to meet a regulated enterprise's non-cooperation by successively moving up a 'pyramid of sanctions' – beginning with a legal citation or warning letter (the most common action, at the bottom of the pyramid), then, if non-cooperation persists, escalating first to intensified surveillance, then administratively-imposed fines, then larger court-imposed civil penalties – and as a last resort (or in the very worst cases) to criminal penalties or delicensure. When an agency possesses and is not afraid to use the full range of responses, Braithwaite observes, regulatory enforcement can expeditiously and effectively proceed at the lower layers of the pyramid.

A significant body of empirical research has analysed *why* some regulatory agencies and individual regulators turn to legalistic enforcement more often than others. Cross-nationally, regulatory agencies in the United States have often been found to employ a more legalistic enforcement style (and impose harsher legal sanctions) than their counterparts in other economically advanced democracies (Kelman, 1981; Braithwaite, 1985; Vogel, 1986; Verweij, 2000). This pattern is illustrated in Kagan and Axelrad (2000) which provides a series of cross-national studies of multinational corporations' engagement with regulatory officials and shows that American regulators tend to be more rule-bound and punitive.

The American tendency towards more legalistic enforcement has been attributed to its political culture, which is particularly mistrustful of both governmental and corporate power (Vogel, 1986; R.A. Kagan, 2001). In the United States, both the political left and the political right worry that regulatory agencies will be captured or corrupted by their ideological opponents. Both sides, therefore, seek to control regulatory authority through detailed rules, formal legal procedures, judicial review and periodic legislative scrutiny – usually triggered by complaints of underenforcement or overenforcement (R.A. Kagan, 2001). For regulatory agency officials, adhering to the rules and demonstrating a strong enforcement record provides a relatively safe harbor in the ongoing political storms (Bardach and Kagan, 1982; R.A. Kagan, 2001). This enforcement pattern does not appear as strong in nations with parliamentary governments, cohesive political parties, robust national bureaucracies, and strong national trade associations. (Scruggs, Chapter 3; Kagan, R.A., 2001).

Enforcement style also tends to vary *within* individual countries – from one regulatory agency to another, across regional field offices of the same agency, and even among individual inspectors in the same program (Scholz and Wei, Chapter 7; Braithwaite *et al*., 1987; Feinstein, 1989; Hutter, 1989; Nielsen, 2006). In Chapter 6, May and Winter helpfully distinguish the various styles of regulatory inspectors in terms of both the formalism of their interactions and their use of coercion, showing that these two dimensions illuminate the variation in inspection styles they observed.

Sociolegal scholars have linked variation in enforcement styles to factors such as statutory design, characteristics of regulated entities and the background political environment (Kagan, 1994). Regulators tend to employ a more cooperative approach when they deal with larger enterprises that have professional compliance staffs and a reputational stake in being seen as good corporate citizens. They pursue more of a legalistic approach when dealing with smaller firms that are less visible to the public, more financially hard-pressed and hence more tempted to evade the law (Shover *et al*., 1984). Regulators also face more pressures to adopt an aggressive, sanction-oriented enforcement style in the aftermath of a serious accident or problem that is attributed to regulatory laxity, or in the wake of a journalistic exposé of ineffective enforcement (Kagan, 1994).

In addition, political factors such as the ideology of the government in power, have been shown to influence regulatory enforcement style. As the costs imposed by the regulatory state have grown, conservative political parties often promise to reduce regulatory burdens on the business sector, while left-of-centre parties typically promise to make regulation more stringent and effective. Once elected, political party leaders can affect agencies' policies and enforcement methods by choosing whom to appoint to leadership positions in an agency; by expanding or contracting agency staffing and resources; by high-publicity legislative oversight hearings; and sometimes by quietly telling regulatory officials how they would like regulatory issues of urgent political concern to be handled (Kagan, 1994, p. 401). In Chapter 7 John T. Scholz and Feng Heng Wei demonstrate that workplace safety officials in American states with Democratic governors and Democrat-controlled legislatures imposed more frequent and larger penalties than did officials in Republican states. Fines imposed by OSHA, the US federal workplace safety agency, declined in the early 1980s after President Reagan, newly elected after denouncing 'excessive government regulation', appointed a new agency head (see Chapter 7, this volume). Conversely, in 1982 and 1983, aggressive oversight hearings by congressional Democrats forced President Reagan's administration to reverse course:

after an initial decline, federal environmental clean-up orders and criminal prosecutions for regulatory offenses quickly increased to levels that exceeded those that prevailed during the preceding Democratic administration (Wood, 1988; Wood and Waterman, 1991). Sociolegal studies in Western Europe have similarly found that enforcement and implementation can be affected by political party dominance and political leaders' concerns (Hutter, 1989; Niemeijer, 1989). In many democracies, political protest and legal action by citizen groups have become almost as important as electoral politics in shaping regulatory agency enforcement activity, and sometimes more so (Gunningham *et al*., 2004).

Responses to Regulation

Governments make and enforce rules in order to change business behaviour and thereby achieve improved outcomes in the world (Parker, 2000). Sociolegal scholars, accordingly, have sought to assess regulation's effects on both businesses' compliance with rules and the attainment of the objectives underlying those rules. They have also sought to explain why some regulated entities readily comply – and even sometimes go beyond compliance – while others resist or comply only reluctantly.

Consistent with the theory of regulatory capture, some scholars have viewed the enactment of regulations as little more than 'symbolic politics', since politicians typically have been more eager to announce new regulatory programs than to fund them adequately (Edelman, 1964). The collapse of many important fisheries, for example, is testimony to the repeated failures of regulatory regimes ostensibly designed to restrict the number of fishing boats and the size of the catch (Stone, 1997). Partly due to political pressures, American officials charged with regulating the savings and loan industry in the 1980s disastrously failed to prevent large numbers of too risky loans, leading to the collapse of many lenders (Rubin, 2000); unfortunately, a similar regulatory failure occurred in Japan (Millhaupt and Miller, 2000). Even when the social problems motivating regulation diminish in scope or severity, we cannot always be certain that *regulation* has caused things to improve, as underlying shifts in the economy or advances in technology may well bring about improvements too. For example, Michael Greenstone (2004) has carefully analysed the impact of the Clean Air Act of 1970 on sulphur dioxide emissions in the United States, finding that regulation played at most only a minor role in the nearly 80 per cent decline in sulphur dioxide pollution.

Although many regulatory programmes do reflect 'symbolic politics' to a certain extent, and although many governmental agencies do lack the resources and political backing to enforce their rules adequately (Gunningham, 1987), the notion that political machinations usually reduce regulatory legislation to ineffectiveness is far from always the case. Many programmes have brought about remarkable changes. To mention just a few examples, regulation has markedly improved the safety of banking, dairy products, electrical systems in housing, pharmaceuticals and motor vehicles. It has sharply reduced death rates in coal mines (Lewis-Beck and Alford, 1980; Braithwaite, 1985). It has compelled manufacturers and municipalities to spend billions of dollars on waste-water and hazardous waste treatment, diminishing many forms of pollution even in an era of rapid industrial and population growth (Easterbrook, 1999; Scruggs, Chapter 3). In the United States, regulation has spurred the elimination of cigarette-smoking from thousands of workplaces and restaurants (Kagan and Skolnick, 1993). Partly by supplementing public enforcement with private causes of action,

regulation has helped increase employment opportunities and earnings for African-Americans in the United States (Burstein and Edwards, 1994).

In explaining businesses' compliance with these and other regulatory regimes, sociolegal scholars have sought to untangle the relative influence of deterrence (that is, the fear of legal sanctions and related adverse publicity) versus social norms (that is, the felt duty to comply with the law or achieve the goals of the regulation) (Thornton *et al.*, 2005). Based on detailed records of inspections of, and compliance by, nursing homes in Australia, John Braithwaite and Toni Makkai (Chapter 8), indicate that variation in compliance is not explained by standard deterrence theory – that is, simply the fear of inspections and sanctions – but rather is best explained by the degree to which chief nurses and their staffs have a strong sense of duty to comply with regulatory norms. May (2004) found that residential construction company officials, in describing their motives to comply with building code provisions, ranked their general duty to comply with the law, as well as their desire to maintain a reputation for quality, as much more important than fear of regulatory fines. Summarizing a number of studies, Vandenbergh (2003, p. 127) concludes that notwithstanding 'the small risks of inspections and the small size of sanctions, compliance rates [for environmental requirements] are widely regarded to be higher than predicted by the standard deterrence model' (see also Weil, 1996).

Although many firms have developed a 'culture of compliance' that does not depend directly on the fear of punishment, such an internalized culture is neither universal nor invariant. Regulatory violations remain far from rare (Rechtschaffen, 2004). In some industries, a culture of compliance arises only when regulatory agencies have established a credible enforcement record (Gunningham *et al.*, 2005). For some regulations, compliance is not cheap, and so firms are reluctant to invest in compliance measures absent assurance that competitors who do not comply will be caught and punished (Thornton *et al.*, 2005). Reflecting on his experience as head of the US Office of Price Administration during the Second World War, Chester Bowles (1971, p. 25) famously quipped that about 20 per cent of regulated firms will readily comply with any regulation, 5 per cent will actively resist complying, and the remaining 75 per cent will go along provided they believe that the recalcitrant 5 per cent will be caught and punished.

As exemplified by the study of OSHA enforcement described in the essay by Wayne B. Gray and John T. Scholz (Chapter 9), sociolegal research has repeatedly revealed that, in some regulatory contexts, the experience of being inspected and sanctioned for non-compliance does result in increases in compliance and the achievement of regulatory objectives (Helland, 1998; Mendeloff and Gray, 2004; Gray and Shadbegian, 2005; Shimshack and Ward, 2005). Likewise, the 'visibility' of regulatory violations to regulatory officials or potential complainants – as enhanced by the frequency of inspections or by regulations that compel firms to make data concerning their regulatory performance readily available to the public – has been associated with higher levels of compliance.

Business commitment to regulatory compliance, it has been shown, is also affected by social pressures, such as the presence of citizen watchdog organizations which have the capacity to draw the attention of news media or regulatory officials to a firm's regulatory violations. Kazumasu Aoki and John W. Cioffi (Chapter 10) find that a multinational corporation's Japanese facility had a stronger record of complying with manufacturing waste disposal regulations than did a parallel facility in the United States, even though governmental inspections in Japan were less frequent and legally threatening. One reason, they suggest, is

that social pressures for compliance were much greater in Japan, partly as a result of horrible episodes of toxic environmental pollution in the 1970s.

In economically advanced democracies, many business managers regard the risk of informal social sanctions as far more salient and economically threatening than even the risk of regulatory penalties. These informal sanctions operate by adversely affecting a firm's reputation and can be triggered by negative publicity about the company's products, practices, or pollution – and also, of course, by any formal legal penalties or enforcement actions taken against the firm. Research shows that many firms today will exceed their regulatory obligations simply to provide themselves with a margin of error to protect themselves from the repercussions of perceived irresponsible conduct (Mehta and Hawkins, 1998; Prakash, 2000; Gunningham *et al*., 2003).

Gunningham, Kagan and Thornton's (2003) cross-national study of the regulatory behaviour of pulp and paper mills confirms these tendencies, as summarized by the essay by Robert Kagan, Neil Gunningham and Dorothy Thornton reprinted as Chapter 11 in this volume. The authors find that business managers speak of having to comply with their facilities' 'social license' – as well as their regulatory licence. Indeed, social pressures were the dominant factor in explaining why many pulp mills invested in costly 'beyond compliance' measures, such as those which reduced unpleasant odours that affected their neighbors. Echoing some related findings in Aoki and Cioffi (Chapter 10), Gunningham, Kagan and Thorton also find that each company's overall management style was a significant factor in explaining variation in corporate regulatory performance.

The same authors emphasize one further relevant point. Whereas normative pressures to comply and a firm's management culture are important in explaining variation in corporate regulatory compliance at any given point in time, business firms in market economies are also subject to fierce economic competition. Their economic licence – which demands cost containment and the maintenance of positive earnings – tends to exert downward pressure on expenditures for both compliance and 'beyond compliance' measures. As a result, governmental regulations, backed by a credible threat of enforcement, are still usually necessary to induce firms to make very large investments when it is necessary to make significant improvements in the achievement of regulatory goals.

New Directions in Regulatory Design

In recent decades, political demands for greater economic efficiency, intensified by the competitive pressures unleashed by the increasing globalization of trade, have induced governments sometimes to 'privatize' or 'deregulate' government-owned monopolies or oligopolies that provide transportation, telecommunications, electric power and water, and other services (Feigenbaum *et al*., 1998). These same pressures, combined with business complaints about regulatory inflexibility, have also led to the search for alternatives to, or modifications of, traditional 'command and control' regulation, by which is generally meant governmental prescription of the implementation of uniform precautionary measures or control technologies for all firms in an industry. Alternatives to traditional governmental regulation seek to make regulation more flexible, giving regulated entities more discretion to identify and ameliorate sources of harm (Richards, 2000).

At the far end of the spectrum of discretion, *self-regulation* delegates rule-making and enforcement functions entirely to regulated firms, their trade associations or private standard setting organizations (Cheit, 1990; Priest, 1997; Haufler, 2002; Nash, 2002; Parker 2002). Extensive systems of self-regulation can be found in sectors such as financial securities (Jackson, 2001), nuclear power (Rees, 1994), forest products (Meidinger, 2003) and chemical manufacturing (Rees, 1997). Professional societies and engineering organizations have established countless private codes and standards – such as 'generally accepted accounting practices', hospital accreditation regimes and standards for appropriate insulation and wiring for electrical appliances (Cheit, 1990).

Self-regulatory systems sometimes arise to protect the collective interests of an industrial sector in the wake of a major disaster caused by an individual member in the sector – such as occurred following the major accidents at the Three Mile Island nuclear reactor in Pennsylvania or the Union Carbide chemical plant in India (Rees, 1994, 1997; Nash, 2002). More generally, businesses have an interest in adopting systems of self-regulation whenever doing so can stave off more costly forms of governmental regulation (Lyon and Maxwell, 2004; Johnston, 2006). When self-regulation succeeds in doing so, it sometimes amounts to little more than a sophisticated form of regulatory capture, a symbolic gesture that appears to have addressed a social problem but in reality has not (Howard *et al*., 2000; King and Lenox, 2000). On the other hand, although self-regulation certainly can provide political cover to an industry, research indicates that at least certain kinds of voluntary business effort can result in demonstrable social improvements (Potoski and Prakash, 2005). Businesses can be motivated to achieve even somewhat costly changes on their own if they face sufficient market pressures to act in a socially responsible manner (Reinhardt, 2000; Gunningham *et al*., 2003; Hay *et al*., 2005; Vogel, 2005) or if the threat of impending regulatory action is sufficiently credible (Segerson and Miceli, 1998).

At the same time that self-regulation and privatization have decentralized regulatory authority for some markets and risks, businesses and policymakers also have tried to make traditional government regulation more flexible and efficient. Ironically, the replacement of government monopolies and regulated cartels with competitive private firms has actually spawned an increased need for governmental controls to address concerns about prices, access to service, service quality and the inevitable externalities generated by competitive firms (Vogel, 1996; Gómez-Ibáñez, 2003). But, even so, governments still face a choice between regulations that tightly constrain the behaviour of firms, requiring them to act in a manner that the regulator deems best for achieving a given regulatory objective (but which may not be the best or most cost-effective option for all firms), or regulations that allow firms some degree of leeway in deciding how to achieve the overall objective. Sometimes this leeway comes about when regulatory enforcement officials adopt a flexible enforcement style. Even in regulatory programmes generally viewed as 'command and control', for example, regulators can 'delegate the details' to regulated entities in permitting or licensing proceedings by requiring them to develop, submit and then follow pollution prevention or risk reduction plans that they themselves tailor to their own particular enterprise (see, for example, Dwyer *et al*., 2000; Gunningham *et al*., 2003, pp. 46–47, 51, 77).

More visible efforts to enhance flexibility arise when regulatory agencies grant formal exemptions from highly prescriptive regulations to certain regulated facilities, usually those that already have a good compliance record and demonstrate some kind of equivalent or even

superior performance. In the early 1980s, for example, the American EPA initiated a 'bubble' programme under which a manufacturing plant could modify the restrictions imposed in its detailed source-by-source air pollution permits as long as it could find ways of ensuring that its overall emissions (into an imaginary plant-wide 'bubble') did not increase (Levin, 1982; Hahn and Hester, 1989). Later, in the 1990s, drawing in part on a pilot study at an Amoco refinery in Yorktown, Virginia, the American EPA established a formal exemption process called Project XL which provided for facility-specific contracts negotiated among firms, the agency and environmental advocacy groups that granted the facility flexibility in return for superior environmental progress and high levels of transparency (Caballero, 1998; Blackman and Mazurek, 2001; Marcus *et al*., 2002).

At the state level, California's Occupational Safety and Health Agency had earlier established a programme under which enforcement officials granted more flexibility to construction firms which had established collaborative worker–management safety programmes that identified and reduced accident rates (Rees, 1988). Other countries have adopted similar programmes that rely on negotiated contracts with regulated entities. Sweden has had a workplace safety regime that provides special training and legal powers to worker safety representatives, facilitating a non-legalistic, site-specific style of regulation (Kelman, 1981). In the Netherlands, government regulators have negotiated 'environmental covenants' with industry associations, committing all firms in the association to collaborate in specifying and achieving regulatory goals (Hazard and Orts, 2000).

In addition to efforts to negotiate exemptions or site-specific regulatory covenants, both legislatures and regulatory agencies have sought to build flexibility into the binding rules that governments impose on firms. A principal way of providing flexibility has been to impose performance goals on firms – instead of mandating specific means to achieve those goals. The advantages of these so-called performance standards have been widely noted (Breyer, 1982; Viscusi, 1983; Coglianese *et al*., 2003). By specifying an end state to achieve, performance standards give regulated firms the ability to choose both the most effective and least costly means of reducing harm. Performance standards also provide firms with an opportunity to innovate, seeking out better or lower-cost strategies to meet the performance target.

