



# 21ST CENTURY REGULATION

DISCOVERING BETTER SOLUTIONS  
FOR ENDURING PROBLEMS



JANUARY 2009

MERCATUS CENTER  
GEORGE MASON UNIVERSITY

## About the Mercatus Center at George Mason University

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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

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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.



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](mailto: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,

A handwritten signature in black ink, appearing to read 'R. Williams', with a long horizontal flourish extending to the right.

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.

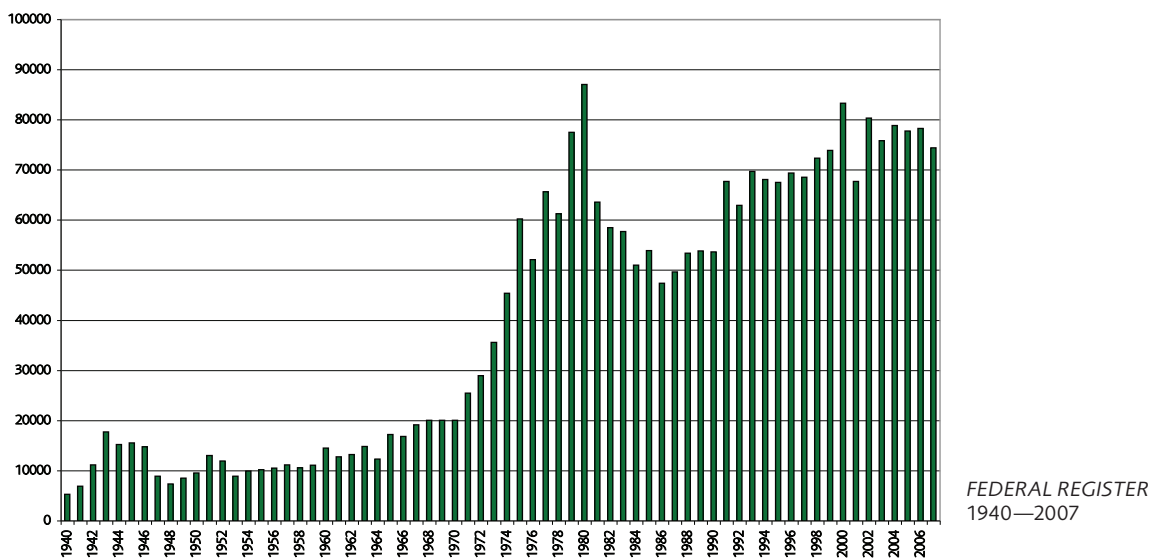
It is a time for change. Let us consider why this is so.

## 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<sup>1</sup>**



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.

