

Testimony

Subcommittee on Investigations and Oversight Committee on Science and Technology U.S. House of Representatives

The Role of Science in Regulatory Reform

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Mr. Chairman, and members of the Subcommittee, thank you for inviting me to testify today. This hearing could not be more timely because the Senate hearing for Cass Sunstein, President Obama's choice to serve as "regulatory czar," will be held very soon and because the president has directed the Office of Management and Budget's (OMB) Office of Information and Regulatory Affairs (OIRA) to rewrite Executive Order 12,866, which governs the structure of regulatory review. Mr. Sunstein's predecessor, John Graham, used OIRA to expand control over regulatory policy to an unprecedented extent, delivering a body blow to the effectiveness of the nation's regulatory system in the name of "reforming" it. Consistent with President Obama's strong plurality in what the pundits call a "change

¹ The Center for Progressive Reform (CPR) is an organization of 60 academics from universities across the country specializing in the legal, economic, and scientific issues that surround federal regulation to protect public health, natural resources, and worker safety. One component of the Center's mission is to circulate academic papers, studies, and other analyses that promote public policy based on the multiple social values that motivated the enactment of our nation's health, safety and environmental laws. We seek to inform the public about scholarship that envisions government as an arena where members of society choose and preserve their collective values. We reject the idea that government's only function is to increase the economic efficiency of private markets. For more information, please see <http://progressivereform.org>.

election,” Mr. Graham’s discredited and destructive approach must be rejected and the role of regulatory czar must be fundamentally redefined.

My testimony today makes three crucial points:

1. **The Obama Administration and Congress should define a new mission for the regulatory czar.** The term “regulatory reform” has become a shorthand reference to the assertion that regulatory agencies--especially in the health and safety arena and most especially with respect to the Environmental Protection Agency (EPA)—must have a heavy net thrown over them to contain their excessive rules and overzealous staff. This approach was never a good idea and, in any event, is outmoded. *The American people need more, not less regulation on every front, from mortgage lending to workplace hazards. The regulatory czar’s mission should be to rescue struggling regulatory agencies by helping them to obtain more resources and stronger legal authority.*
2. **OIRA should stop reviewing individual regulatory proposals.** Empirical studies reveal that OIRA has served for well over 30 years as a killing ground for protective regulations. Except during the Clinton Administration, OIRA’s threat to target any given regulatory proposal has chilled the development of strong and effective regulation. *OIRA has plenty of work to do formulating regulatory policy and should leave the drafting of individual rule regulatory impact analyses and the making of final decisions to agency experts, supervised by Obama political appointees.*
3. **OIRA must stay out of science policy.** OIRA is a small office, comprised of approximately 40-50 professionals, the vast majority of whom are economists. During the Graham era of kingdom-building, five or six of these positions were set aside to hire scientists, who proceeded to propose radical changes in the way research would be used to make regulatory policy. *OIRA is not competent to propose science policy in the regulatory arena and should abandon this role.*

A New Mission for the Regulatory Czar and OIRA

Regulatory Killing Ground

The Reagan Administration introduced the requirement--continued by all subsequent presidents--that agencies must produce a cost-benefit analysis for every “significant rule,” a term of art meaning requirements imposing more than \$100 million in compliance costs. President Reagan and his successors also prohibited agencies from proposing or adopting rules until they are approved by economists at OIRA. This requirement gives this small office an unwarranted choke-hold over regulatory decisions.

Cost-benefit analyses are designed to provide a *quantified*—or numerical—estimate of both the potential costs and benefits of a proposed rule. Potential costs include whatever money companies will be compelled to spend to implement the remedies proposed in the rule, such as installation of pollution control equipment or obtaining and enforcing the use of hard hats and respirators for workers dealing with hazardous conditions or materials. When a rule requires the use of an emerging technology, prices fall as the market expands, lowering compliance costs. But these dynamics are ignored and compliance

costs are routinely overstated by industries opposing the new rules, and agencies do a poor job of critically evaluating such claims.