Some have suggested that an even better approach is for governments simply to tax businesses for the generation of harms, at levels that are equivalent to the costs those harms impose on society (Pigou, 1932). These kinds of regulatory tax scheme are intended primarily to change firm behaviour, not necessarily to raise revenue. In theory, taxes will maximize regulatory efficiency by ensuring that firms achieve the cheapest and most optimal reduction in harms. As attractive as they may be in theory, however, regulatory taxes have been only infrequently adopted in practice. Gjalt Huppes and Robert A. Kagan (Chapter 12), offer an empirical account of one of the few attempts to use taxes as a regulatory tool. They examine two tax schemes adopted in the Netherlands that were designed to reduce pollution. They found that a tax on the discharge of environmental harmful industrial effluents, enacted in the 1970s and enforced by well-regarded local water authorities, sharply reduced pollution. In contrast, they found that a second tax programme, designed to reduce water pollution from the agricultural use of manure, was far less effective, largely because of the difficulty of monitoring compliance in a decentralized industry of many small producers. Huppes and Kagan conclude that technical measurement and monitoring difficulties and low organizational capacity constrain the effectiveness of regulatory taxes.

Like taxes, tradable permit systems are another market-based alternative to conventional regulation (see, for example, Dales, 1968; Tietenberg, 1985). With tradable permits, the government makes an initial allocation of permits based on an overall level of harm deemed acceptable, but then allows businesses to trade these permits with each other. The approach is actually similar to performance standards, but instead of requiring every firm or facility to meet the same level of performance, firms can trade permits with each other and thereby vary their level depending on the specific control costs they face. Firms also have an incentive to improve their performance below their permitted levels, so that they can sell the excess credits.

The United States successfully adopted a permit trading system in the 1980s to accompany a mandated phase-down in the use of lead additives in gasoline (Nussbaum, 1991; Nichols, 1997; Newell and Rogers, 2004). Subsequently, it adopted still more prominent permit trading programme in the 1990s to encourage utilities to develop their own plans for cutting sulphur dioxide emissions, a major source of acid rain (Stewart, 2001, pp. 103–12). In Chapter 13 of this volume, Robert N. Stavins summarizes the lessons of the American experience with sulphur dioxide emissions trading, a regulatory programme which met targeted emissions reductions at a significant cost savings due to the fact that firms with lower control costs could reduce more and sell their excess permits to firms with higher control costs. Like Huppes and Kagan in their study of regulatory taxes, Stavins concluded that the successful adoption and implementation of this trading system depended ultimately on institutional and political factors, such as the establishment of a market clearinghouse for permits, thereby lowering transaction costs associated with trading, and the development of affordable and effective monitoring methods.

In situations where monitoring is difficult or costly, regulators have sometimes imposed rules requiring firms to identify risks posed by their own operations and develop their own set of internal policies and monitoring procedures. For example, food-processing facilities in nearly every developed country must now comply with a regulatory approach known as HACCP, an acronym which stands for Hazard Analysis and Critical Control Point (May, 2002). Under HACCP regulations, food processors must identify all possible points in the production process where food contamination can occur, develop measures for preventing contamination at these critical control points, and establish internal procedures for monitoring and documenting employee compliance with these measures. Sometimes described as 'enforced' or 'mandated' self-regulation (Bardach and Kagan, 1982; Braithwaite, 1982; Rees, 1988; Hutter, 2001), regulations like HACCP aim directly at the conduct and quality of a business's management, seeking to make it more systematic and preventive. As Cary Coglianese and David Lazer show in Chapter 14, such management-based regulation may be most useful both when monitoring is difficult and when firms have sufficiently heterogeneous operations that there exists no uniform means of reducing the targeted harm. Yet precisely because management-based regulation may be used in situations where monitoring can be difficult, this regulatory approach can present significant oversight challenges. When governments have shifted to HACCP or other management-based approaches, for example, they have often needed to re-tool their inspection personnel so that they can go beyond filling out checklists and try to assess the quality or adequacy of firms' planning. Getting small businesses to understand and take management-based regulation seriously can also require governments to invest resources in compliance assistance programmes (Fairman and Yapp, 2005).

As another alternative to conventional regulation, governments have sometimes required enterprises simply to report or publicize the risks associated with their products or processes, thus providing government, consumers and communities with information relevant to firms' social performance. Information disclosure has long been the major thrust of regulatory systems governing securities markets and other aspects of corporate finance (see, for example, Stigler, 1964; Benston, 1973; Simon, 1989). Such disclosure strategies are also found increasingly in a variety of areas of social regulation (Graham, 2002; Jin and Leslie, 2003). For example, the US Congress in 1986 established a Toxic Release Inventory (TRI) that requires certain companies to measure and publicly disclose the levels of toxic chemicals in their air and water emissions (Hamilton, 2005). That reporting obligation alone, some researchers have reported, stimulated manufacturers to reduce their on-site inventories and releases of hazardous materials (Konar and Cohen, 1997; Fung and O'Rourke, 2000) – an outcome consistent with the view that business firms can be concerned about compliance with their 'social licence' as well as with specific regulatory requirements (Kleindorfer and Orts, 1998; Gunningham *et al*., 2003; Vogel, 2005).

Although much research has been supportive of flexibility-enhancing regulatory innovations like information disclosure, performance standards, market-based incentives and management-based regulation, the research literature also points to some of the potential limitations of these approaches. As with any approach to law and policy, the newer approaches to regulation can be implemented ineffectually, failing to achieve regulatory goals or even creating unintended side-effects. Peter J. May's analysis in Chapter 15 of this volume provides a noteworthy example of some of the potential problems that can arise when governments give more discretion to regulated firms. Examining the effects of a performance-based approach to building codes adopted in New Zealand, May found that many builders used the discretion they were granted to experiment with cheaper, less suitable building materials and techniques. Even though these alternatives apparently satisfied the specific performance standards for structural integrity, they failed to provide adequate protection from wet weather – an aspect of overall performance not clearly addressed by the standards – and consequently parts of many new buildings throughout the country experienced problems with mildew and deterioration. The implication for newer approaches to regulation seems clear. At the same time that these approaches temper the rigidity that can accompany conventional regulatory strategies, they present particular needs for effective monitoring and enforcement since they are being used, inherently, in contexts where firms' private interests do not comport completely with the overall demands society places on business.

About this Volume

The essays reproduced in the following pages of this volume, all of which have been published elsewhere, have been selected not only for their clarity and insight, but also because they cover a wide range of topics that have been central to sociolegal research on regulation. Many other studies of equal merit, and even perhaps some of greater merit, have not been included. We were constrained to include only essays published in academic journals. Hence we excluded excellent essays that were published in books, as well as chapters of excellent monographs. Furthermore, in the interest of providing as many diverse readings as possible,

we were compelled to exclude some excellent but longer essays, including lengthy law journal articles.

Even with the broad methodological and substantive diversity reflected in the essays reproduced in this volume, those that we have selected still do not adequately represent the entire range of social scientific approaches to the study of regulation, or the entire range of social control processes that might be considered spheres of 'regulation'. All branches of law – criminal law, contract law, tort law, traffic law and so on – have some regulatory function, for they are designed to deter behaviours that have been politically defined as harmful or anti-social, and thereby to encourage socially responsible behaviour. But in conventional legal discourse, which we used in our selection criteria for this volume, the term 'regulation' has been reserved for bodies of law that are elaborated through the promulgation of specialized rules, enforced by government agencies and aimed at the behaviour of business firms, other large organizations, and professional service providers. Whereas criminal and civil law typically are enforced via prosecutions and lawsuits against alleged violators, brought *after* a harmful act or omission has occurred, regulation is primarily prophylactic in purpose, designed to prevent harmful actions before they occur. Furthermore, unlike civil law enforcement, where the initial costs are borne by injured parties who must gather evidence and hire lawyers, in regulatory programmes (as in the enforcement of criminal law by police departments) the government shoulders the cost of investigation and prosecution of complaints.

Programmes of governmental regulation are often superimposed on pre-existing forms of private ordering. The first line of defence against dangerous products and unfair practices is generally the incentive system created by the marketplace. The threat of developing a bad reputation and losing business motivates many enterprises to establish quality control systems of various kinds. Contract and tort law provide a second line of defence. By enabling victims of broken promises or negligent behaviour to threaten enterprises with legal penalties, they create incentives for responsible behaviour, inducing many companies and trade organizations to create systems of self-regulation (Rees, 1994; Gunningham and Rees, 1997). The essays reprinted in this volume, however, focus on legally binding programmes, authorized by statutory laws and enforced primarily by governmental agencies.

Even within the sphere of governmental laws and regulatory programmes, the essays in this volume – nor those that could be fitted into any single compendium – are not fully representative of all the important research on regulation. We have tended to select empirical essays rather than primarily theoretical works, thus excluding some classic and significant essays by economists (for example, Coase, 1960; Becker, 1976). The essays in this volume are also primarily about social or protective regulation, rather than economic regulation aimed at controlling prices, market entry, or competition.

There are still further limitations. This collection emphasizes essays of relatively *contemporary* regulatory processes, thus excluding much valuable research by historians of regulation (for example, McGraw, 1984; Andrews, 1999; Morag-Levine, 2003). The essays also generally focus tightly on one particular regulatory programme – in one country, or at most two or three countries – thus excluding major books and essays that examine the factors that have driven and shaped the spread of regulation across many countries (for example, Braithwaite and Drahos, 2000). Furthermore, because the general thrust of sociolegal research has been on domestic regulation in economically advanced democracies, this volume pays

little attention to the international regulatory regimes nor to national regulatory processes in developing countries.

Notwithstanding these limitations, this volume does still contain a highly diverse and illustrative collection of the last generation's worth of leading research on regulation and regulatory processes. Taken together, the work reprinted in this collection maps out the key lines of inquiry in sociolegal studies of regulation, shows the contours of the answers that have emerged to date and raises new and yet unanswered questions. It is our hope that the reader of this collection will conclude, as we do, that the sociolegal study of regulation holds both exciting intellectual challenges and enormous implications for social justice and welfare. In bringing together this varied work in a single collection, we seek to stimulate, entice, and prepare still others to join in the next generation's worth of study on one of the most significant legal developments in our global society.

Cary Coglianese and Robert A. Kagan

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Perspectives

Nanotechnology and the need for risk governance

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Abstract

After identifying the main characteristics and prospects of nanotechnology as an emerging technology, the paper presents the general risks associated with nanotechnology applications and the deficits of the risk governance process today, concluding with recommendations to governments, industry, international organizations and other stakeholders. The International Risk Governance Council (IRGC) has identified a governance gap between the requirements pertaining to the nano- rather than the micro-/macro- technologies. The novel attributes of nanotechnology demand different routes for risk-benefit assessment and risk management, and at present, nanotechnology innovation proceeds ahead of the policy and regulatory environment. In the shorter term, the governance gap is significant for those passive nanostructures that are currently in production and have high exposure rates; and is especially significant for the several 'active' nanoscale structures and nanosystems that we can expect to be on the market in the near future. Active nanoscale structures and nanosystems have the potential to affect not only human health and the environment but also aspects of social lifestyle, human identity and cultural values. The main recommendations of the report deal with selected higher risk nanotechnology applications, short- and long-term issues, and global models for nanotechnology governance.

Background

Defining nanotechnology

Nanotechnology is still in an early phase of development, and is sometimes compared in the literature to information technology in the 1960's and biotechnology in the 1980's. Nanotechnology refers to the development and application of materials, devices and systems with fundamentally new properties and functions because of their structures in the range of about 1–100 nanometres (Siegel et al., 1999). It involves the manipulation and/or creation of material structures at the nanoscale, in the atomic, molecular and supramolecular realm. At the nanoscale, the characteristics of matter can be significantly changed, particularly under 10–20 nm, because of properties such as the dominance of quantum effects, confinement effects, molecular recognition, and an increase in relative surface area. Downsized material structures of the same chemical elements change their mechanical, optical, magnetic and electronic properties, as well as chemical reactivity leading to surprising and unpredicted, or unpredictable, effects. In essence, nanodevices exist in a

unique realm, where the properties of matter are governed by a complex combination of classic physics and quantum mechanics. At the nanometer scale manufacturing capabilities (including by selfassembly, templating, stamping, and fragmentation) are broad and can lead to numerous efficient outcomes.

Nanoscience is the result of interdisciplinary cooperation between physics, chemistry, biotechnology, material sciences and engineering toward studying assemblies of atoms and molecules. More than in other domains, nanotechnology requires the integration of many scientific, engineering and technical disciplines and competences. Applications of nanotechnology will penetrate nearly all sectors and spheres of life (communication, health, labour, mobility, housing, relaxation, energy, food) and will be accompanied by changes in the social, economic, ethical and ecological spheres.

As with other new technologies, nanotechnology evokes enthusiasm and high expectations: for new progress in science and technology, new productive applications and economic potential on the one hand; and for concerns about risks and unforeseen side effects on the other (Roco and Bainbridge, 2001, 2005; Roco and Tomellini, 2002). At this point in time, the assessment of the social, juridical and ethical consequences of nanotechnology relies more on hypothetical or even speculative assumptions than on rigorous scientific analysis (Hanssen and van Est, 2004). Various science fiction scenarios and literary narratives have picked up nanotechnology as a major theme of their projections for the future.

The promise of nanotechnology

The Research and Development (R&D) areas of focus are shifting progressively from passive nanostructures to nanosystems as suggested in Figure 1 (Roco, 2005a). In 2000, the US National Science Foundation (NSF) estimated that $1 trillion worth of products worldwide would incorporate nanotechnology in key functional components by the year 2015 (Roco and Bainbridge, 2001). The corresponding industries will require about 2 million workers in nanotechnology, and about three times as many jobs in supporting activities. These estimates were based on a broad industry survey and analysis in the Americas, Europe, Asia and Australia, and continue to hold in 2005.

Nanotechnology promises to be one of the defining technologies of the 21st century. Based on the ability to measure, manipulate and organise material on the nanoscale – it is set to have

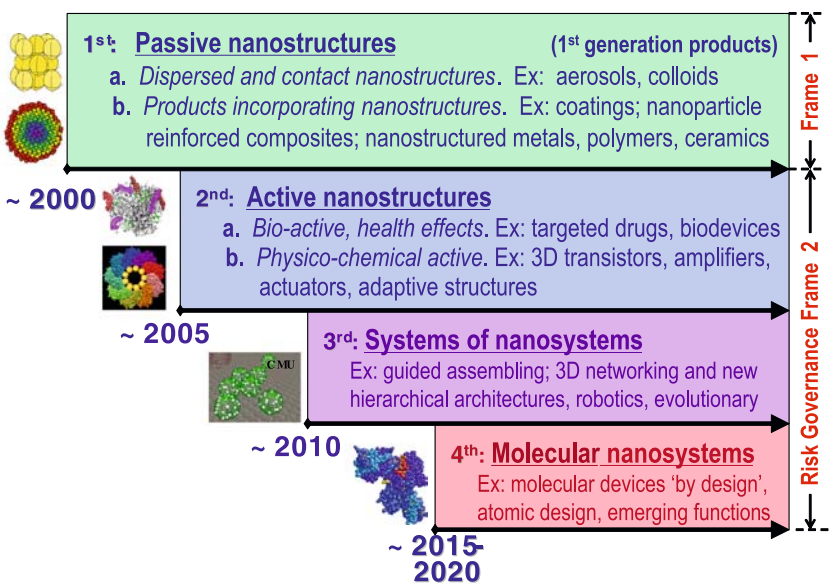

Figure 1. Timeline for beginning of industrial prototyping and nanotechnology commercialisation: Four overlapping generations of products and processes.

significant implications (Roco and Bainbridge, 2005). Envisaged breakthroughs for nanotechnology include order-of-magnitude increases in computer efficiency, advanced pharmaceuticals, biocompatible materials, nerve and tissue repair, surface coatings, catalysts, sensors, telecommunications and pollution control. This potential has encouraged a dramatic rise in R&D expenditure and all developed countries and many countries in development have begun to invest in nanotechnology. Government investments in each of the US, Japan, EU and the "Rest of the world" (including Canada, China, Australia, Korea, Taiwan, and Singapore) reached about $1 billion for R&D in 2005, with the fastest growing being the "Rest of the world". The US National Nanotechnology Initiative (NNI) announced in 2000 has been followed by nanotechnology R&D programmes in about 60 countries within 5 years. In 2005, the US Government spent $1200 million through its National Nanotechnology Initiative, Japan about $950 million, whilst the European Commission has allocated $1.3 billion under its multi-annual Sixth Framework Programme (DTI, 2002). Corresponding R&D investments for nanotechnology by industry worldwide are at about the same level in 2005 but with a higher rate of yearly increase as compared to government investments.

Significant applications of nanosciences and nanoengineering lie in the fields of, inter alia, medicine, pharmaceutics, cosmetics (such as sun creams), biotechnology, processed food, chemical engineering, high performance materials, electronics, information technologies, precision mechanics, optics, analytics, energy production and environmental sciences (Jopp, 2003). A range of projected beneficial applications are also related to nanotechnology, for example, the conservation of resources and the diminishment of pollution. Thousands of new patents are being announced in this area each year (Huang et al., 2004). Titanium dioxide, carbon black, zinc oxide and iron oxide make up the majority of the nanoparticles in industry, however, there are dozens of other nanostructures and particles at the research stage that could enter the manufacturing world soon as part of the first generation of nanoproducts (see evolution of nanotechnology in Figure 1). The Small Times survey, using the NNI definition of nanotechnology, has identified over 700 products incorporating nanotechnology in the US alone (Small Times, 2005).

What is special about nanotechnology as an emerging field?

Nanotechnology has many characteristics which both increase its potential and provide new issues for global risk governance. Also, the implications of nanotechnology are broad because its applications are at the confluence with modern biology, digital revolution and cognitive sciences (nano-bio-info-cogno converging technologies or NBIC in Roco and Bainbridge, 2003), and many long-term outcomes are the result of NBIC integration.