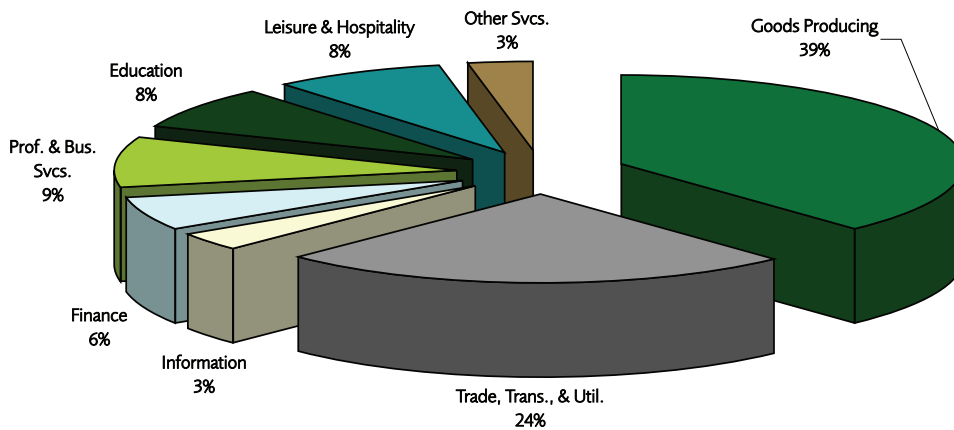
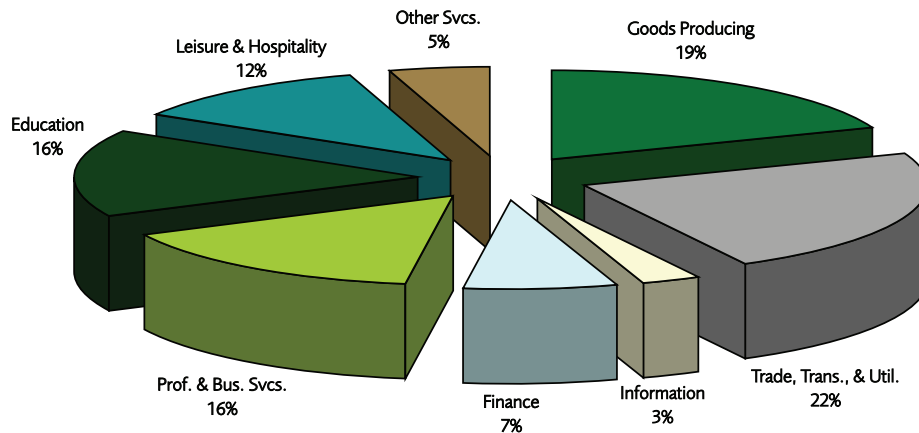
## AS TIME GOES BY . . .

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.<sup>2</sup> 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<sup>3</sup>****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](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.<sup>4</sup> 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.<sup>5</sup> 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.<sup>6</sup>

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?<sup>7</sup>

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](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

EXCECUTIVE SUMMARY	10
EXCECUTIVE SUMMARIES	15
Performance Accountability For Regulations Henry Wray	15
Improving The Regulatory Process Throughout Its Life Cycle: Nine Recommendations To A New Administration Scott Farrow	16
Facilitated Market Solutions For Social Problems Richard A. Williams and Andrew Perraut	17
Rethinking Protection Of Competition And Competitors Bruce Yandle	18
Lessons For New Technologies Gary E. Marchant	19
PERFORMANCE ACCOUNTABILITY FOR REGULATIONS HENRY WRAY	20
IMPROVING THE REGULATORY PROCESS THROUGHOUT ITS LIFE CYCLE: NINE RECOMMENDATIONS TO A NEW ADMINISTRATION SCOTT FARROW	34
FACILITATED MARKET SOLUTIONS FOR SOCIAL PROBLEMS RICHARD A. WILLIAMS AND ANDREW PERRAUT	48
RETHINKING PROTECTION OF COMPETITION AND COMPETITORS BRUCE YANDLE	55
LESSONS FOR NEW TECHNOLOGIES GARY E. MARCHANT	68
ABOUT THE AUTHORS	80

# 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.<sup>1</sup>

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<sup>2</sup>

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](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?<sup>3</sup>

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<sup>4</sup>

## 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.<sup>5</sup>
- 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.<sup>6</sup>

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.<sup>7</sup>

### 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.<sup>8</sup>

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.<sup>9</sup>

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 mediation 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.<sup>10</sup>

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.<sup>11</sup>

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.<sup>12</sup>

Regulators then face two seemingly competing interests: consumer safety and business competition.<sup>13</sup> 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.<sup>14</sup>

#### 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.<sup>15</sup> 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.<sup>16</sup>

## 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 consis-

tent 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.<sup>1</sup> 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.<sup>2</sup>

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*.<sup>3</sup> 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.<sup>4</sup> 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.<sup>5</sup>

## 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.<sup>6</sup>

### 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.<sup>7</sup>

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.<sup>8</sup>

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.”<sup>9</sup> 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 restric-

tions in the Unfunded Mandates Reform Act that severely limit its application.<sup>10</sup>