Potential benefits of a regulatory proposal include the harm that will be avoided if the regulation is implemented. Economists also insist on quantifying these benefits in monetary terms, an ostensibly straightforward approach that causes huge problems in practice. “Monetizing” human suffering or the irrevocable loss of natural resources is controversial from an ethical perspective. And much of the harm addressed by health and safety regulation is very difficult to reduce to numbers. An equally important problem is that the economists also insist on treating these figures as if they were any other kind of financial investments. People expect to receive a “return” on investments of money that increase the value of the initial amount over time. In essence, people get paid for allowing others—the banks or the government—to use their money. The economists argue that if someone who is exposed to a hazardous chemical today will not die of cancer for 25 more years, the value of the life saved by a regulatory intervention should be quantified as if it was such an investment. So the question becomes how much money would we need to invest today, at a rate of return of either three or seven percent (numbers specified by OIRA), to come up with \$6.8 million (a common estimate of the value of saving one life) in 30 years. This practice is known as “discounting.”

Because cost-benefit number-crunching deals with such uncertainty, these analyses can run to hundreds of pages of complex, dense, and highly technical data, projections, modeling, and mathematical formulas that deter any but the most determined stakeholders from challenging these analytical bottom lines. As troubling, distilling the series of arbitrary assumptions that underlie such calculations into a small set of numbers leaves a misleading impression of objectivity when, in fact, such analyses are notoriously susceptible to manipulation, making them ideal useful political cover for decisions to weaken regulations.

Although this point is rejected by cost-benefit enthusiasts, retrospective examinations of regulatory decisionmaking shows that the primary impact of such analyses is to weaken the protection of health, safety, and the environment, not strengthen it. Professor David Driesen undertook a comprehensive review of studies and reports documenting the impact of OIRA review, concluding that the process slowed and reduced the stringency of environmental, safety, and health regulation in “dozens of cases.” David M. Driesen, “Is Cost-Benefit Neutral?,” *University of Colorado Law Review* 77 (2006): 335, 355. He examined 25 rules identified by a Government Accountability Office (GAO) study as significantly affected by OIRA review in 2001-2002. GAO-03-929, *RULEMAKING: OMB’s Role in Reviews of Agencies Draft Rules and the Transparency of Those Reviews* (2003). He found that the OMB’s recommended changes would have reduced regulatory protections with respect to 24, while the remaining change was neutral.

In a similar vein, Professors Lisa Bressman and Michael Vandenbergh interviewed 35 top EPA political appointees during the first Bush and Clinton Administrations. Lisa Schultz Bressman & Michael P. Vandenbergh, “Inside the Administrative State: A Critical Look at the Practice of Presidential Control,” *Michigan Law Review* 105 (2006): 47, 50, 75. These respondents said that the OIRA review “regularly skews rulemaking in a deregulatory direction” and that OIRA staff use “cost-benefit analysis to impose its own normative preference for deregulation.” Professor Steven Croley’s work substantiates these conclusions. Steven Croley, “White House Review of Agency Rulemaking: An Empirical Investigation,” *University of Chicago Law Review* 70 (2003): 821, 877.

Lastly, Professors Lisa Heinzerling and Frank Ackerman applied traditional cost-benefit analysis to three regulatory decisions made in the 1960's and 1970's that are widely regarded today as unqualified successes. Frank Ackerman & Lisa Heinzerling, "Applying Cost-Benefit to Past Decisions: Was Environmental Protection Ever a Good Idea?," *Admin. L. Rev.* 57 (2005): 155. They concluded that the use of this methodology would have resulted in the reversal of all three decisions: lead would have stayed in gasoline instead of being removed; the Grand Canyon would have been dammed to generate hydroelectric power; and workers would have experienced uncontrolled exposure to vinyl chloride.

OIRA is staffed by approximately 40-50 economists who cannot possibly review every regulatory proposal thoroughly. Nevertheless, the threat of OIRA review is deeply disruptive of rulemaking. Because agencies do not know which cost-benefit analysis economists may find objectionable, they must gird up for battle over each regulation they are developing. These elaborate preparations, and the subsequent fights that do break out between OIRA and agency staff, slow rulemaking substantially.