Most importantly, nanotechnology:

- *Offers a broad technology platform* (for industry, biomedicine, environment and an almost indefinite array of potential applications).
- *Reaches the basic level of organisation of atoms and molecules*, where the fundamental properties and functions of all manmade and living systems are defined.
- *Reverses the trend of specialisation of scientific disciplines*, providing unifying concepts for research and education, and leading to system integration in engineering and technology.
- *Has stimulated all developed countries and many countries in development to invest in nanotechnology* (worldwide R&D investment exceeds $8B in 2005).
- *Has broadened and changed manufacturing capabilities* (including by selfassembling and top-down fabrication) with the promise of more efficient outcomes.
- *Has influenced the speed and scope of R&D that exceeds for now the capacity of regulators to assess human and environmental impact*.
- *Has become one of the main drivers for technological/economic change and industrial competition*.

In response to these specific characteristics of nanotechnology, the national R&D programmes established in the last five years are highly integrative and involve multiple funding agencies. For illustration, the initial strategy of the National Nanotechnology Initiative in the US in 2000 was based on long-term planning, inclusiveness of potential contributors, the establishment of multidisciplinary partnerships amongst government,

industry and international organisations, and the support of societal dimension studies from the beginning (Roco, 2004a).

Four generations of nanotechnology products and processes

Four overlapping generations of new nanotechnology products and processes (called below "nanoproducts") have been identified which have the potential for development in the interval 2000–2020: passive nanostructures, active nanostructures, systems of nanosystems, and heterogeneous molecular nanosystems (Figure 1; Roco, 2004a). Each generation of products is marked by the creation of commercial prototypes using systematic control of the respective phenomena and manufacturing processing. Products may have components corresponding to different generations. The rudimentary capabilities of nanotechnology today for systematic control and manufacture at the nanoscale are expected to evolve significantly in complexity and degree of integration by 2020.

- *First generation of products, mainly after* $\sim$ 2000 *– : passive (steady function) nanostructures* include nanostructured coatings, dispersion of nanoparticles, surface nanopatterning, ultraprecision engineering, and bulk materials (nanostructured metals, polymers and ceramics). These nanostructured materials have steady or quasi-steady structures and functions (such as mechanical behaviour and chemical reactivity) during their use. The primary outcomes are components (such as particles, wires, nanotubes, etc.) with improved properties and functions because of their nanostructure. One may identify two subcategories: *(a) dispersed and contact surface nanostructures* such as nanoscale colloids (including cosmetics), aerosols and powders that may have significant exposure to biosystems; and *(b) products incorporating nanostructures* such as nanoscale layers in transistors or bulk materials. In nanomedicine, one would include joint replacement with biocompatible nanostructured materials and non-invasive and invasive diagnostics with nanoparticles and quantum dots for rapid patient monitoring. In nanoelectronics, one would include the scaling down "masked-lithography of thin-films" approach with simple nanoscale components (for example, nanolayers). Potentially high risk products include nanoparticles in cosmetics or food, which have high scale production and increased exposure rates. Other examples are ultrafine powders with fire and explosion hazards.
- *Second generation of products*, $\sim$ 2005 *– : active (evolving function) nanostructures*, for example, new transistors, amplifiers, targeted drugs and chemicals, actuators, molecular machines, light-driven molecular motors, plasmonics, nanoscale fluidics, laser-emitting devices, and adaptive structures. An 'active' nanostructure changes its state in time during its operation, for illustration, an actuator changes its dimensions, and a drug delivery particle changes its morphology and chemical composition. The new state may also be subject to other successive changes in the mechanical, electronic, magnetic, photonic, biological properties and other effects. One may identify two subcategories: *(a) bioactive nanostructures* with potential effects on human health and ecosystems; and *(b) physico-chemical active nanostructures*. Typical active nanostructures are components in nanoelectromechanical systems (NEMS), nanobiodevices, energy storage devices, and sensors which change their state during measurement. In nanomedicine, one would include cognitive capacity-assisting and enhancing devices, targeted cancer therapies, sensors for in vivo monitoring, localised drug delivery, neural stimulation and cardiac therapies. In nanoelectronics, one would include "directed self-assembly" structures leading to Complementary Metal-Oxide Semiconductors (CMOS) scaled to its ultimate limits (5–10 nm) and the possible "post-CMOS" (but still "electron charge-based") integrating nanocomponents and nanodevices such as carbon-nanotube and single-electron "transistors". Examples of potentially high-risk products are: nano-bio interface devices, neuro-prosthesis, reactive devices placed in the environment, active devices in the human body, and devices for surveillance. Several potentially higher risk areas are: nanobiotechnology, neuro-electronic interfaces, nanoelectromechanical systems, agriculture and food systems and hybrid nanomanu facturing.

- *Third Generation*, ~ 2010 – *: system of nanosystems*, use various syntheses and assembling techniques such as bio-assembling; networking at the nanoscale and multiscale and hierarchical architectures, robotics on surfaces, modular nanosystems, chemo-mechanical processing of molecular assemblies, and quantum-based nanoscale systems. In nanomedicine, one would include artificial organs built from the nanoscale, improved cell-material interactions for cell conditioning, and scaffolds for tissue engineering. In nanoelectronics, one would include possible new devices based on state variables other than electric charge (e.g., electron-spin, nuclear-spin or photonic states). Potential high risk products include: emerging behaviour robotics, evolutionary artificial organs, modified viruses and bacteria, and brain modification. Several potentially higher risk areas are: nanorobotics, regenerative medicine, brain-machine interface, nanoengineering in agriculture, nanosystems used for manufacturing and product processing, and other converging technologies applications.
- *Fourth generation*, ~ 2015/2020 – *: involves heterogeneous molecular nanosystems*, where each molecule in the nanosystem has a specific structure and plays a different role. Molecules will be used as devices and fundamentally new functions will emerge from their engineered structures and architectures. This is approaching the way biological systems work, but in comparison biological systems are water-based, process the information relatively slowly, and have multiple hierarchical scales. Designing new atomic and molecular assemblies is expected to increase in importance, including macromolecules ''by design'' to self-assemble on multiple scales, nanoscale machines, subcellular interventions, directed and multiscale self-assembling, controlled interaction between light and matter with relevance to energy conversion, and exploiting quantum control. Nano-bio-info and cognitive sciences convergence will play an increased role in this generation. In nanomedicine, one would include nanoscale genetic therapies, cell ageing therapies, and nanoscale controlled stem cell therapies. In nanoelectronics, one would envision molecular and supramolecular components ''by design'' as modular components for transistors. Examples of potential high risk products are: molecular devices 'by design', molecules with atomic design, large nano-bio or hybrid systems with emerging functions, evolutionary cells and self-replication of large nanostructured systems. Several potentially higher risk areas are: neuromorphic engineering, complex systems, molecular nanosystems used for manufacturing and product processing, and human–machine interface.

Governance and risk governance of nanotechnology

Governance includes the processes, conventions and institutions that determine:

- How power is exercised in view of managing resources and interests;
- How important decisions are made and conflicts resolved; and
- How various stakeholders are accorded participation in these processes;

In the most common current usage of the term, ''Governance'' is seen as implying a move away from the previous *government* approach (a top-down legislative approach which attempts to regulate the behaviour of people and institutions in quite detailed and compartmentalised ways) to *governance* (which attempts to set the parameters of the system within which people and institutions behave so that self-regulation achieves the desired outcomes), or put more simply, the replacement of traditional ''powers over'' with contextual ''powers to''. In such a system, permeable and flexible system boundaries facilitate communication and support the achievement of higher level goals, while the government role will continue in this context. These assumptions underline the switch from *government* alone to *governance* in debates about the modernisation of policy systems implying a transition from constraining to enabling types of policy or regulation (i.e. from ''sticks'' to ''carrots'') (Lyall and Tait, 2005).

Risk governance includes the totality of actors, rules, conventions, processes, and mechanisms concerned with how relevant risk information is collected, analysed and communicated and management decisions are taken. Risk governance:

- Encompasses all the risk-relevant decisions and actions;

- Is of particular importance in situations where the nature of the risk requires the collaboration and coordination between various stakeholders (no single decision-making authority available);
- Calls for the consideration of contextual factors such as: (a) institutional arrangements (e.g. regulatory and legal framework and coordination mechanisms such as markets, incentives or self-imposed norms); and (b) socio-political culture and perceptions.

Governance and risk governance are important concepts for assessing and managing the implications of nanotechnology which looks set to become the next focus for heated debate about the relationship between new technologies, risk and sustainability (ETC Group, 2003; Burke, 2003). On one hand, it promises smaller, lighter and faster devices using fewer raw materials and consuming less energy (Roco and Bainbridge, 2001). On the other hand, as the media hype surrounding the Prince of Wales' intervention in May 2003 has shown, there is genuine alarm about the disruptive potential of interventions at the nanoscale (Oliver, 2003; Porritt, 2003). The Prince is just the latest in a series of commentators to express fears about self-replicating nanomachines capable of smothering the world in 'grey goo' (Joy, 2000; Porritt, 2003, or for a current fictional account, Crichton, 2002). These concerns about nanotechnology resonate with long-standing social science analysis of technology running 'out of control' (Winner, 1977). Along with the relatively low levels of information about nanotechnology available, and the low public trust in industry and government (Macoubrie, 2005), these factors are leading to an increasing risk of poor public perception. A particular concern is that *insufficient formal and informal education* will result in the misuse or inefficient application of nanotechnology. Education and training is a relatively long-term process that cannot be addressed by shorter term activities such as 'public relation' outreach.

A survey on current risk governance activities (Part A: The Role of government) in eleven economies and nanotechnology R&D in 27 economies has been published by the IRGC (Roco and Litten, 2005).

Deficits of the risk governance system for nanotechnology today

Types of deficits

The main deficit of risk governance for the first generation of passive nanostructures (nanoparticles, coatings, nanostructured materials) is the relatively low level of knowledge of the new properties and functions on toxicity and bioaccumulation, limited understanding of the nanomaterials exposure rates, and the gaps in the regulatory systems at the national and global levels.

The main deficit for the following generations (2nd to 4th) of nanoproducts (including active nanodevices, nano-bio applications, and nanosystems) is the uncertain/unknown evolution of the technology and human effects (for example, health, changes at birth, brain understanding and cognitive issues and human evolution), as well as a framework through which organisations and policies can address such uncertainties. More specifically, the following potential gaps can be identified:

- At this point in time the presence and characteristics of nanomaterials in the work place and in the environment are *measured and assessed* below optimal level. Some hazards and exposures are well under control, while others have not found the necessary attention (this deficit is dominant for the first and second generation). For example, there is no established system to monitor *in situ* nanoparticles in air, water, soil or biosystems. There is a need for metrology specific for nanoscale measurements for various nanoparticle delivery methods, both in the environment (particularly for ecotoxicity) and in medical fields (particularly for toxicity). Categorisation methods based on nanoparticle properties are not yet available in the pre-assessment phase where data has to be obtained for a range of nanoparticle sizes. Currently one has to scale down the complexity into manageable pieces using techniques such as decision trees. The existing risk assessment procedures and regulatory measures must be re-evaluated for nanoparticles.
- *Knowledge in EHS and sustainability* including quantification of hazards, exposures and risk

assessment (this deficit is dominant for the first generation). These are essential elements of governance processes for nanotechnology.

- There is a *relatively fragmented governmental institutional structure and legal authority* supporting risk governance of nanotechnology, with gaps and overlaps in the regulatory systems at the national and global levels (this deficit is true for all generations). For example, use of animal testing varies by country. End-of-pipe solutions concerning risk governance should be complemented with practices to *improve the 'behaviour' and responsibility (liability) of the different stakeholders* in the process of innovation. Civil organisations are asking that the *testing of nanomaterials be undertaken preferably by independent partners with greater transparency, and that the test results are disclosed.*
- The *simple cause-effect approach for single events* should be replaced by a proactive, *corrective approach with adaptive management for a system* which is disturbed by given events (Roco, 2005b). For example, the current environmental protection agencies regulations for ultrafine particles in air refer only to one measuring event. The life cycle, multiple nanoparticle interactions in the atmosphere, the effect of bioorganisms and the persistence of particles in the system are not considered. This is particularly necessary for nanotechnology applications belonging to the second to fourth generation.
- *The long-term effects on human development* are not well addressed, in part because of the limited scenarios available for the second to fourth generations of nanoproducts (relating to the third and fourth generation). For example, it is difficult to evaluate changes in human cognition as a result of understanding the brain nanostructure and applying nanomedicine. In another example, it is difficult to evaluate changes in life expectancy as a result of artificial tissues and organs generated using nanotechnology.
- A major deficit of nanotechnology risk governance today is the *weak 'coordination' of nanotechnology safety issues between the different actors and stakeholders*: science, industry, consumers, government regulators, civil society, and international bodies. For example, there is a gap between regulatory provisions, areas of relevance, and different standards for the same product. The US agencies generally regulate products, while in the EC the main regulations are on the process. There is an underdeveloped science/policy interface for nanotechnology which creates a communication gap between nanotechnology scientists, engineers and political decision makers. This deficit is true for all generations.
- *Knowledge of nanotechnology implications by specialists and general knowledge of nanotechnology by the general public* are limited in comparison to the rapid development of nanotechnology knowledge. The effectiveness of public debate of nanotechnology may depend on reducing this gap earlier. This deficit is true for all generations.
- There are *proportionally lower resources* for risk governance in the total R&D budgets as compared to the higher level of perceived needs. Also, there is relatively low human capital available to address those issues. Research and education, which supports safety and risk assessment, should be better focused and levels increased. There are no published methodologies or standardised risk assessment tools (CBAN, 2006). Current risk assessment tools may not be suitable for nano-sized materials due to toxicity and exposure unknowns. There is limited information on nano-sized particle behaviour in gas and fluid streams in environment, working place and biosystems. Exposure routes are not fully understood. This deficit is true for all generations.
- *Regulatory uncertainty is hampering industrial innovation,* particularly for small enterprises. There is an opportunity risk for the industrial sector in not developing nanotechnology products because of some concerns regarding future regulation. The inability to estimate the true risk profile of companies dealing with nanotechnology is resulting in a deficit in the risk transfer mechanism through insurance (Hett, 2004). This deficit is true for the second to fourth generations.
- *Cognitive deficit*: bias in cognitive processes may affect risk governance. Examples are: status quo bias, overconfidence bias (people's overestimation of the degree of control over their environment and other people), and false consensus

(seeking out opinions that confirm our beliefs and hypothesis) (Slovic, 1992; Roxburgh, 2003). Differences in perception affect public trust (one needs realism rather than excessive optimist or pessimism). This deficit is true for all generations but in particular is important for the third and fourth generations.

- The use of nanotechnology for *potentially new weapons* is a sensitive issue because of its secrecy, broad spectrum of possible applications, and unexpected consequences.
- *The international agreements on nanotechnology are not sufficiently focused on broader issues of interest to humanity* such as resources (water, energy, and food) and the environment. This deficit is particularly relevant for the third and fourth generations. *International trade activities* related to nanotechnology are not well established in key areas such as crossing national borders, export control, dual civil-military use, and the movement of experts and students (UNIDO, 2005). There is a gap in levels of control and power between those countries who are promoting nanotechnology, those who are implementing it, and those who will be impact by it (the latter of which do not have the infrastructure of the other two groups to efficiently respond to technological development). For example, the introduction of nanotechnology products in developing countries and the reduced or increased use of special metals may impact on commodity dependent developing countries (ETC Group, 2005). There is *no international framework with which* to address risk governance of nanotechnology at a global level and to provide consistency in areas such as reciprocal recognition of specific tests and regulations. This deficit is true for all generations.

Several of the gaps identified above are similar to other emerging technologies, and must be evaluated in the common context.

While the international benchmarking performed in over 20 countries in 1997–1999 (Siegel et al., 1999) provided seeds for the formation of an international nanotechnology expert community, the policies and regulatory frameworks of various countries have remained fragmented until today. An international call for addressing global challenges in nanotechnology research (Roco, 2001), and for addressing societal dimensions of nanotechnology at the international level (Roco, 2003), have all contributed to the collaborative development of nanotechnology, but have had a relatively limited effect on nanotechnology governance efforts and the harmonisation of risk governance methods and structures. An APEC study (Tegart et al., 2001) raised the issue of the opportunities for developing countries as early as 2001. However, given these opportunities there is also the danger that necessary precautions are not being taken in order to become the first one to grasp them. Nevertheless, this problem is beginning to be recognised and in June of 2004, the first broad international dialogue on responsible nanotechnology R&D brought together government leaders of national efforts from 25 countries and the European Community (Meridian Institute, 2004). The 2004 Dialogue yielded a set of principles, structured priorities, and recommended mechanisms for interaction and cooperation, including sharing data on environmental, health and safety issues. The follow-up meeting was hosted by the EC in July 2005 and the third Dialogue will be held in Japan in 2006.

As much as these new risks need to be addressed by science and risk managers alike, one should be aware that unintended consequences cannot be avoided particularly in a new technology reaching at the foundation of life and touching upon fundamental materials properties. A special category is caused by unexpected events for which it is difficult to calculate probabilities and which have surprise effects (so-called 'wildcards', Rejeski, 2005). Such events may be intrinsic to the technology (such as malfunctioning of the equipment leading to new properties for nanostructures, or accidental release into the environment), or may be caused by external events (for instance, a natural disaster such as an earthquake, or a media event leading to a risky public perception).

Knowledge gap in evaluating impacts on environment, health, and safety

Current national and international governance systems reflect learned knowledge and experience developed in the research and practice of bulk and micro technology. It is as yet unknown whether the novel risk characteristics of nanotechnology applications can be adequately managed within

these governance systems. The gap in knowledge is being addressed to some extent at national level through the accumulation of available data for the potential redrafting of legislation for substances with new characteristics e.g. the National Toxicology Program in the US (National Toxicology Program, 2005). However, there is a clear need for an international organisation to collect the information available worldwide; and to consider high-quality, globally applicable governance approaches to current and future potential risks.

The potential for risk has been widely considered, as has the potential for future applications. However, the lack or scarcity of quantitative data – and the fact that risks are as yet complex, uncertain and ambiguous – results in a largely qualitative assessment of risk based on expert elicitation. Risk perception is also subject to extensive ambiguity. There is a general convergence of views on the short-term potential benefits to humankind e.g. innovative cancer therapies, which become more contested when considering long term 'benefits' such as longevity and birth modification. Perception of the risks attached to these applications is still more mixed as the more 'risky' applications are a long way from the product market.