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.<sup>11</sup>

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.<sup>12</sup> 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.<sup>13</sup> The mandatory reviews the agencies did conduct had little impact since they usually concluded that no changes were needed.<sup>14</sup>

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.<sup>15</sup> Still another problem was that agencies said they lacked the data necessary to conduct effective reviews.<sup>16</sup> As the GAO noted, other studies have likewise identified problems limiting the effectiveness of retrospective reviews.<sup>17</sup>

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.<sup>18</sup>

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.”<sup>19</sup>

### 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).<sup>20</sup>

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.<sup>21</sup>

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 policy-making, spending decisions, and program oversight are seriously handicapped by insufficient attention to program performance and results."<sup>22</sup> 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.<sup>23</sup> 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.<sup>24</sup> Agencies must also prepare annual performance plans containing goals and measures for each of their program activities, which must include indicators assessing outcomes.<sup>25</sup> Finally, agencies must report to Congress and to the public annually on their performance results against these goals and measures.<sup>26</sup>

The GPRA operates at a higher level than individual rules, focusing on federal departments and agencies as a whole.<sup>27</sup> 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:<sup>28</sup>

- 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.<sup>29</sup> 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.<sup>30</sup>

### 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.<sup>31</sup> 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.<sup>32</sup> 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.<sup>33</sup>

## 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.<sup>34</sup> 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.<sup>35</sup> 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.

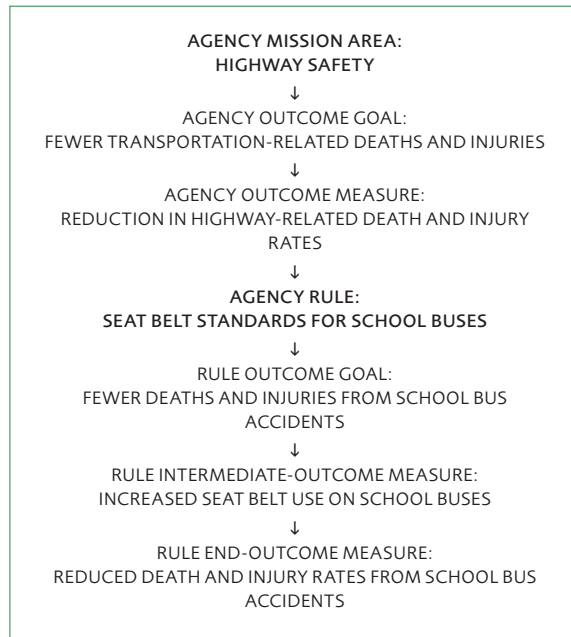
rules should not be problematic. The proposal envisions goals that are expressed as tangible and measurable results—not abstract rhetorical assertions of the public interest that sometimes pass for statements of purpose. A far greater challenge is to convert those results into specific performance measures 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

FIGURE 1



2 gives examples of actual performance goals and measures for federal regulatory programs.<sup>36</sup> While not broken down to specific rules, they illustrate the kinds of goals and measures that could be applied to rules.

## 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**<sup>37</sup> 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 prod- ucts	Prevalence of salmonella on raw meat and poultry products (annual targets expressed as percent- age reductions)  Percentage of ready- to-eat meat and poultry products testing positive for listeria bacteria (annual targets expressed as percent- age reductions)
Transportation Department: Railroad Safety Program	Reduction in transporta- tion-related deaths and injuries	Fewer rail-related acci- dents 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 rat- ings 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 (an- nual 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.”<sup>38</sup> 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.<sup>39</sup> The act also created the Office of Information and Regulatory Affairs (OIRA) within the OMB.