Current applications, such as suntan lotion and self-cleaning windows, contain passive nanostructures and although they do not have the potential to transform society may have unknown consequences, e.g. being able to enter the blood stream through the skin or enter the environment when washed off. The near-future 'active' applications and more long-term higher risk applications have been largely considered hypothetically and there is extensive divergence in the assessment considering both the potential for risk and significance for human health and the environment. For example, the ability for nanoscale structures to cross the blood-brain barrier can be considered to be of extremely high significance as this barrier is impenetrable to most substances and therefore little is known of the potential effects. However, an alternative view is that this ability is a benefit which could aid neural diseases such as Alzheimer's, and to exercise too much precaution over unknown effects would pose an even greater risk to society (Wildavsky, 1990). There is a knowledge gap between what we need to know – especially concerning near-future 'active' applications and more long-term higher risk applications – and what we currently have available to us. Many applications are in the market now and some may be in the market within the next five years, and it is essential that scenario planning of potential levels of hazard and routes of exposure should be commenced. A prudent judgment can then be made of what governance structures and systems need to be in place should a particular scenario occur.

Societal infrastructure deficit

The current regulatory measures generally deal with a single event, cause-and-effect, and do not consider the life cycle of products, secondary effects and interactions with other events. The regulatory organisations and measures are fragmented from the area of jurisdiction, type of regulation (product, process, etc.), intervention levels, and national and international harmonisation of assessment and management procedures. An integrated governance approach for anticipatory and corrective measures is, however, necessary for an emerging technology that will have trans-boundary and global implications. The international collaboration deficit highlights the need for more aligned global infrastructural initiatives and harmonised risk regulations. Other deficits are in approaches for education and dissemination of knowledge, in gaps in the regulatory environment within a country and between countries, and in gaps between the portfolio of products and portfolio of waste disposal regulations.

Communication and engagement deficit

The public does not currently have a strong awareness of the nature and potential benefits and risks of nanotechnology. However this is likely to change rapidly as more products enter the market and the media becomes more active in publishing the applications and potential risks to a wider audience. Public awareness of risk tends to be higher if it is felt that individuals or societal institutions are not able to exercise personal or institutional control over it (e.g. lack of labelling on products containing an engineered nanostructure), if the technology is stigmatised (e.g. uncertain scientific knowledge and media hype); and if insufficient information is communicated to them concerning how risks are and can be controlled

(IRGC, 2005). It is therefore essential that the potential for risks and the governance systems being put in place to deal with these potential risks are communicated to the public as soon as possible. Trust between governments, businesses, academics, international organisations and the public needs to be enhanced though open dialogue and public involvement. As trust is highly related to the perception of performance and institutional agency, governance structures need to develop adaptable and flexible approaches to the governance of nanotechnology so that the benefits can be harnessed and unavoidable risks mitigated. The patience of the public may also be short while waiting for the new nanoproducts: the production of revolutionary new products typically takes over 10 years from the discovery.

Role for the IRGC

Governments and industry around the world are searching for the best governance practices; assessment and management models. EU, US, Japan and other countries are already discussing together with over twenty other countries modalities of international collaboration for safe development of nanotechnology (see Meridian Institute, 2004). Yet these activities have not been focused on risk governance and several barriers have been noted. These barriers are partly due to the fear that international cooperation may be dominated by a few powerful countries, and partly due to the promise of reaping high economic benefit for being first in a market with high profit expectations. There is therefore a niche for an independent, international and multi-disciplinary organisation such as IRGC to contribute to the development of policy and regulations on nanotechnology. IRGC has identified a governance gap between the requirements pertaining to the micro- rather than the macro- technologies. The novel attributes of nanotechnology demand different routes for risk-benefit assessment, appraisal of concerns and risk management. At present, nanotechnology innovation proceeds ahead of the policy and regulatory environment. In the shorter term, the governance gap is relevant for passive nanostructures that are currently in production and have high exposure rates; and for the 'active' nanoscale structures and nanosystems, which society can expect to be on the market in the near future. It is essential that advice and recommendations are provided to governments, businesses, scientific communities and international organisations in order that public awareness is stimulated by trust through open dialogue and action, rather than media hype and stigmatisation.

A candidate for looking at risk governance issues is the risk governance framework developed by the International Risk Governance Council (IRGC, 2005) that provides an orientation for developing a best practice approach to risk governance for emerging technologies.

The IRGC risk governance framework and its specifics for nanotechnology

Purpose of the IRGC approach

The IRGC framework puts forward an integrated concept for risk governance that provides guidance for the development of comprehensive assessment and management strategies to cope with risks, in particular emerging risks at the global level. The framework integrates scientific, economic, social and cultural aspects and includes the effective engagement of stakeholders (IRGC, 2005). The concept of risk governance comprises a broad picture of risk: not only does it include what has been termed 'risk management' or 'risk analysis', it also looks at how risk-related decision-making unfolds when a range of actors are involved, requiring coordination and possibly reconciliation between a profusion of roles, perspectives, goals and activities. The IRGC framework offers two major innovations to the risk field: the inclusion of the societal context and a new categorisation of risk-related knowledge.

The application of the IRGC framework to the risk governance of nanotechnology has resulted in two novel approaches: the categorisation of nanotechnology products and processes into four generations, and the use of two frames to evaluate the immediate and the future implications of evolving generation of nanotechnology applications.

Inclusion of the societal context: Besides the generic elements of risk assessment, risk management and risk communication, the framework gives equal importance to contextual aspects which, either are directly integrated in a model risk

process comprising the above as well as additional elements or, otherwise form the basic conditions for making any risk-related decision. Contextual aspects of the first category include the structure and interplay of the different actors dealing with risks, how these actors may differently perceive the risks and what concerns they have regarding their likely consequences. Examples of the second category include the policy-making or regulatory style as well as the socio-political impacts prevalent within the entities and institutions having a role in the risk process, their organisational imperatives and the capacity needed for effective risk governance. Linking the context with risk governance, the framework reflects the important role of risk-benefit evaluation and the need for resolving risk–risk trade-offs (what are risk–risk-trade-offs?). Consideration of societal and cultural context in nanotechnology governance is essential because of the broad implications of the new technology on society (Roco, 2003). The inclusion of social implications should be done using expertise specific for new sciences such as nanoscience (Collins and Evans, 2002). Also, consideration should be given to the power relationships that are at work in society, and the sources of power and ''levers'' of power that different groups use to pursue their interests and objectives.

Categorisation of risk-related knowledge: The framework also proposes a categorisation of risk which is based on the different states of knowledge about each particular risk, distinguishing between 'simple', 'complex', 'uncertain' and 'ambiguous' risk problems.

- *Simple risk* refers to products where there is a clear cause and effect connection to behaviour of materials and their implications.
- *Complexity* refers to the difficulty of identifying and quantifying causal links between a multitude of potential causal agents and specific observed effects in a system or a system component. The nature of this difficulty may be traced back to interactive effects among these agents (synergism and antagonisms), long delay periods between cause and effect, inter-individual variation, intervening variables, and others. Scientists and technologists have still insufficient knowledge about the cause-effect chains regarding technological developments as well as their possible impacts in the various areas of nanotechnology applications. However, understanding the characteristics of a complex system component rather than the entire system may still be sufficient for designing risk management measures that are able to reduce or control risks that pertain to the entire system.
- *Uncertainty*. In the context of technological systems and their impacts, human knowledge is always incomplete and selective and thus contingent on uncertain assumptions, assertions and predictions (Functowicz and Ravetz, 1993; Ravetz 1999). It is obvious that the modelled probability distributions within a numerical relational system can only represent an approximation of the empirical relational system with which to understand and predict uncertain events. It therefore seems prudent to include other, additional, aspects of uncertainty such as variability of impacted individuals and organisations, strategic responses to opportunities, system boundaries in modelling effects and plain ignorance (Morgan and Henrion, 1990; van Asselt, 2000, pp. 93–138). All these different elements have one feature in common: they reduce the strength of confidence in the estimated cause and effect chain. If uncertainty plays a large role, and in particular the factors of system boundaries and ignorance, the estimation of technological impacts becomes fuzzy. The evolution of an active nanostructure may be typically uncertain within a given system. Uncertainty can often be addressed by collecting new data, developing better assessment models, and by singling out discrete cause-effect chains and the system components from the system as a whole.
- *Ambiguity* may be a misleading because it has different connotations in everyday English language. In the context of nanotechnology, it includes two aspects. Firstly, it denotes the variability of (reasonable) interpretations based on identical observations or assessments. What does it mean if, for example, nano-particles are able to penetrate brain tissues but do not cause any observable harm? Can this be interpreted as an adverse effect or is it just a bodily response without any health implications? Secondly, it denotes the variability of normative evaluation with respect to the tolerability or acceptability of observed effects on a given value or norm. Many scientific disputes do not refer to

differences in methodology, measurements or dose-response functions, but to the question of whether the observed or assumed impacts violate or meet predefined values. Often it is also contested which values are (will be) actually of issue or are (will be) subjected to discussion and how essential these values are and for which groups. High complexity and uncertainty favour the emergence of ambiguity, but there are also quite a few simple and highly probable risks that can cause controversy and thus ambiguity.

The first three categories (simple/complex/uncertain) relate to the properties of our knowledge about nanostructures being able to generate specific hazards, while ''ambiguity'' is a property of knowledge about human responses to the hazard. For all risk generating nanoproducts we will have to consider the degree of complexity (simply to highly complex) and uncertainty (from certain to highly uncertain). Ambiguity as a property of the public response can be overlaid on any of the other two categories, and when this happens it changes dramatically the approach to dealing with the risk issues involved.

Turning to the field of nanotechnology, risk-related knowledge can be characterised currently as complex for passive nanostructures with new properties and functions, uncertain for active nanostructures and nanosystems, and ambiguous for large nanostructured systems and molecular nanosystems, although these categories could change as knowledge and public perception evolve further. Because nanotechnology development is an open, complex system, a suitable approach is using adaptive, corrective measures on the system instead of adopting simple cause- and effective measures for individual activities. The complexity, uncertainty and ambiguity dimensions interact in the domain of nanotechnology. Many diverse actors are dealing with this technology. On the one side, there are the promoters, producers and embedders of nanoscience and nanotechnology (scientists, technologists, technology assessment experts and administrative promoters) also called 'insiders' (Garud and Ahlstrom, 1997) or 'enactors' (Rip, 2002, 2004a, b). There are, further, interested organisations, pressure groups, individual consumers and citizens, public authorities at the demand side, also called 'outsiders' or 'comparative selectors'. The diversity of the involved actors inevitably makes innovation in the domain of nanotechnology a social learning process (Tait & Williams, 1999; Williams & Russell, 2002).

The framework's risk process, or risk handling chain is illustrated in Figure 2. It breaks down into three main phases: 'pre-assessment', 'appraisal', and 'management'. The appraisal step includes traditional risk assessment and the novel element of concern assessment. Both elements of the appraisal process are directed towards the best scientific analysis of physical impacts as well as the social impacts that one can expect from the application of the technologies in question. An interim phase, comprising the 'characterisation' and 'evaluation' of risk, is placed between the appraisal and management phases and, depending on whether those charged with the assessment or those responsible for management are better equipped to perform the associated tasks, can be assigned to either of them – thus concluding the appraisal phase or marking the start of the management phase. Risk evaluation refers to the judgment of tolerability or acceptability of a given risk. The risk process has 'communication' as a companion to all phases of addressing and handling risk and is itself of a cyclical nature. However, the clear sequence of phases and steps offered by this process is primarily a logical and functional one and will not always correspond to reality.

For nanotechnology, there are significant differences between various areas of relevance and between the four generations of nanotechnology products. A critical aspect is knowledge development for the field. A major challenge is that decisions and implementation actions (for R&D, infrastructure investments and regulations) need to be done before most of the processes and products of nanotechnology are known.

The following sections will follow the risk governance framework step by step and explain in which way the framework could help to establish more effective and publicly responsive governance structures for dealing with potential nanotechnology applications in terms of risks and benefits.

Pre-assessment: two frames for nanotechnology risk debates

The IRGC framework addresses wider governance issues pertinent to the context of a risk and the

overall risk process, thus acknowledging the many different pathways that different countries or risk communities may pursue for dealing with risk. Pre-assessment builds on the observation that collective decisions about risks are the outcome of a 'mosaic' of interactions between governmental or administrative actors, science communities, corporate actors and actors from civil society at large. Many interactions are relevant to only same parts of the process. The interplay of these actors includes public participation, stakeholder involvement and the formal (horizontal and vertical) structures within which it occurs.

A systematic review of potential benefits and risks of an emerging technology needs to start with an analysis of what major societal actors, such as, governments, companies, the scientific community, NGOs and the general public defines as areas of concern or impacts that they will label as risk problems (rather than opportunities or innovation potentials, etc.). In technical terms this is called 'framing'. Framing in this context encompasses the selection and interpretation of phenomena as relevant risk topics (Tversky & Kahneman, 1981; Van der Sluijs et al., 2003; Goodwin & Wright, 2004). With respect to nanotechnology we have identified two major frames under which the risks have been discussed in the present debate:

- *Frame 1.* The context of classic technology assessment looking into the impacts derived from the application of nanoparticles and other passive nanostructured materials in different areas of application (such as paint, cosmetics, food, and coatings). This frame is most suitable for issues related to the first generation of nanoproducts (passive nanostructures, Figure 3). The property or behaviour of some passive nanostructures may be complex, typically for system components. Depending on the

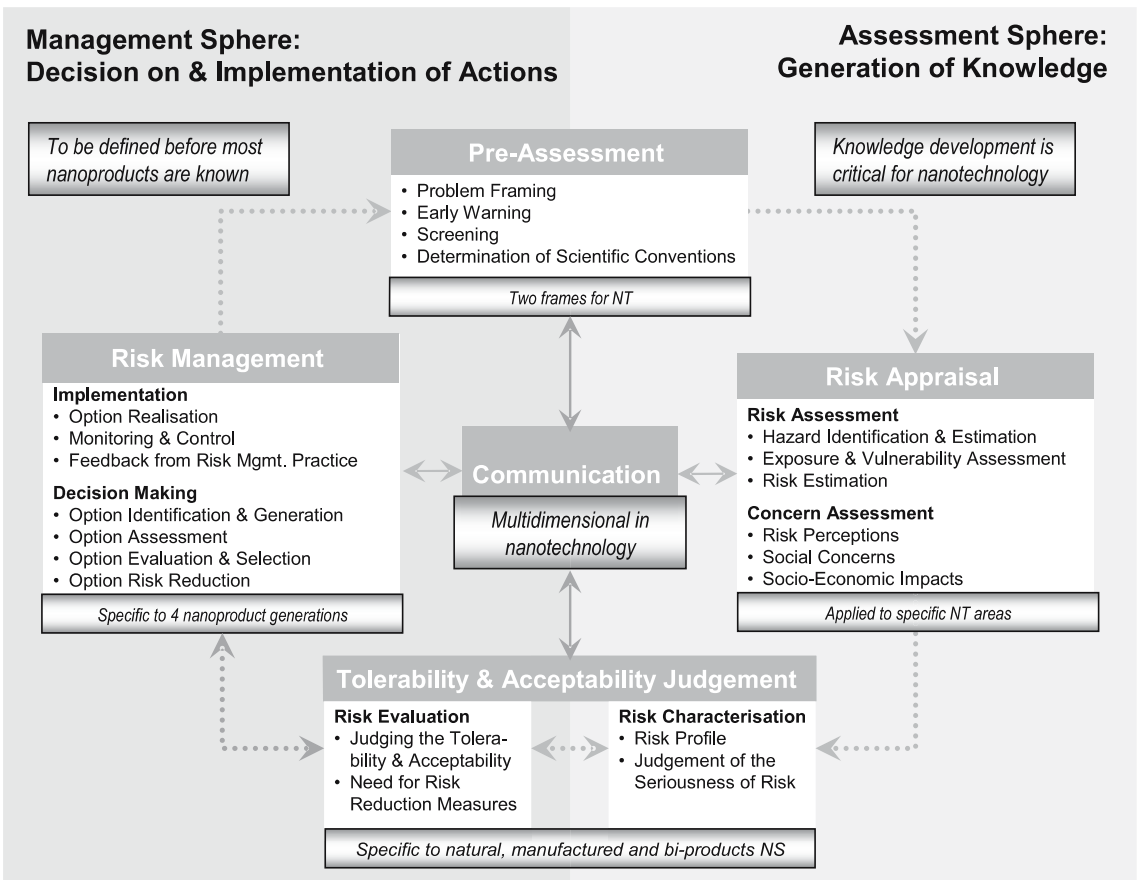

Figure 2. Steps in IRGC risk assessment and management framework for nanotechnology (NT); NS denotes nanostructures.

application there will also be more or less uncertainty when predicting positive or negative impacts for the economy, environment and society.

- *Frame 2*. The context of social desirability of innovations looking into processes of modernisation, changes in the interface between humans and machines/products and ethical issues of the boundaries of intervention into the environment and the human body. This frame addresses better the issues related to the future generations of nanoproducts (active nanostructures and nanosystems, Figure 3) and long-term implications of nanotechnology (Roco, 2004a). The behaviour of active nanostructures and systems typically changes in time and is complex: it may be uncertain for many system components and tends to be uncertain for the system as a whole (at least from today's perspective). Frame 2 is more likely to be associated with higher degrees of ambiguity by considering current knowledge and perspective on nanotechnology.

The context for Frame 1 (see Figure 4) is focused on complexity within system components where the passive nanostructures are applied. There is a scientific debate on the implications of the novel aspects of nanoparticles on human health and the environment. The major actors here are scientific communities, product and process developers, governmental bodies and local institutions including regulatory agencies, NGOs, ad hoc commissions, and technology assessment institutes. The goal of this frame is to understand and recognise potential health risks before they materialise in larger quantity. The evidence in this debate relates to toxicological experiments, simulation and monitoring of actual exposure. A major conflict lies in the question of how much precaution is necessary when applying these nanoparticles. Several NGOs advocate a very precautionary approach by which application is restricted to highly investigated products while others, such as most industries, favour a slow penetration approach combing plausibility checks (do we expect anything more serious than what we have already?) combined with constant monitoring.