**The Regulatory Flexibility Act**<sup>40</sup> 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<sup>41</sup> 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**<sup>42</sup> 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.<sup>43</sup> The act does not apply to independent regulatory agencies.<sup>44</sup>

**The Congressional Review Act**<sup>45</sup> 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.<sup>46</sup> 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.<sup>47</sup> 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.<sup>48</sup>

**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.<sup>49</sup> 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.”<sup>50</sup>

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.”<sup>51</sup>

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.<sup>52</sup> 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.<sup>1</sup> One cost estimate puts the burden at about 10 percent of the economy.<sup>2</sup> 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.<sup>3</sup> 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<sup>4</sup> (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.<sup>5</sup> 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](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](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](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.<sup>6</sup> 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.<sup>7</sup> 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."<sup>8</sup> 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.<sup>9</sup> The GAO espoused this cycle most clearly in regard to Homeland Security but also applies it in a broader perspective.<sup>10</sup> 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>.

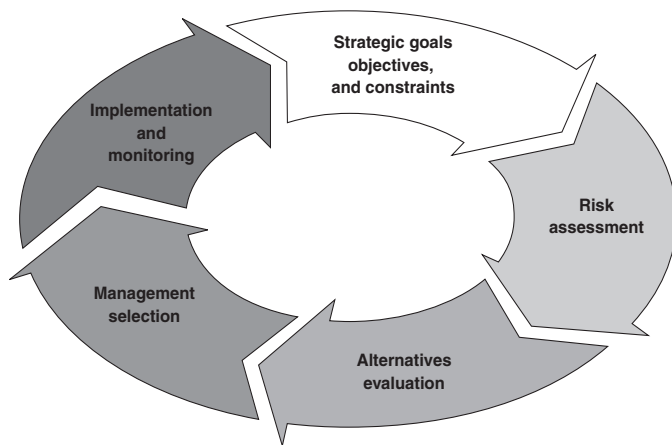
7. The reform attempts since 1980 include the following: (1) Paperwork Reduction Act (PRA), (2) Regulatory Flexibility Act of 1980 (RFA), (3) Small Business Regulatory Enforcement Fairness Act (SBREFA), (4) Unfunded Mandates Reform Act of 1995 (UMRA), (5) Congressional Review Act (CRA), (6) Government Paperwork Elimination Act (GPEA), (7) Truth in Regulating Act (TIRA), (8) Information Quality Act (IQIA), (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,<sup>11</sup> particularly related to their performance. Furthermore, the GPRa measures produced by the agencies typically ignore economic performance,<sup>12</sup> 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.<sup>13</sup> 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.<sup>14</sup> 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](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*,<sup>15</sup> known as the “Yellow Book.”<sup>15</sup> 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.<sup>16</sup>

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 led 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,<sup>17</sup> 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.<sup>18</sup> There is a history of suggestions to create a regulatory budget<sup>19</sup> 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.<sup>20</sup>

#### 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* (Chicago: 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](http://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