The flowchart in Figure 4 suggests that the main steps in the research and regulation of nanomaterials implications once released either in the environment or at the working place. The implications affect people, biosphere and surrounding infrastructure. The risk governance should ensure safety in all those areas of the outlined close loop.

The context for Frame 2 (see Figure 5) is more complicated. Component complexity is increasing and the dynamic behaviour and multifunctionality of the nanostructure may lead to uncertainty within the respective system. It is also directed towards ambiguity. The main argument is that

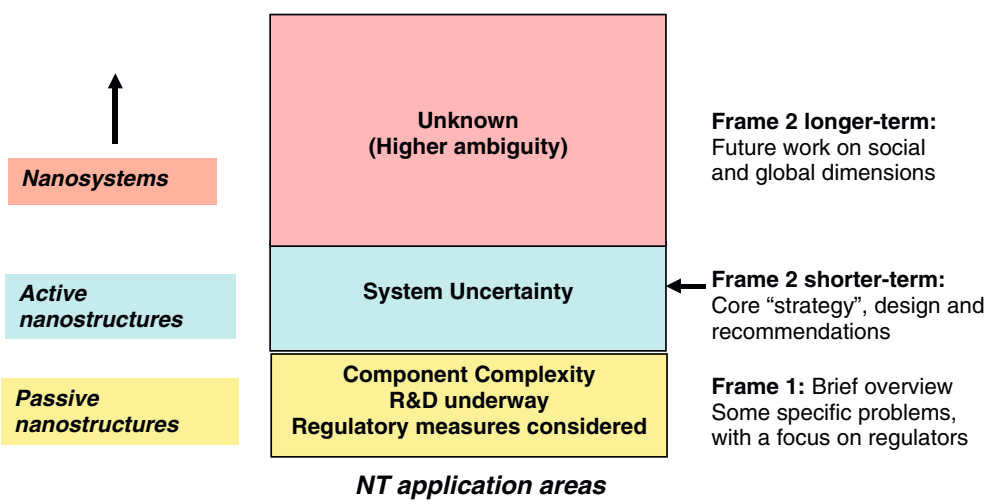

Figure 3. Strategies as a function of the generation of nanoproducts: Application to Frame 1 and Frame 2.

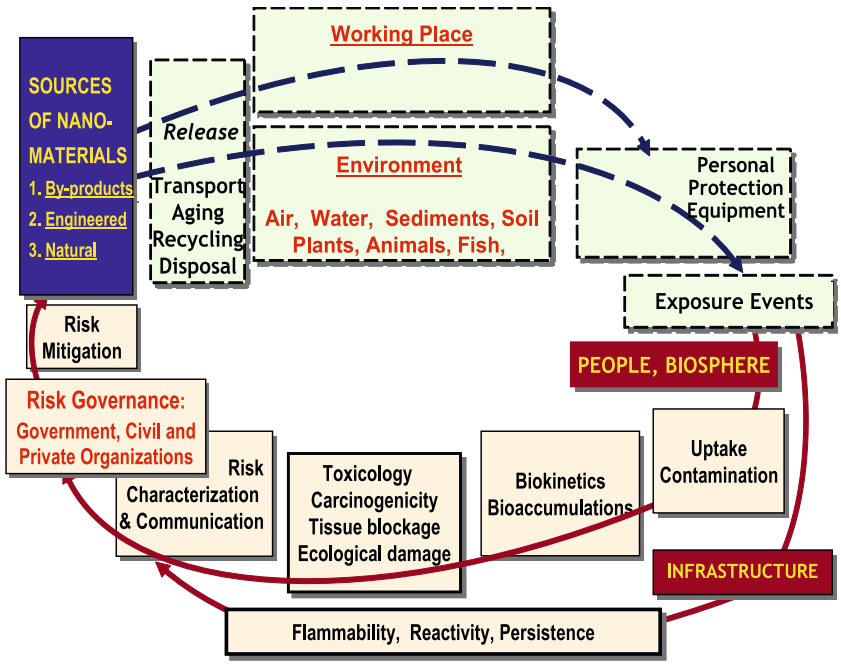

Figure 4. Environmental, health and safety (EHS) research and regulatory for nanomaterials (Frame 1): key physico-biological processes and decision steps during the life-cycle of nanomaterials released either in the environment or at the working place (modified from Roco (2005b)).

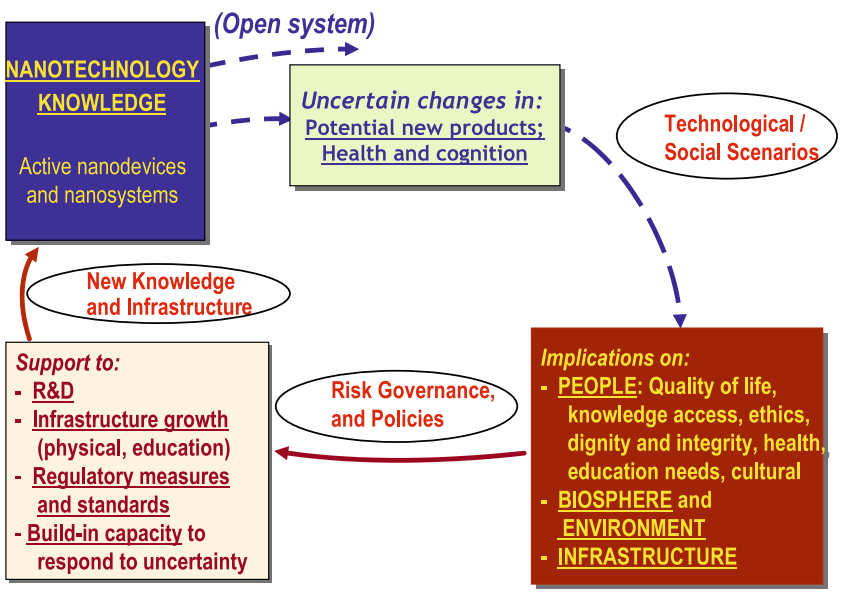

Figure 5. Risk governance for active nanostructures and nanosystems (Frame 2): key decision processes in the open loop approach (modified from Roco (2005b)).

nanotechnology represents a new class of processes and applications that may threaten human identity; speed up the pace of modernisation beyond the speed that human societies can cope with; and transform our environment into directions that nobody can realistically predict. This debate, focusing on what is desirable, leads different actors to assess technological trajectories on criteria that had not previously been considered. Inversely, discussions about what can be technologically possible can steer the formation of judgements about desirable societal changes (Grin et al., 1997; Grin and Grunwald, 1999; Grin, 2004; Goorden, 2003). The debate on nanotechnology seems to pursue both directions. On one hand, new applications and future visions of the technology provoke new ideas and reflections about human identity and the mind, while, on the other hand, new ethical considerations about sustainability direct nanotechnology research into applications that were not originally pursued by the engineering community.

The flowchart in Figure 5 suggests that the 'open system' loop begins with nanotechnology knowledge creation leading to new products, health and cognition developments. By using scientific, technological and social scenarios one may estimate the long-term potential implications on people, biosphere and surrounding infrastructure. On this basis, risk governance and public policies could be formulated which address the further development of nanotechnology and evaluate its risks. In turn, this may lead to new R&D programmes, infrastructure growth, suitable regulatory measures and standards, and institutional capacity to respond to uncertainty. The new knowledge created to lead to new outcomes is generally different from the previous cycle (''open system'').

Ethical implications of nanotechnology development on risk governance are particularly important for frame 2. Stakeholders must achieve understanding and engage issues of ethical and social responsibility with regard to individuals and affected institutions. Societal implications of distribution of benefits and unexpected consequences of the new technology may create tensions if not properly addressed (Baumgartner et al., 2003; Weil, 2003).

The concern of frame 2 is therefore characterised by a mixture of beliefs, values and visions that are not exclusively linked to nanotechnology but are, at least partially, associated with it. This frame is shared by many cultural opinion leaders, religious groups, parts of the humanities and social sciences, and often individuals who are disappointed with the direction of technological and social change. Traditional impact assessment or risk analysis will have no bearing on the arguments that are exchanged in this debate (Tait, 2001). The evidence that is part of this debate refers to narratives that show plausible (or implausible) links between social and perception threats and combination of technologies including nanotechnology. Examples are neurochips to be implanted in the human brain, nanomachines used in warfare, plants with biochips, and other ''futuristic'' applications. The main message is: 'Stop this process before it is too late'.

It is important in the pre-assessment phase and beyond to distinguish these two very different frames, 1 and 2, and understand the linkage between them. Each frame demands very different forms of handling and appraisal. In particular, the selection of management strategies needs to be adapted to the characteristics of the frame. At the same time, an incident in frame 1 (for example, accidental exposure leading to a visible health impact) may serve as a promoter for transmitting the concerns to frame 2 (same may be true from frame 2 to frame 1) assuring the attention of a larger audience. It may trigger a chain reaction starting with a given health event, leading further to the image that modern societies cannot even deal with simple health hazards and cumulating in the conviction that humans should refrain from such complex technologies since they cannot control them. An additional risk challenge is the effect of occasionally occurring hazards.

The other areas of pre-assessment are close related to the issue of framing. Early warning signals can be assigned to watching potential impacts of nanoparticles and/or watching the societal debate and the evolution of concerns with respect to the ambiguity of the nanotechnology applications. Depending on the dominant frame, the third step ''pre-screening'' is also affected. The risks of nanoparticles will be allocated to the classic risk assessment and management route. The second frame looking into societal and ethical implications and into nanotech's role in a technological culture requires risk analysts to focus on the concern assessment route with a strong participatory ele-

ment. Evaluating the acceptability of nanotechnology as a promoter of modernisation cannot be done on technical, medical and ecological criteria alone. Here social, cultural, religious and ethical views need to be included and integrated. Finally, the scientific conventions (fourth step in pre-assessment) also depend on the respective reference frame. The usual toxicological and epidemiological methods need to be applied in the first frame, scientific methods of concern analysis, empirical attitude and value research, and ethical reasoning are more appropriate for the second frame (Roco and Bainbridge, 2003, 2005, EC, 2004).

Structuring risk governance into the two frames is important to enable the development of critical knowledge for effective risk management. If they are not decoupled, it will impede the generation of targeted data for improved risk management of Frame 1 nanomaterials. Meeting the research needs required for Frame 1 necessitates an approach that is based on classic and modified research instruments and requires cooperation among technical, medical and ecological disciplines. The research scope can be contained to established technology assessment procedures. So, timely and reliable results can be expected. The need for further research and assessments does not interfere with the present speed of diffusion. Research for Frame 2 questions, however, require a more holistic and transdisciplinary approach. This includes a strong social science involvement, the incorporation of stakeholder preferences, and intense reflections by legal and ethical scholars. It should be avoided to have the two frames mixed because they rely on different research and decision making pathways.

Risk assessment

The assessment process in the IRGC framework (see Figure 2) consists of two parts: risk assessment and concern assessment. They fit well the dualism of frame 1 and frame 2 that have been discussed above. The first assessment step covers the usual steps of:

- Hazard identification and estimation
- Exposure and vulnerability assessment
- Risk estimation
- Conclusion on major challenge for risk assessment applied to specific nanotechnology areas (categorisation of risk with regard to degree and cause of complexity, uncertainty and/or ambiguity).

As explained in the first section 'Background' of this paper, nanostructures and particularly nanoparticles not only exhibit new properties which one can make use of in many industrial and pharmaceutical applications, but also there is already evidence that these chemical, physical, and biological properties may have possibly harmful consequences for human health, nature and environment. However, the existence of anthropogenic and natural nanoparticles has been known to science for a long time; certain nanoparticles have been characterised and their effects are well established in the scientific literature. In spite of this limited knowledge, one can predict that the development and use of the first generation of nanoproducts will largely increase the variety of species of nanoparticles, their density in our human and natural environment and the probability for human beings to get into physical contact with them or to incorporate them.

In order to structure the problem for risk analysis that contains uncertainty and complexity, it was proposed using expert information and influence diagrams for the EHS effects of nanomaterials to be studied (Morgan, 2005). The following paragraphs summarise the results of the present studies on different risk categories.

How can the risks be characterised? The increased reactivity of some nanostructured materials, a size many times smaller than the human eye can see, and the new physical and chemical properties and functions of nanosystems, will result in the potential for newly emerging risks, such as, penetration into and reaction with the human body; release into and reaction with human surroundings (eg. work place, environment, and on disposal); changes in degradability and persistence in the environment; and longer term societal issues such as, social control and nanoscale-based genetic changes. These risks also have the potential to be global in nature, for instance, economic and military imbalances and widespread environmental contamination. In addition 'active' nanodevices may evolve in the environment and start self-propelling activities where they are released which may require additional risk governance management measures.

Health risks. From the beginning of the debate on nanotechnology, there has been an intense discussion on the potential risks (Wolfson, 2003). This subject has not only been debated by nanoscientists but also increasingly by representatives of the social sciences and humanities (See e.g. Roco and Bainbridge, 2001, 2005; Fogelberg and Glimell, 2003; Johannsson, 2003), by NGOs as well as by social and political institutions.

In general, free nanoparticles and other nanostructures do raise health and safety concerns. One reason is that these smaller particles have a much larger surface to mass ratio compared to the larger particles; they are likely to penetrate cells in the body and take on different structures than they would have at their larger scale. Their chemical reactivity and bio-activity may vary with particle size. The risk of accumulation in cells and toxicity depend on the exposure route, material and size (Maynard & Kuempel, 2005).

Since all of the complex relationships are not well-known it is difficult to evaluate the toxicity of novel nanoparticles coming from these new technologies. Most of the assumptions on the potential adverse health impacts come from emergence of evidence in air pollution, in the effects from the inhalation of welding fumes and extrapolation from the extensive body of knowledge on the health effects of existing micrometer sized particles. There are, however, a number of long-term studies underway which should clarify the current assumptions. One theory suggests that the finer particulate in air pollution, those in the nanoscale range, may be responsible for increasing blood coagulation, leading to increased blood viscosity and causing cardiac ischaemia. Other hypotheses include an effect on neutrophil deformity and atherosclerotic plaque progression and destabilisation.

There is also a general picture that is emerging from animal studies – that on a mass dose basis, pulmonary toxicity is enhanced when particle size is reduced from the micrometer to the nanometre range. The increase in the materials' toxicity appears to be partly linked to the increase in the particles surface area (causing a catalytic effect and generating free radicals); however, it also seems that there is a difference in toxicity, depending on the materials. That is, some materials in the nanometre range are more toxic, leaving the final verdict on a material's toxicity to a case-by-case basis – for example, single high exposure to non-fibrous, non-cytotoxic particles, like carbon black, titanium dioxide, talc, can produce transient pulmonary inflammation. Following repeated exposure, there appears to be a risk of sustained inflammation, lung damage with hypertrophy, epithelia hyperplasia and interstitial fibrosis due to overload (exceeding the capacity of the alveolar macrophage's capacity for phagoctose leading to the secretion of inflammatory mediators).

Exposure to non-fibrous, cytotoxic particles, like silica are more likely to directly affect the alveolar macrophages due to its surface area chemistry and free radical generation potential (production of oxidative stress). For example, toxicological studies have shown that low exposure to micrometer-sized particles of quartz cause severe lung inflammation, cell death, and fibrosis. It has also been shown to cause tumours in rat studies. Current thinking suggests that these effects are related to the surface of the quartz, which is reactive and generates free radicals leading to oxidative damage. Studies on exposure to coal and silicates have found that similar effects can be expected if the dose is sufficiently high causing overload, and that this relates to the total surface area of the particles inhaled. In essence, cells and organs may demonstrate toxic response even to non-toxic substances when they are exposed to high enough doses in the nano-sized range.

Concern relating to the exposure to nano-sized fibrous particles is similar to those for non-fibrous particles, in this case, pulmonary toxicity and or cytotoxicity. The history of asbestos is still fresh in our mind and there is fear that nano-sized fibres may introduce similar problems. Fibres such as those coming from carbon nanotubes could also cause a problem, not only due to their shape and dimension, but also because of their potential to be combined with iron or other metals. The addition of these metals could cause catalytic effects having free-radical-releasing pro-inflammatory properties. Current animal studies using nano-sized particles, such as titanium dioxide, barium sulphate, metallic cobalt and metallic nickel, found that metallic nickel demonstrated statistically significantly greater inflammation responses than either cobalt or titanium dioxide and that cobalt was more inflammogenic than titanium dioxide. Nickel and cobalt but not titanium dioxide caused lipid peroxidation.

There has also been some concern voiced about the possibility for nano-sized particles to translocate to liver and other organs; however this may be dependent on the differences in exposure conditions, chemical composition and particle size.

Risk of changing human condition. Development of active nanostructures and nanosystems and hybrid bio-nanostructures has raised concerns about human development risks. These include devices which interface with human tissue and nervous system, artificial organs, genetic modification, brain and body control, hybrid viruses and bacteria, as well as economical and cultural development.

Risk of explosion. Traditionally, it is known that dust explosions can occur in manufacturing sites that use fine particles of sugar, flour, animal feed and in operations that produce sawdust, organic chemicals plastics, metal powers and coal. The major factor influencing the ignition sensitivity and explosion violence of the dust cloud is the size of the particle or the total surface area per unit volume. Generally, as the particle size decreases the specific surface area increases, and the dust explosion and the ease of ignition also increases, although this effect is not linear and for some materials the effects plateaus at the smaller size range. There seems to be no lower particle size limits established below which dust explosions couldn't occur.

It may be possible that the increased surface area of nanoparticles could also increase the likelihood that they become self-charged, and ignite. Nanopowders, again, because of their large specific surfaces areas, may become highly charged in use. There is also concern that they may persist airborne longer, as well as be harder to detect. Unfortunately for now, there appears to be no data on the explosion characteristic for nanopowders, and the Health and Safety Executive of Great Britain (HSE, 2004) suggests that extrapolation of the data for larger particles to the nanosize range cannot be accurately done due to the changes in both the chemical and physical properties. The law of quantum physics comes into play at the smaller size of particles, and the behaviour of the surface starts to dominate the bulk behaviour of the material. For example, some materials that are conductors of electricity become insulators at the nanosize range.

Ecological risk. Nanomaterials may affect ecosystems through the activities surrounding their fabrication or their release into the environment during production, use or disposal. Their impact may be important because of their size, reactivity, bioaccumulation and persistence. However, one must analyse each type of application individually. Robichaud et al. (2005) have shown that the relative environmental risk during fabrication of single-walled nanotubes, bucky balls, one variety of quantum dots, alumoxane and titanium dioxide nanoparticles, was comparatively low in relation to other common manufacturing processes now in use. In another example, Oberdorster et al. (2004, 2005) found situations when nanoparticles reach the brain of living organisms. Colvin et al. (2003) have shown that surface treatment of nanoparticles may reduce or eliminate the toxic effect of some engineered nanoparticles.

What does that mean for risk assessment?. Although the steps of assessment will follow the traditional path of hazard identification and estimation, exposure and vulnerability assessment and risk estimation, the specific methods for conducting these analyses might be different from the normal toxicological routines. For example, the traditional filter and gravimetric methods used for particulates cannot be used for particles at this range, and the currently available technology is rather expensive. One method used to sample for nanoparticles is the low-pressure nano-cascade impactor, which uses five impactor plates from sizes between 10 and 100 nm. Another method uses a filter and passive sampler, however, it seems that the sample has to be sized and counted by transmission electron microscope, which makes the lab analysis rather expensive.

Concern assessment

In addition to risk assessment, the IRGC model includes a concern assessment. This is particularly important for dealing with the frame 2. What do we know about public concerns when it comes to nanotechnology?

Although nanotechnology is still an emerging field, the battle lines being drawn up around it are

analogous to those involved in earlier controversies over nuclear power, GM crops, biotechnology and mobile phone masts, and are likely to change rapidly in response to particular developments (Tait J. 2005. Private communication). Lining up on one side are those who see nanotechnology as an area of exciting potential for the economy, society and the environment. Challenging them are those who remain sceptical about the possible vested interests lying behind the science, the questionable nature of the commitments bound up in R&D processes, and the known and unknown risks that could be unleashed by its application. Since many new technologies experienced a strong public opposition after their often euphoric introduction, it is important to understand in advance potential public reactions and potential mobilisation effects by relevant social groups.

Nanotechnology and its implications have been analysed from a societal perspective (Roco and Bainbridge, 2001, 2005), and from an NGO perspective (ETC, 2003; Arnall, 2003 (for Greenpeace); Komm-paassion Group, 2005, Environmental Defence, 2005) with respect to the *ethical, legal and other social issues (ELSI)*. Furthermore, governmental organisations have established/funded technology assessments of nanotechnology. Key "society structural" risks include the regulatory environment (risks may be raised by gaps in the regulatory system), the portfolio of processes and products used in industry, and waste handling policies. Several "wildcard" risks include accidents, terrorist attacks, use of military nanoproducts (Altmann, 2006), and impact mass media products (movies, books, etc.). One of the more notable contributions to the social risk debate is a report by the ETC Group, a Canadian NGO, which hit the headlines in February 2003 with its assessment of the potential dangers of nanotechnology. Demanding a moratorium on commercialisation, the report warns of a Pandora's Box of potential hazards, ranging from "nanoparticle contamination, to grey goo and cyborgs, to the amplification of weapons of mass destruction" (ETC Group, 2003). In the same month, the UK Government's Better Regulation Taskforce called for the development of a new regulatory framework for nanotechnology, and for an early and informed dialogue between scientists and the general public about its impacts (Better Regulation Taskforce, 2003).

For improving our understanding of the likely responses of the population and particularly major NGOs, concern assessment is linked to risk perception and stakeholders concerns. It is necessary to investigate the evolving socio-cultural and political context in which research at the nanoscale is conducted, the societal needs that nanotechnology may satisfy, and the popular images that experts, politicians, and representatives of the various publics associate with nanoscience and nanotechnology. The past research on public attitudes and political mobilisation has demonstrated that the effectiveness of public protest does not depend so much on the number of people concerned about a technology but rather on the composition of the groups that are willing to act publicly in favour or against the implementation of such technologies (Hampel et al., 2000).

Public perception of technological risks depends on two sets of variables: the first set includes the well-known psychological factors such as perceived threat, familiarity, personal control options, and positive risk-benefit ratio (Slovic, 1992; Boholm 1998). The second set includes political and cultural factors such as perceived equity and justice, visions about future developments and effects on one's interests and values (Wynne, 1984; Tait, 2001; Renn, 2004a). While the first set of components can be predicted to some degree on the basis of the properties of the technology itself and the situation of its introduction, the second set is almost impossible to predict. The social, political and cultural embedding of a new technology is always contingent on situational, randomly assorted combination of circumstances that impedes any systematic approach for anticipation. Within the second evolving frame, however, the symbolic nature of nanotechnology representing fast modernisation, efficiency and artificiality, provides us with some hints of where the debate might go in the future.

Comparative qualitative studies have been conducted to investigate the *public perception of nanotechnology* (e.g. Gaskell et al., 2004), and several approaches from a broader Science, Technology and Society (STS) perspective analyse the potential social concerns and societal impacts of nanotechnology applications, e.g. Bainbridge (2002), Fogelberg and Glimell (2003), Johansson (2003), Sweeney et al. (2003), Wolfson (2003), Cobb and Macoubrie (2004), Spinardi and

Williams (2005), and Williams (2005). Looking at the empirical results in the United States and Europe so far, it is interesting to note that the concern linked to the second frame (about the science-fiction notion of self-reproducing nanorobots or other more exotic applications of nanotechnology that could harm humans directly) has been rarely found in the few surveys conducted until today (the theses of Joy, 2000, and others have not found much resonance in the public). Rather, critical remarks centre on the concern that nanotechnology would be misused by some people to harm other people, exacerbating existing social inequalities and conflicts. In contrast, most respondents associated quite a number of direct but non-specific benefits and found a number of ways to express confidence that nanotechnology would help human beings achieve legitimate goals (Bainbridge, 2002).

In order to understand the risk perception side of nanotechnology large opinion surveys are only of limited value. The main problem here is that for more than 90 percent of the respondents in European as well as US surveys the term nanotechnology has no meaning or has weak meaning and evokes educated guesses at best (Roco and Bainbridge, 2001). Even if the term is explained to the interview partners, the response is a direct reaction to the verbal stimulus and thus more an artefact of the questionnaire than a valid representation of a person's attitude. A more promising method would be to conduct focus groups in which proponents and opponents of nanotechnology would be given the opportunity to develop their arguments in front of representatives of the general public or selected groups and then ask the respondents to share their impressions and evaluations. Several of these studies are underway, partially combined with citizen juries or citizen panels, which are asked to investigate the public's preferences for regulatory actions after they have been informed about the likely impacts of nanotechnology.

A recent survey of the US public using a method of informing the participants before asking their opinion supports the general impression of an attentive public that welcomes nanotechnology as helping the economy to prosper but also has deep suspicion about industry and distrust in government (Macoubrie, 2005). The study concludes with some major findings:

- Major benefits are anticipated by the public and welcomed
- Public wants to be included in the regulatory process
- There is a lack of support for a ban on nanotechnology, but there is a high demand for effective regulation
- There is low public trust in government: participants believed the trust situation could be improved by more testing before products are approved for free distribution and by providing more unbiased information to the public
- The influence of media on public attitude formation is still low; most people have not heard about nanotechnology before
- Industry is seen with a high degree of suspicion

The report recommends that under the present low trust situation industry and regulators need to place special effort on improving transparency and including the public in regulatory decision making.

Risk characterisation

Four levels of knowledge characterisation are presented in Table 1.

Risk evaluation

Risk evaluation comprises three major steps for both frame 1 and 2:

- Scientific (evidence-based) 'risk profile' focused on risk assessment and concern assessment.
- Societal (value-based) balancing of benefits and risks (including societal needs, contribution to quality of life, contribution to sustainability, potential for substitution and compensation, policy imperatives, choice of technology, and overall risk-benefits balance).
- Conclusion on whether risk is acceptable, tolerable, unacceptable or not defined.

Corporate risk managers as well as regulatory agencies have the task to collect all of the information from the assessment processes and make a judgement about the balance between the potentially negative and positive impacts. Such a judgement cannot be made for nanotechnology as a whole although some advocates of the second frame would like governments to make such

Table 1. Risk characteristics and their implications for risk management with reference to nanotechnology

Knowledge characterisation	Management strategy	Appropriate instruments	Stakeholder participation
1 'Simple' risk problems *Frame 1: Naturally nanostructured materials, where chemical composition determines properties*	*Routine-based*: (tolerability/acceptability judgement) (risk reduction)	→ Applying 'traditional' decision-making – Risk-benefit analysis – Risk–risk trade-offs – Trial and error – Technical standards – Economic incentives – Education, labelling, information – Voluntary agreements	Instrumental discourse
2 Component complexity-induced risk problems *Frame 1: Passive nanostructures with new properties and functions for same chemical composition; 1st generation of nanoproducts*	*Risk-informed*: (risk agent and causal chain)	→ Characterising the available evidence – Expert consensus seeking tools: – Delphi or consensus conferencing – Meta analysis – Scenario construction, etc. – Results fed into routine operation	Epistemological discourse
	Robustness-focussed: (risk absorbing system)	→ Improving buffer capacity of risk target through: – Additional safety factors – Redundancy and diversity in designing safety devices – Improving coping capacity – Establishing high reliability organisations	
3 System uncertainty-induced risk problems *Frame 2: Active nanostructures and nanosystems*	*Precaution-based*: (risk agent)	→ Using hazard characteristics such as persistence, ubiquity etc. as proxies for risk estimates Tools include: – Containment – ALARA (as low as reasonably achievable) and ALARP (as low as reasonably possible) – BACT (best available control technology), etc.	Reflective discourse
	Resilience-focussed: (risk absorbing system)	→ Improving capability to cope with surprises – Diversity of means to accomplish desired benefits – Avoiding high vulnerability – Allowing for flexible responses – Preparedness for adaptation	
4 Unknown; Higher ambiguity-induced risk problems *Frame 2: Large nanosystems and molecular nanosystems*	*Discourse-based*:	→ Application of conflict resolution methods for reaching consensus or tolerance for risk evaluation results and management option selection	Participative discourse

Table 1. Risk characteristics and their implications for risk management with reference to nanotechnology

Knowledge characterisation	Management strategy	Appropriate instruments	Stakeholder participation
		– Integration of stakeholder involvement in reaching closure Emphasis on communication and social discourse	

sweeping generalisations. It is rather necessary to look at each application, collect what is known about the impacts and then delineate a judgment of acceptability or tolerability.

The term '*tolerable*' refers to an activity that is seen as worth pursuing (for the benefit it carries) yet it requires additional efforts for risk reduction within reasonable limits. The term '*acceptable*' refers to an activity where the remaining risks are so low that additional efforts for risk reduction are not seen as necessary. If tolerability and acceptability are located in a risk diagram (with probabilities on the y-axis and extent of consequences on the x-axis), the well known traffic light model emerges (Figure 6). In this variant of the model the red zone signifies intolerable risk, the yellow one indicates tolerable risk in need of further management actions (in accordance with the 'as low as reasonably possible' – ALARP – principle) and the green zone shows acceptable or even negligible risk. The grey area illustrates the border lines: the first border identifying the area where one gets close to certainty (probability = 1) and the second where one gets close to indefinite losses. In the first case, most legal documents and ethical schools prohibit the tolerance of risks that will lead to certain losses of life. However, certain losses of artefacts, money or other material assets may be tolerable. The same is true for indefinite losses. Many ethicists would not accept the possibility of an indefinite loss of human lives even if the probability were extremely small. This is not true for

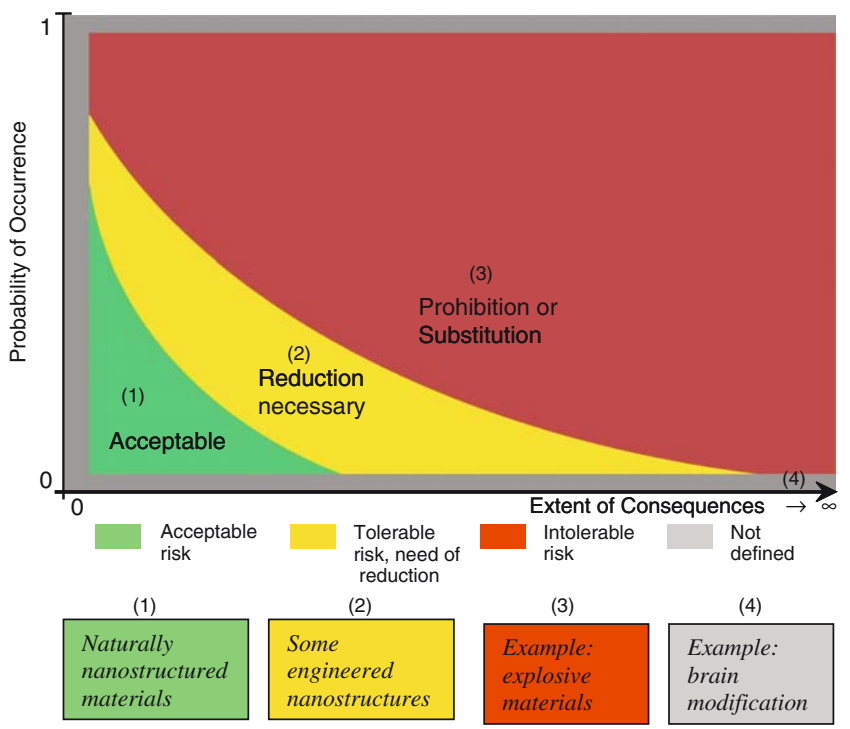

Figure 6. Acceptable, tolerable, intolerable and undefined risks relative to benefits (Traffic Light Model, a stakeholder perspective).

other types of losses. Therefore we leave these boundary areas undefined.

To draw the line between 'intolerable' and 'tolerable' as well as 'tolerable' and 'acceptable' is one of the most difficult tasks of risk governance. The UK Health and Safety Executive have developed a procedure for chemical risks based on risk–risk comparisons (Löfstedt, 1997). Some Swiss cantons such as Basle County experimented with Round Tables as a means to reach consensus on drawing the two lines, whereby participants in the Round Table represented industry, administrators, county officials, environmentalists, and neighbourhood groups (RISKO, 2000). Irrespective of the selected means to support this task, the judgement on acceptability or tolerability is contingent on making use of a variety of different knowledge sources. One needs to include the risk estimates derived from the risk assessment stage, and additional assessment data from the concern assessment. Both frames need to be represented at this stage.

Arriving at a balanced judgment means that nanotechnology will deliver sustainable added value for society, economy and industry only if it is possible to control and manage the unintended impact and risks in the sense of a societally accepted balance. It is not sufficient to include the 'physical-risk' approach, although undoubtedly important, because it addresses only part of what is at stake within culturally plural, morally concerned and educated societies (Grove-White et al., 2000; AEBC, 2001).

Risk management

The task of managing risks once the judgment on tolerability or acceptability has been made can be described in terms of classic decision theory, i.e. in the following steps (Morgan, 1990; Keeney 1992; Hammond et al., 1999):

- *Identification and generation of risk management options*: Generic risk management options include risk avoidance, risk prevention, risk reduction, risk transfer and – also an option to take into account – self-retention. Risk management by means of risk reduction can be accomplished by many different means, including the reduction of pollution at source via environmentally benign manufacturing and measures for cleaning polluted areas. Among the potential technical options, protection technology and personal protective equipment may be used for protecting oneself against nanoparticles in the air. It is, for example, assumed that the traditional aerosol control measures should work for nanoparticles if the collection devices used match the size of the particles. It should be stressed, however, that filter effectiveness for particles smaller than 15 nm is still uncertain. Traditional respiratory protection should also work for particles over 15 nm; however, it is very critical that the facemask fits. It is also important to note that the NPR 100 respirators have not been tested with nanoscale particulates. It is also recommended that impervious gloves and clothing be used to minimize dermal exposure.
- *Assessment of risk management options with respect to predefined criteria*: Each of the options will have desired and unintended consequences which relate to the risks that they are supposed to reduce. In most instances, an assessment should be done according to the following criteria:
  - *Effectiveness*: Does the option achieve the desired effect?
  - *Efficiency*: Does the option achieve the desired effect with the least resource consumption?
  - *Minimisation of external side effects*: Does the option infringe on other valuable goods, benefits or services such as competitiveness, public health, environmental quality, social cohesion, etc.? Does it impair the efficiency and acceptance of the governance system itself?
  - *Sustainability*: Does the option contribute to the overall goal of sustainability? Does it assist in sustaining vital ecological functions, economic prosperity and social cohesion?
  - *Fairness*: Does the option burden the subjects of regulation in a fair and equitable manner?
  - *Political and legal implementability*: Is the option compatible with legal requirements and political programmes?
  - *Ethical acceptability*: Is the option morally acceptable?
  - *Public acceptance*: Will the option be accepted by those individuals who are affected

by it? Are there cultural preferences or symbolic connotations that have a strong influence on how the risks are perceived?

Measuring management options against these criteria may create conflicting messages and results. Many measures that prove to be effective may turn out to be inefficient or unfair to those who will be burdened. Other measures may be sustainable but not accepted by the public or important stakeholders. In addition, finding the most acceptable solution may impair or compromise the risk governance system itself. These problems are aggravated when dealing with global risks. What appears to be efficient in one country may not work at all in another country. Risk managers are therefore well advised to make use of the many excellent guidance documents on how to handle risk trade-offs and how to employ decision analytic tools for dealing with conflicting evidence and values (c.f. Viscusi, 1994; Wiener, 1998; Van der Sluijs et al., 2003; Goodwin & Wright, 2004).