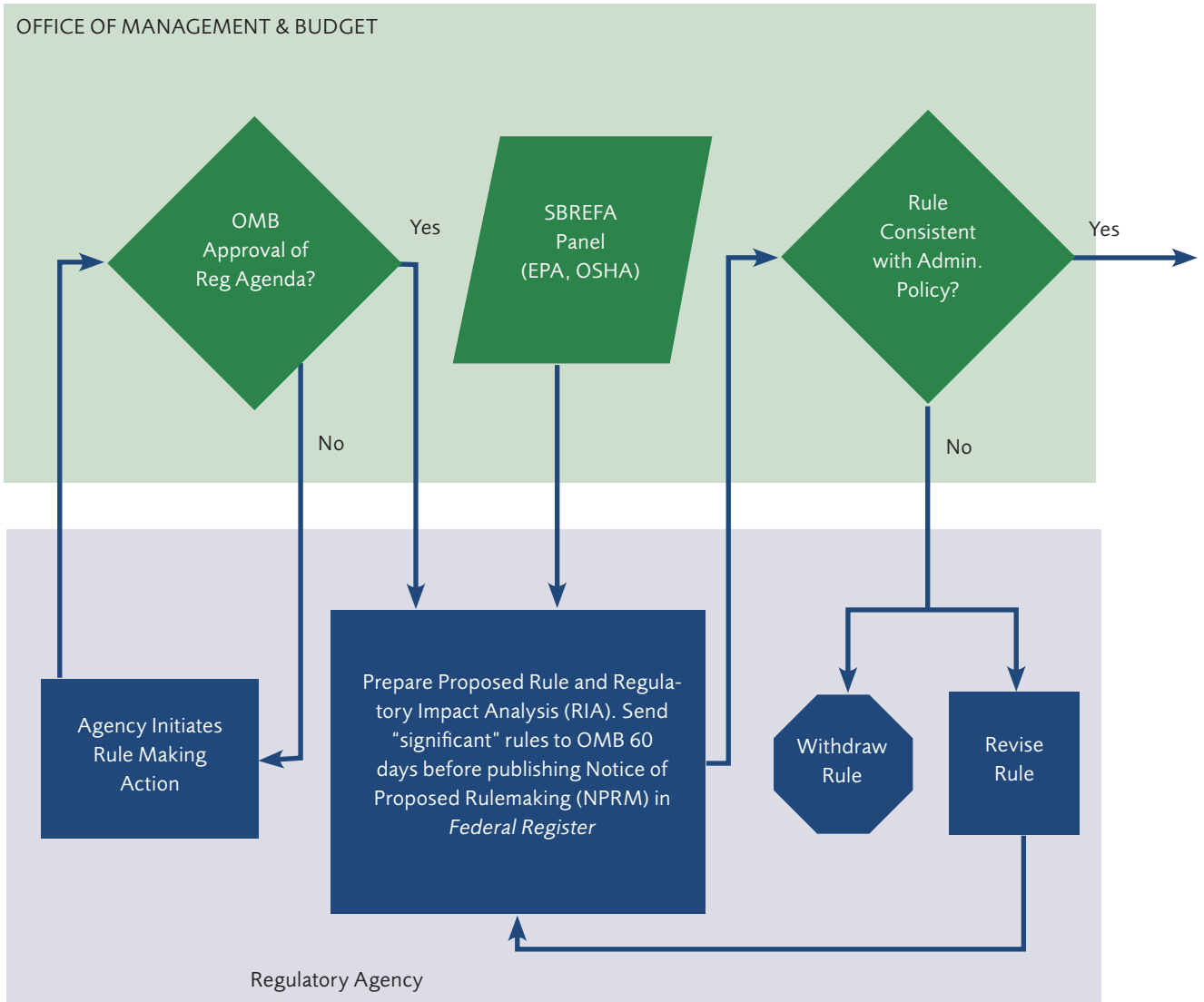
Information for monitoring and strategic review