- *Evaluation of risk management options*: Similar to risk evaluation, this step integrates the evidence on how the options perform with regard to the evaluation criteria with a value judgement about the relative weight each criterion should be assigned. Ideally, the evidence should come from experts and the relative weights from politically legitimate decision makers. In practical risk management, the evaluation of options is done in close cooperation between experts and decision makers. As pointed out later, this is the step in which direct stakeholder involvement and public participation is particularly important and is therefore best assured by making use of a variety methods (Rowe & Freyer, 2000; OECD, 2002).
- *Selection of risk management options*: Once the different options are evaluated, a decision has to be made as to which options are selected and which rejected. This decision is obvious if one or more options turn out to be dominant (relatively better on all criteria). Otherwise, trade-offs have to be made that need legitimisation (Graham & Wiener, 1995). A legitimate decision can be made on the basis of formal balancing tools (such as cost-benefit or multi-criteria-decision analysis), by the respective decision makers (given his decision is informed by a holistic view of the problem) or in conjunction with participatory procedures.
- *Implementation of risk management options*: It is the task of risk management to oversee and control the implementation process. In many instances implementation is delegated, as when governments take decisions but leave their implementation to other public or private bodies or to the general public. However, the risk management team has at any rate the implicit mandate to supervise the implementation process or at least monitor its outcome.
- *Monitoring of option performance*: The last step refers to the systematic observation of the effects of the options once they are implemented. The monitoring system should be designed to assess intended as well as unintended consequences. Often a formal policy assessment study is issued in order to explore the consequences of a given set of risk management measures on different dimensions of what humans' value. In addition to generating feedback for the effectiveness of the options taken to reduce the risks, the monitoring phase should also provide new information on early warning signals for both new risks and old risks viewed from a new perspective. It is advisable to have the institutions performing the risk and concern assessments participate in monitoring and supervision so that their analytic skills and experience can be utilised in evaluating the performance of the selected management options.

For nanotechnology, options should be embedded in a set of *scenarios* particularly for frame 2. Those scenarios could be labelled as follows:

1. "*Fears were groundless*" – no significant additional hazard emerges, people start to get used to products based on nanotechnology. Negative health hazards do not show up and the concerns about social and ethical issues loose ground. Public attention moves to other issues. If this scenario materialises, the normal methods of risk management such as risk-benefit balancing will be sufficient.
2. "*Innocent until proven otherwise*" – only way of testing is to approve release of products, then await signal symptoms. This scenario is based

on a trial-and error approach. The main management tool here is monitoring and some containment in order to avoid irreversible damage.

3. "*Not my generation*" – effects are highly latent; problem affects future generations: nanotechnology is applied in many areas without any visible impact on health or the environment. But unintended and unexpected effects show up after a long time period. If this scenario is considered realistic, risk management tools such as containment (limiting application in space and time so that it can be withdrawn once the negative impacts become visible) and strict monitoring are most appropriate.
4. "*Ends justified by means*" – realisable benefits (medical, water filtration, energy conversion, food resources) can outweigh adverse effects: This scenario implies that some applications are regarded as legitimate and others not. This scenario is likely to become realistic if the second discourse on ethical and societal issues becomes a dominant theme in society. Managing agencies are then required to distinguish between different applications and conduct an extensive social benefit (or social need) and risk comparison to distinguish between legitimate and illegitimate applications.
5. "*Too hot to handle*" – Insurers introduce exclusions to product liability insurance policies for specific nanotechnology applications. This scenario implies that the uncertainties drive insurance companies to withdraw liability policies from the market. Potential producers will refrain from marketing products with nanotechnology because of fear of liability. Risk management institutions may change the rules of liability and work together with insurance companies to share the financial risks.
6. "*Not invented here*" – sceptics of the technology invoke precautionary principle or other barriers and succeed in imposing a de facto moratorium on all major applications. The result is that the respective industry moves out and only the final products may be imported into the country. This scenario will restrict the action of regulators and promoters of this technology. The only risk management option is to control imported products.
7. "*No, thanks*" – consumers follow lead of anti-technology NGOs and boycott products with nanotechnology. This scenario assumes that negative communication can convince consumers to refrain from buying these products. Risk management agencies need to engage more in risk communication and trust building exercises to assure the consumer that the regulation is able to protect them.

There may be other scenarios to consider. The main point here is to acknowledge that the choice of risk management measures depends on the scenarios that are taken into consideration. Prudent risk management would include contingency plans for dealing with a whole variety of scenarios in order to be well prepared for changes in economy, society and politics.

Based on the distinction between simple risk, component and system complexity, uncertainty, and ambiguity it is possible to design generic strategies of risk management to be applied to classes of risks, thus simplifying the risk management process as outlined above. Table 1 provides an application of this management tool that has been described in more detail in IRGC (2005) for nanotechnology.

Stakeholder participation

Although, there have been various attempts in recent years to engage business and policymakers in anticipatory debates about emerging technologies – for example the 'Digital Futures' project on e-commerce (Wilsdon, 2001) – methods for this type of upstream engagement are not well developed. A central aim of applying the IRGC model will be to stimulate participatory innovation in this area, and generate better platforms for stakeholder involvement.

How can stakeholder involvement be implemented? Again it is helpful to distinguish between simple, complex, high uncertainty and high ambiguity risk problems (Renn, 2004b). How to deal with these different risk categories is explained in the last column of Table 1 and more specifically in Figure 7. Stakeholder participation is important for both frames 1 and 2 and there are four cases in which different forms of stakeholder involvement in nanotechnology governance should be considered:

- *Simple risk problems*: For making judgements about simple risk problems a sophisticated

approach to involve all potentially affected parties is not necessary. Most actors would not even seek to participate since the expected results are more or less obvious. In terms of cooperative strategies, an '*instrumental discourse*' among agency staff, directly affected groups (such as product or activity providers and immediately exposed individuals) as well as enforcement personnel is advisable. One should be aware, however, that often risks that appear simple turn out to be more complex, uncertain or ambiguous as originally assessed. It is therefore essential to revisit these risks regularly and monitor the outcomes carefully.

- *Complex risk problems associated with components*: The proper handling of complexity in risk appraisal and risk management requires transparency over the subjective judgements and the inclusion of knowledge elements that have shaped the parameters on both sides of the cost-benefit equation. In nanotechnology, complexity often refers to each component while the whole system itself can be well defined. Resolving complexity necessitates a discursive

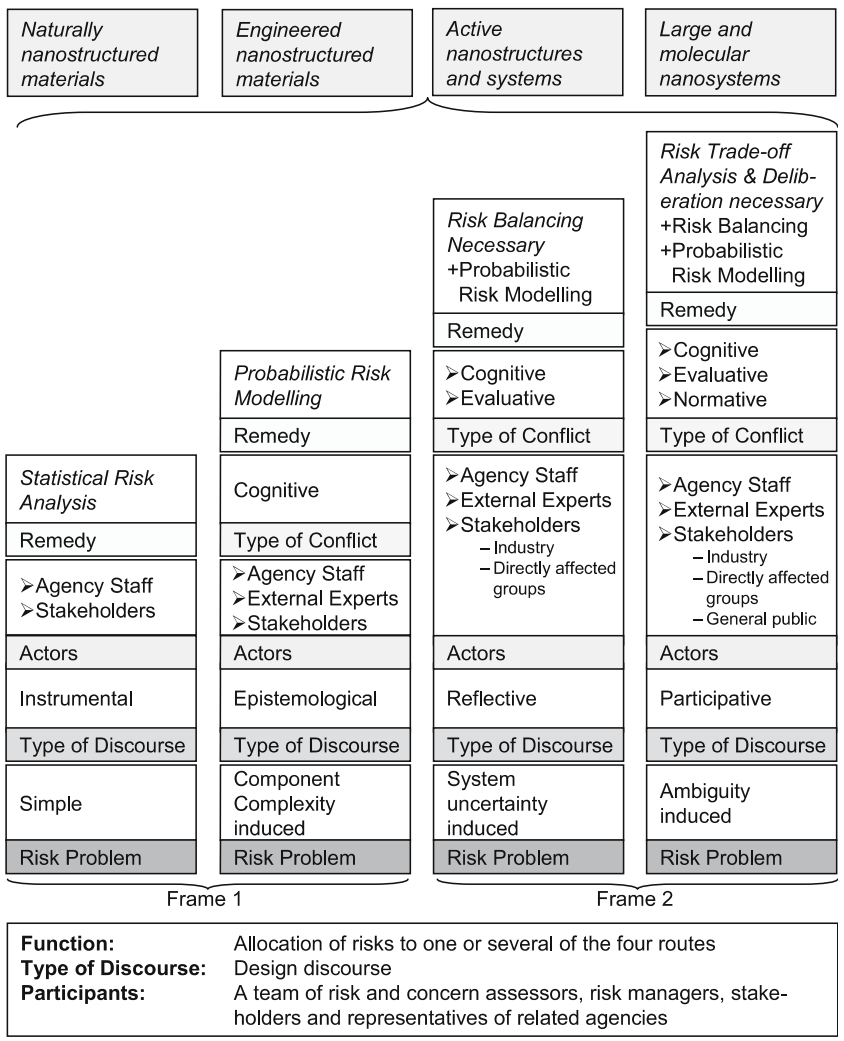

Figure 7. The risk management escalator and stakeholder involvement (from simple via complex and uncertain to ambiguous phenomena) with reference to nanotechnology.

procedure during the appraisal phase with a direct link to the tolerability and acceptability judgement and risk management. Input for handling complexity could be provided by an '*epistemological discourse*' aimed at finding the best estimates for characterising the risks under consideration. This discourse should be inspired by different science camps and the participation of experts and knowledge carriers. They may come from academia, government, industry or civil society but their legitimacy to participate is by bringing new or additional knowledge to the negotiating table. The goal is to resolve cognitive conflicts. Exercises such as Delphi, Group Delphi and consensus workshops would be most advisable to serve the goals of an epistemological discourse (Webler et al., 1991; Gregory et al., 2001).

- *Risk problems due to high unresolved system uncertainty*: Characterising risks, evaluating risks and designing options for risk reduction pose special challenges in situations of high uncertainty about the risk estimates. How can one judge the severity of a situation when the potential damage and its probability are unknown or highly uncertain? In this dilemma, risk managers are well advised to include the main stakeholders in the evaluation process and ask them to find a consensus on the extra margin of safety in which they would be willing to invest in exchange for avoiding potentially catastrophic consequences. This type of deliberation called '*reflective discourse*' relies on a collective reflection about balancing the possibilities for over- and under-protection. If too much protection is sought, innovations may be prevented or stalled; if we go for too little protection, society may experience unpleasant surprises. The classic question of 'how safe is safe enough' is replaced by the question of 'how much uncertainty and ignorance are the main actors willing to accept in exchange for some given benefit'. It is recommended that policy makers, representatives of major stakeholder groups, and scientists take part in this type of discourse. The reflective discourse can take different forms: round tables, open space forums, negotiated rule-making exercises, mediation or mixed advisory committees including scientists and other stakeholders (Amy, 1983; Perrit, 1986; Rowe & Frewer, 2000).
- *Risk problems relating to high ambiguity due to unknown future developments and differences in value judgements*: If major ambiguities are associated with a risk problem, it is not enough to demonstrate that risk regulators are open to public concerns and address the issues that many people wish them to take care of. In these cases the process of risk evaluation needs to be open to public input and new forms of deliberation. This starts with revisiting the question of proper framing. Is the issue really a risk problem or is it in fact an issue of lifestyle and future vision? The aim is to find consensus on the dimensions of ambiguity that need to be addressed in comparing risks and benefits and balancing the pros and cons. High ambiguities require the most inclusive strategy for participation since not only directly affected groups but also those indirectly affected have something to contribute to this debate. Resolving ambiguities in risk debates requires a '*participative discourse*', a platform where competing arguments, beliefs and values are openly discussed. The opportunity for resolving these conflicting expectations lies in the process of identifying common values, defining options that allow people to live their own vision of a 'good life' without compromising the vision of others, to find equitable and just distribution rules when it comes to common resources and to activate institutional means for reaching common welfare so all can reap the collective benefits instead of a few (coping with the classic commoners' dilemma). Available sets of deliberative processes include citizen panels, citizen juries, consensus conferences, ombudspersons, citizen advisory commissions, and similar participatory instruments (Dienel, 1989; Fiorino, 1990; Armour, 1995; Durant & Joss, 1995; Applegate, 1998).

Categorising risks according to the quality and nature of available information on risk may, of course, be contested among the stakeholders. Who decides whether a risk issue can be categorised as simple, complex, uncertain or ambiguous? It seems prudent to have a screening board perform this challenging task. This board should consist of members of the risk and concern assessment team, of risk managers and key stakeholders (such as industry, NGOs and representatives of related

regulatory or governmental agencies). The type of discourse required for this task is called *design discourse*. It is aimed at selecting the appropriate risk and concern assessment policy, defining priorities in handling risks, organising the appropriate involvement procedures and specifying the conditions under which the further steps of the risk handling process will be conducted. Figure 7 provides an overview of the different requirements for participation and stakeholder involvement for the four classes of risk problems and the design discourse.

Risk communication

Risk communication is needed throughout the whole risk handling chain, from the framing of the issue to the monitoring of risk management impacts. In the risk governance framework for nanotechnology risk communication is equally important in all four generations of development and within both frame 1 and frame 2. Communication has to be a means to ensure that (Lundgreen, 1994; OECD, 2002):

- those who are central to risk framing, risk and concern assessment or risk management understand what is happening, how they are to be involved, and, where appropriate, what their responsibilities are, and,
- others outside the immediate risk appraisal or risk management process are informed and engaged.

The first task of risk communication, i.e. facilitating an exchange of information among risk professionals, has often been underestimated in the literature. A close communication link between risk/concern assessors and risk managers, particularly in the phases of pre-assessment and tolerability/acceptability judgement, is crucial for improving overall governance. Similarly, co-operation among natural and social scientists, close teamwork between legal and technical staff and continuous communication between policy makers and scientists are all important prerequisites for enhancing risk management performance. This is particularly important for the initial screening phase where the allocation of risks is performed.

The second task that of communicating risk appropriately to the outside world, is also a very challenging endeavour. Many representatives of stakeholder groups and, particularly, members of the affected and non-affected public are often unfamiliar with the approaches used to assess and manage risks and/or pursue a specific agenda, trying to achieve extensive consideration of their own viewpoints. They face difficulties when asked to differentiate between the potentially harmful properties of a substance (hazards) and the risk estimates that depend on both the properties of the substance, the exposure to humans, and the scenario of its uses (Morgan et al., 2002).

Recommendations

Research recommendations

Key research needs for the first generation of nanoproducts (''Frame 1'' for nanotechnology risk debate) are: (1) Testing strategies for assessing toxicity and eco-toxicity, including pre-market testing and life-cycle assessment; (2) Best metrics for assessing particle toxicity and eco-toxicity; (3) Research into disposal, dispersion, and waste treatment of nano-engineered materials. (4) Exposure monitoring methodologies, including research into the effectiveness of current engineering controls and person protective equipment (Glove boxes, hoods, air filters, etc.); (5) Evaluate the probability and severity of risk for nanotechnology applications, including the benefits and the risks of not doing anything (for example, replacement of non-renewable energy sources); (6) Risk assessment methodologies; and (7) Communication and education concerning EHS and ELSI, including full disclosure and transparency.

Key research needs for the next generations of nanoproducts (''Frame 2'' for nanotechnology risk debate) are: (1) Identifying the hazards and exposures using scenarios (see science and technology scenarios presented in Nano Frontiers, 2006); (2) Matrix for assessing the identified hazards; (3) Estimation of exposure for events with great uncertainties; (4) Identifying and assessing the major concerns of stakeholders and public interest groups; (5) Investigating the ethical and social dimensions of the expected impacts; (6) Developing appropriate methods of decision making in face of great uncertainties and ambiguities including stakeholder involvement; and (7) Developing capacity to address uncertain/

unknown and highly controversial developments as part of risk governance at national and global levels. Key research needs for each of frame 1 and frame 2 are identified in Table 2.

Risk communication recommendations

In order to design an effective risk communication programme it is essential to take into account the two frames of nanotechnology (for the first and second–fourth generations of nanotechnology products, respectively, as defined before), and for each frame to consider the differences between the risks associated with (a) human health and biosystems on one side, and (b) physical infrastructure (surrounding of the biological systems) on the other side. Risk communication should avoid the strategic mistake of grouping all applications of nanoscale technologies under the single descriptor ''nanotechnology'' because this would blur the distinction between the two frames and their subcategories and runs the risk of discrediting the whole nanotechnology development if there is a singular incident or some other problems related to a specific application. The second major point is to have separate risk communication programmes for each of the two frames.

The first communication strategy (for both frames 1 and 2) should be designed to enlighten the discussion about the benefits and non-intended side effects and the means to identify and quantify those effects. Communication tools here refer to internet based documentation of scientific research, product labelling, press releases, consumer hot lines and similar activities.

The second strategy (particularly for frame 2) should be directed towards a broader debate on the desirability of special applications of nanotechnology in the light of ethical and social issues. The main message here could be that it is not nanotechnology that creates the problem but rather the use of this technology in a controversial application. It is certainly legitimate to reject special applications (such as using neurochips in the human brain for control of its functions without a medical justification) without having to oppose the technology that makes such an application technically feasible.

A third major strategy in risk communication is to provide public information on the principles and procedures used to test nanotechnology products, to assess potential health or ecological impacts and to monitor the effects, as well as to inform the public on investment policies in research, development and production. If people have the reassurance that public authorities take special care and attention to protect the population against unintended consequences of this new technology, they may be willing to invest some more trust than today in the capacity of society to control the risks and be aware of and responsive to remaining uncertainties.

It is notable that public engagement does not solve the problem; it only (and not inevitably) increases credibility and trust. It is not a guarantee to success with or without the support of positive factual evidence. The inclusion of media stakeholders in risk communication efforts may help to accelerate the pubic engagement efforts.

Recommendations to deal with trans-boundary issues

In an interdependent world, the risks faced by any individual, company, region or country depends not only on its own choices but also on those of

Table 2. Key research needs for the two nanotechnology risk frames

Nanotechnology risk debate	Hazard	Exposure	Risk
Frame 1	Testing strategies for assessing toxicity; Best metrics for assessing particle toxicity	Exposure monitoring methodologies; Methods for reducing exposure and protective equipment	Risk assessment methodologies; Communication and education concerning EHS and ELSI.
Frame 2	Identifying the hazards using scenarios; Matrix for assessing the identified hazards	Estimation of exposure for events with great uncertainties using methods such as casual chain	Communication and education concerning EHS and ELSI; Developing capacity to address uncertain/ unknown and ambiguous developments.

others. Nor do these entities face one risk at a time: they need to find strategies to deal with a series of interrelated risks that are often ill-defined or outside of their control. In the context of nanotechnology, the risks faced in one country, for instance, may be affected by risk management failures in another country. For example, if due to lax risk regulation a major incident occurs in one country involving nanoparticles, this will have repercussions on the debate on nanotechnology in many other countries. In particular, in connection with the second frame, evidence that control mechanisms do not work in one place may fuel a fierce debate in other parts of the world about the acceptability of this technology in general.

The more interdependencies that exist within a particular setting (be this a set of organisational units, companies, a geographical area or a number of countries etc.) and the more that this setting's entities – or participants – decide not to invest in risk reduction, while being able to influence other entities, the less incentive each potentially affected participant will have to invest in protection. At the same time, however, each participant would have been better off had all the other participants invested in risk-reducing measures. In other words, weak links may lead to suboptimal behaviour by everyone. This is particularly a problem for countries with a record of effective and precautious regulatory actions since this positive record can become worthless if a major incident occurs in another country due to regulatory oversight. Creating incentives for all countries to participate in risk governance is a key issue. This may be done by using cost benefit studies (to show that it is in their own interest), using better methods of communication, and designing insurance policies which take this into account.

The role of international organisations dealing with technical, economical and policy issues (OECD, UNIDO, ISO, ASTM and others), international industry and academic organisations (SRC International; International Electronics Manufacturing Initiative, ICON and others), and NGOs (ex: ETC Group, Greenpeace, Woodrow Wilson Center and others) need to be further explored.

For situations in which some participants are reluctant to adopt protective measures to reduce the chances of negative incidents, a solution might be found in a public–private partnership. This is particularly true if the risks to be dealt with are associated with competing interpretations (ambiguities) about their acceptability as well as with conflicts about the rigour necessary to monitor and regulate side effects. Both conditions seem to apply to nanotechnology. Quite a few countries perceive here an opportunity to gain a competitive advantage by developing nanotechnology products faster than competing nations. This is certainly a major reason for proposing international regulation and common strategies for risk management.

A way to structure a private–public partnership is to have government standards and regulations coupled with third party inspections and insurance to enforce these measures. Such a management-based regulatory strategy will encourage the addressees of the regulation, often the corporate sector, to reduce their risks from e.g. accidents and disasters. It also shifts the locus of decision-making from the government regulatory authority to private companies which are as a result required to do their own planning as to how they will meet a set of standards or regulations (Coglianese & Lazer, 2003). This, in turn, can enable companies to choose those means and measures which are most fit for purpose within their specific environment and, eventually, may lead to a superior allocation of resources compared to more top-down forms of regulation. The combination of third party inspections in conjunction with private insurance is consequently a powerful combination of public oversight and market mechanisms that can convince many companies of the advantages of implementing the necessary measures to make their products based on nanotechnology safer.

It is critical that International Standards and best practices be communicated globally. This will require special effort by institutions to penetrate developing and developed countries in a reasonable time frame to help stakeholders understand the importance of regulatory actions and public–private cooperation to ensure that the opportunities are sought and the risks are either avoided or at least reduced. Mechanisms need to be established to maintain and communicate best practices in this respect, standards and knowledge and communicate to governments, industry, entrepreneurs, and universities as quickly as possible.

Recommendations to various stakeholders

These general recommendations need to be implemented by social actors. The days are gone when regulatory actions were the sole responsibility of governments. The complexity of the subject, the different types of agency among and between the different actors, the scope of responsibilities and accountability, the trans-boundary nature of benefits and risks as well as the delicate balances of power and interests make it inevitable that governmental, economic, scientific and civil actors cooperate for the purpose of better regulation of nanotechnology. Many of the recommendations and suggestions developed above are directed towards governments, but national governments are often unable to operate effectively on the global level. They need the cooperation of private often trans-nationally operating companies and civil society actors who increasingly organise themselves on the global level.

The private sector is a major player in the development and diffusion of nanotechnology. It is in the best interest of private investors to assure that minimum standards for safety and health protection are established and enforced internationally and that potential risks are investigated and assessed before actual damage occurs. The international business community is well aware that the development of nanotechnology applications depends heavily on public confidence in the ability of industry and government to control risks and on the flexibility and creativity of the business sector to deal with new information and research results about potential impacts, be they positive or negative.

Due to the lack of global governance structures in dealing with nanotechnology regulation, one of the most promising routes for private actors is the establishment of voluntary codes or rules with respect to minimum requirements for assuring safety and risk control. One major incident in a remote country can trigger international reactions that might go far beyond the actual case. Therefore, it is important for internationally operating companies to make sure that all their facilities follow identical EHS-standards and requirements if actual practices may be formed according to local or regional traditions. Beyond the harmonisation of standards in multinational companies, voluntary agreements and codes for the entire industry may also help to reduce risks and sustain public trust and confidence.

One possibility to consider is the establishment of a certification system that would force all companies to adhere to specific rules when applying for this certificate. Such a system could be modelled according to the Forest Stewardship Council or similar organisational settings. Another possibility may be the establishment and enforcement of international standards (for example ISO-standards) that require companies to follow predefined rules for safety and protection of public health. Demonstrating that private industry has done what it can to protect the public and the environment is the best guarantee that the benefits of this technology will unfold and thus improve living standards as well as public confidence.

Voluntary agreements, certificates or international standards are suitable instruments for dealing with potential risks of nanotechnology applications in short term until formal norms would be established. The second frame includes concerns about social disturbance, threat to human identity and cultural values. The ambiguity associated with these endpoints of risks demands a more discursive and participatory approach and private industry should be willing and prepared to engage in such a dialogue programme. One could think of public statements about ethical implications of one's own research including the promise not to engage in certain ethically problematic areas of application (even if they are legal). Another possibility is to initiate public forums or Round Tables amongst major stakeholders and concerned groups with the objective being to explore potential social risks and design barriers to prevent them from occurring. If industry can convey the message that they take these concerns seriously, and are willing to shape and reshape their own policies in accordance with reasonable demands of precaution against such social risks, the struggle for more trust and confidence can lead to success.

Both voluntary agreements and new forms of dialogue and public consultation are also attractive to non-governmental organisations as it is in their interest to make sure that environmental quality and public health are assured through the appropriate means. Often they also pursue secondary goals such as equity, social justice and assistance to the poor and these concerns can be

Table 3. Recommendations to stakeholders

Stakeholder	Recommendations
Academia	• Conduct research for physico-chemical knowledge EHS, ELSI, and on new methods for risk analysis and management specific for individual nanotechnology applications • Educate a new generation of nanotechnologists sensitive and knowledgeable about risk governance, in the context of converging technologies (nano, bio, info, cognitive) and international relations. • Conduct public outreach and engagement, participate in public debates on nanotechnology and its benefits and risks • Engage impartially in risk related issues, without bias towards industry interests or pressure group values
Industry	• Adopt self-regulations that can be implemented faster (in few years) than regulations (generally requiring about 10 years from genesis to application). A focus should be on best practices for risk governance. • Public disclosure of testing and possible risks of nanomaterials • Assess potential implications and scenarios of nanotechnology development for potential response in the preparation of the workforce, investment needs, and measures for disposal of used products. Earlier in technology development, one should evaluate the risk to researchers, other workers, and waste handlers. • Develop mechanisms to exchange information with other industries, academia, public, and government
Government	• Support R&D for EHS, education and ELSI and integrate the results from the beginning of large R&D projects and planning for nanotechnology investments • Prepare and implement a new risk governance approach based on adaptive corrections at the societal system level. In the short-term and when suitable, adapt existing legislation to nanotechnology development • Build capacity to address accidents and other unexpected situations • Provide incentives to reduce risks; for example, replace polluting materials with 'green' substitutes • Prepare long-term plans and scenarios of nanotechnology development, and anticipatory measures in risk governance on this basis. Evaluate the relationship between regulations and innovation • Support studies on implications of nanotechnology on existing national legislation, professional codes, nomenclature and standards, human rights and international agreements. Support the use of metrology in risk governance decisions • Address equal access to nanotechnology benefits and equity issues in society • Prepare longitudinal surveys (each six to 24 months) on public perception • Develop a communication strategy to keep industry, small-business, user and civil organisations informed on representative developments and EHS aspects of the new technology. Consider a clearinghouse of information role for government organisations • Adopt transparent oversight processes with public input • Encourage international collaborations in risk governance
User, public, NGOs and civil organisations	• Create a safety reporting system covering research laboratories, industry production lines, transportation, and environment. • Create user organisations to clearly articulate the diversity of applications, uncertainties and implications of nanotechnology in short- and long-term • Develop continuous channel of communications with industry, academia, and government • Facilitate public participation in addressing philosophical and religious beliefs
International organisations	• Communication among government and non-government organisations in various countries • Encourage and support coherent policies and regulatory frameworks for nanotechnology • Establish shared data bases for EHS/Education/ELSI results and develop programmes for periodical exchanges of information • Support studies on macroeconomic trends, trade implications and avoiding possible international disruptions, particularly for developing countries that do not have the capacity to fully protect their interests • Coordinate intellectual property issues for nanotechnology • Establish certification programmes for risk governance in an organisation • Connect risk management practices to international practices and standards (ISO)

integrated into the policies of voluntary agreements and public forums. The constructive processing of conflicts in suitable arenas is probably the most effective way to control the risks while still enjoying the benefits.

Table 3 lists more specific recommendations for the main societal actors in regulating nanotechnology. The list includes suggestions for private industry, academia, governments, civil society actors and international organisations. Being an international organisation, IRGC can assist private companies, social associations and NGOs to deal with both frames simultaneously. It can also provide advice on what kind of voluntary codes of conduct are needed and offer a platform for exchanging views and concerns on the issues belonging to the second frame. Risk managers and regulators should selectively focus on those aspects of the conceptual framework for risk governance of nanotechnology presented in this paper that are essential for their nanotechnology application (s).

The role of the IRGC

This paper has aimed to develop a conceptual framework for the global governance of risks associated with those technical areas and applications of nanotechnology for which there is an apparent need for improved approaches to risk and safety issues.

Risk governance for nanotechnology is an important issue for the IRGC as it touches its main mission and relates to all the major elements of the IRGC risk governance model (see Figures 2 and 8). Given the dominance of the two frames of the nanotechnology debate (for the first and second–fourth generations of nanotechnology products, respectively), there is a real danger that the response of national risk management agencies is not sufficiently adequate to address the problems and challenges in both frames at the national and global levels and hence may lose trust and perceived competence. It is important that the risk management agencies are prepared to consider all the stages of the risk governance process and develop tools that address the challenges on each step in the process. This implies that sufficient resources are invested in risk governance and that the persons dealing with this issue are adequately trained and prepared for improving their performance. Beyond the national governments, IRGC is convinced that cooperation between governmental agencies, the private sector, civil society actors and the science communities is crucial for a governance structure that is effective, efficient and fair. It can design and inspire processes aiming at internationally agreeable standards and rules and it can promote and actively participate

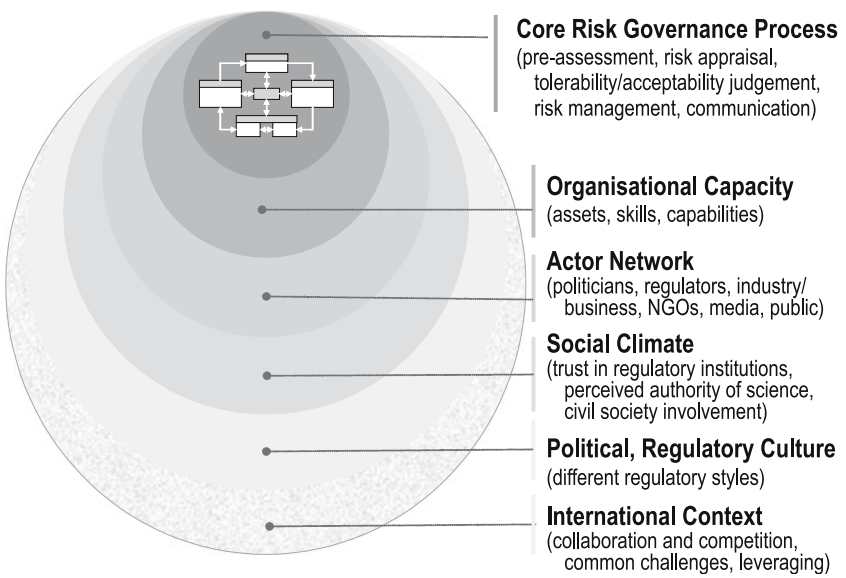

Figure 8. Risk governance overview.

in dialogues on the many still intangible implications of the second to fourth application of nanotechnology.

Besides the core risk governance process outlined in this paper, the risk governance of nanotechnology should involve during its implementation various organisations and actors in a social, political, regulatory and international context during its implementation (Figure 8).

The IRGC could facilitate such processes. It can provide models and assistance and expertise in doing risk assessment and concern assessment. Although, the IRGC has no analytic capacity to perform these assessments themselves it can help to set up the global and long-term frameworks for research plans and regulations, assist in developing or applying methods and analytical techniques, and facilitate the necessary involvement and communication process. Furthermore it can provide checklists for an effective and efficient risk management plan and help to detect weak links in the system. Most important is the role of the IRGC to initiate and promote international strategies for dealing with nanotechnology risks and making suggestions for effective public–private partnerships. At this point, IRGC is committed to perform the following concrete tasks:

- *Risk assessment*. IRGC intends to carry out a risk assessment for selected application areas which have been identified as important by various stakeholders:
  - Environmental contamination and remediation (soil, air, water, biosystems)
  - Worker safety
  - Medical treatments
  - Agriculture
  - Food systems
  - Nanotubes (as a stand alone subject to be characterised in more depth)
- *Concern assessment*. Of special interest in this context is the concern assessment phase, a novel element that the IRGC has suggested as a supplement to the classic risk assessment. Risk managers need to be informed about the structure and strength of the various frames that individuals and groups associate with nanotechnology. For this purpose, IRGC have conducted global surveys with the leading individuals of government, industry, NGOs, international organisations and others. In addition interviews with civil society groups such as consumer unions, environmental groups, religious communities, and others need to be conducted and interpreted. If simultaneously done in many countries, one can compare insights from all of the international studies and conduct a systematic evaluation in terms of intensity of concerns, types of concerns and willingness to act. Such an analysis is not only a means for identifying potential barriers and obstacles to the diffusion of nanotechnology it is also an important input for the construction of scenarios and for the identification of potential opportunities based on revealed preferences of the main actors. In addition, risk managers being able to understand the frames that govern the perception process would be better equipped to design appropriate risk management and risk communication strategies.
- *Risk management*. As a primary outcome of these assessments IRGC will contribute towards developing models for risk governance policies, dealing with disagreements, responding to changes in time, and overall international interactions. These models will be debated and agreed amongst key stakeholders at an international conference resulting in a final set of recommendations for risk governance of frame 1 and frame 2. Activities for increasing public awareness of nanotechnology and participation in making investment decisions will also be evaluated in this context as a method for reducing risk.
- *Risk communication*. IRCG will develop a white paper on nanotechnology risk governance and surveys of key stakeholders. The reports will be disseminated to key potential users and posted on the IRGC website. In addition, IRGC will facilitate the production of risk communication material by different agencies and organisations. It will also provide a platform for different actors in this debate to exchange ideas, concerns, and insights with the goal to reach consensus on the appropriate regulatory actions, possible private–public partnerships and risk education and communication needs. A clearinghouse role for collecting and disseminating important information on risk governance and use of databases is considered.

A potential future role for international bodies

Stakeholders can contribute to framing the issues related to the risks of nanotechnology by adopting a proactive approach. For example, one should focus on how one can engineer safe nanostructures and nanosystems instead of observing that some nanostructures are not safe. In another example, collaboration should take place among various specialised organisations (such as the International Dialogue (2004) and the National Institute for Occupational Science and Health (US)) to create and maintain data bases for knowledge on toxicity for nanomaterials, regulations, R&D needs and investment needs.

National or international exercises for constructing scenarios that appear relevant to the context of the diffusion of nanotechnology and the likely social reactions to it should also take place. The scenarios suggested in this report may serve as default options for designing more specific scenarios that relate to the specific situation and the contextual conditions of the countries selected for the analysis. Academic researchers, developers, potential users and important other actors should be actively involved in this scenario building exercise in order to get an adequate representation of societal forces that ultimately shape the future of nanotechnology.

Last, but not least a targeted and effective communication programme is necessary which includes suggestions for a special educational initiative in the context of the worldwide activities to enhance public understanding of sciences and humanities. One could imagine that an international expert organisation may help agencies, NGOs or companies to design specific communication and educational material such as Internet presentations, brochures, press releases, consumer product labels and others. One should be aware, however, that those means only affect the first frame of the debate. For meeting the challenges of the second frame, other communication means are needed such as an open forum on the use and abuse of nanotechnology for medical, military or other controversial purposes. In addition, citizen panels or joint action committees (including consumer associations, unions, employers, etc,) could be convened to draft recommendation for regulatory provisions that would inhibit the potential misuse of nanotechnology. All these activities would be able to preserve or even restore trust in the risk managing agencies.

Closing remarks

By considering the particularities of nanotechnology as an emerging technology, the proposed conceptual framework and recommendation guidelines on risk governance provide a step forward in assisting risk management agencies as well as private companies to integrate scientific assessments and concern assessments into one appraisal process and to select the appropriate risk management and stakeholder involvement strategies.

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