## 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.



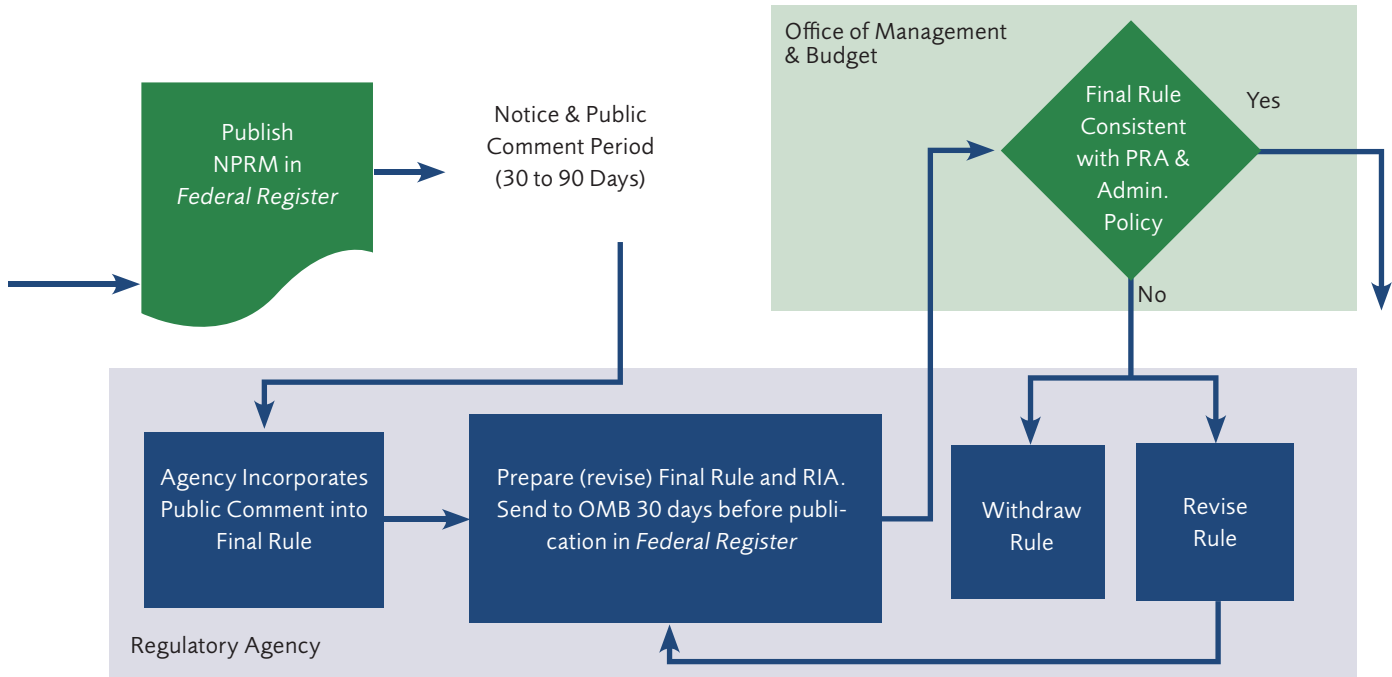
**APPENDIX:  
THE REGULATORY PROCESS: PART I (DUDLEY 2005)**



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.

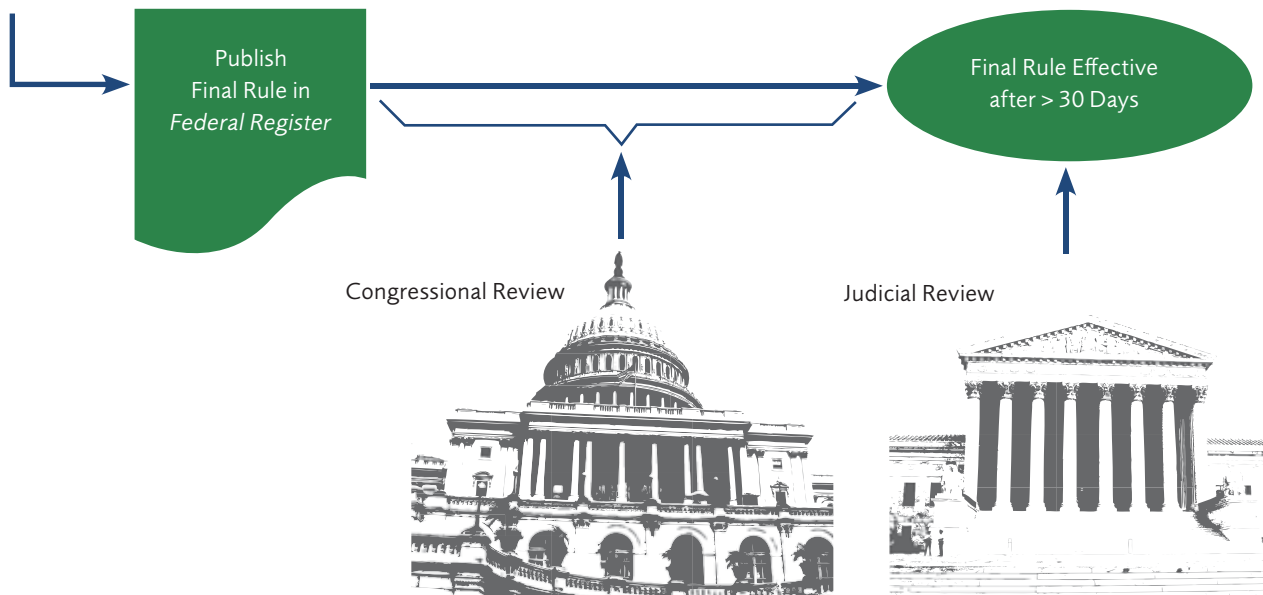
## THE REGULATORY PROCESS: PART II (DUDLEY 2005)

### 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<sup>1</sup>

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.<sup>2</sup> Even where an industry's products have "negative" attributes, markets work through a process called "unfolding."<sup>3</sup> 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."<sup>4</sup> 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.<sup>5</sup> 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.<sup>6</sup> 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.<sup>7</sup> 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.<sup>8</sup> 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.<sup>9</sup>

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.<sup>10</sup> 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 met 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.<sup>11</sup>

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.”<sup>12</sup> 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 matter. 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 manufacturers 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.<sup>13</sup> 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.<sup>14</sup> 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.

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.

## 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,

# 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.<sup>1</sup> 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.<sup>2</sup> 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.<sup>3</sup>

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.<sup>4</sup>

When firms in an industry use regulation strategically, they are able to raise competitors' costs or shut out competition entirely.<sup>5</sup> Paradoxically, even antitrust law enforcement can fall victim to anti-competitive behavior.<sup>6</sup> Firms already operating in a market, per-

haps inefficiently, can use antitrust merger reviews as a way to fend off unwanted takeovers.<sup>7</sup> 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.<sup>8</sup> 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.<sup>9</sup> 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.<sup>10</sup> 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.<sup>11</sup> 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<sup>12</sup>), 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 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.<sup>13</sup> 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.<sup>14</sup> 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.<sup>15</sup> 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?"

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).

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.



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.<sup>16</sup> 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.<sup>17</sup>

### 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](http://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](http://www.iso.org).

17. SGS, which is also located in Geneva, Switzerland, ([www.sgs.org](http://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.<sup>18</sup> 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>.

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.<sup>1</sup> 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.”<sup>2</sup> 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.<sup>3</sup> 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.<sup>4</sup>

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.”<sup>5</sup>

*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.”<sup>6</sup> 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.”<sup>7</sup>

*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.”<sup>8</sup> 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.”<sup>9</sup> 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.”<sup>10</sup>

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 maintains 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.<sup>11</sup> 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.<sup>12</sup> 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.<sup>13</sup> 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.<sup>14</sup> 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.<sup>15</sup> 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.<sup>16</sup>

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."<sup>17</sup> 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."<sup>18</sup>

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."<sup>19</sup> 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.<sup>20</sup>

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](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](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.<sup>21</sup>

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.<sup>22</sup> 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.<sup>23</sup> 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 is 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.<sup>24</sup>

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.<sup>25</sup>

## 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,<sup>26</sup> 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.<sup>27</sup> 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.<sup>28</sup> 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.<sup>29</sup>

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.”<sup>30</sup> 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.<sup>31</sup> 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.”<sup>32</sup> 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.<sup>33</sup> 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).<sup>34</sup> Moreover, the EU’s own “commu-

nication” 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.”<sup>35</sup>

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)<sup>36</sup>, 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.<sup>37</sup> 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.<sup>38</sup> 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.<sup>39</sup> 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<sup>40</sup> 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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