Acute Regulatory Dysfunction

As the studies I just mentioned demonstrate, beginning with the first Reagan Administration, OIRA has served mainly to suppress and delay regulation thought to be excessive. This focus is hardly appropriate for the challenges confronting today's regulatory system. The allegation that these agencies have run amok, and are galloping across the tundra regulating without common sense and at an unaffordable cost to industry is no more credible than the argument made shortly before the current economic crisis an overweening Securities and Exchange Commission was thwarting financial institutions from bringing prosperity to the world. Instead, like the SEC, regulatory agencies covering the full spectrum of safety, health, environmental and financial protection of Americans are in a frighteningly dysfunctional state that threatens the well-being of every American.

The place to start in rescuing this failed system is to announce a fundamental re-orientation of the OIRA. Rather than chiding regulators for their alleged excesses, the OIRA should be helping agencies like the Consumer Product Safety Commission (CPSC), the Environmental Protection Agency (EPA), the Food and Drug Administration (FDA), the National Highway Traffic Safety Administration (NHTSA), and the Occupational Safety and Health Administration (OSHA) to produce smarter, better government. Rescuing these agencies by giving them adequate resources to fulfill their statutory mandates, helping them to develop strong, proactive agendas, and ensuring that they receive enhanced legal authority to take decisive action should be the top priorities for the regulatory czar and his OIRA staff.

This reorientation of roles is urgent, as illustrated by the acute and dangerous regulatory dysfunction that makes headlines every day. These incidents inflict real injury. They occur because these five agencies lack the resources and the political will to carry out their vitally important statutory missions effectively. The ranks of the civil service are decimated. The agencies are overburdened by mischievous Bush Administration "midnight regulations" and illegal regulatory decisions now under challenge in the courts. Congress has not reviewed or refreshed many of their authorizing statutes in at least two decades. Their budget resources are a fraction of what they need to fulfill mandates made infinitely more complex by the importation of foreign products, food, and pollution.

In 2007, for example, CPSC oversaw the recall of millions of consumer products, including Chinese-made toys that were slathered in lead paint and children's art sets that included little beads containing gamma hydroxybutyric acid (GHB), a powerful substance commonly referred to as the "date rape drug." Some toddlers who gummed or swallowed the beads had seizures and went into comas. As the media reacted to these events, it became clear that *80 percent of the toys sold in America* are imported from abroad, primarily from China, which has no meaningful health and safety regulation. The CPSC fields only 15 inspectors to screen such imports. Just last month, *Time Magazine* broke a story about the import of Chinese dry wall laced with sulfurous chemicals and used in thousands of homes in Florida, Texas, Louisiana, and other states. Homeowners and renters who could not afford to live anywhere else were exposed to fumes that caused severe adverse health effects from headaches to respiratory failure. The CPSC was mentioned as an after-thought in most news accounts, with state officials desperate to find a way to stop the imports and extract an explanation from manufacturers. Congress wrote the Consumer Product Safety Improvement Act in response to such scandals, but these new mandates remain underfunded and the statute never came to grips with the implications of dangerous imports, instead asking the agency to report back on its recommendations for change in three years.

A few weeks ago, GAO issued a report warning that EPA's capacity to deal with new climate change regulations was fundamentally compromised. GAO also moved EPA's ineffective regulation of toxic chemicals to its list of highest priority problems for government overall. As explained in a landmark series published by the *Philadelphia Inquirer*, Bush-era Clean Air Act regulations dealing with conventional pollutants were routinely overturned by judicial panels that ironically included the most conservative Bush appointees, indicating how far the Agency has strayed from implementing the laws as Congress intended. See "Smoke and Mirrors: The Subversion of EPA," http://www.philly.com/inquirer/front_page/20081207_An_Eroding_Mission_at_EPA.html. Regulation of mercury is in limbo, at least 15 years overdue. The Bush Administration OMB persuaded the president to overturn the advice of EPA's senior political appointees recommending a more stringent standard for ozone pollution, one that EPA's top scientists said was absolutely necessary to limit damage to crops, forests, and other natural resources. Clean Water Act protections are mired in a "no win" debate between point and non-point sources, with federal and state regulators lacking the fundamental tools they need to bring non-point pollution under control. The EPA's Integrated Risk Information System (IRIS) lacks inhalation values—the highest levels of airborne toxics that can be tolerated without adverse health effects—for many common hazardous air pollutants, and without these values, effective regulation is impossible. EPA has years of work ahead of it to correct these mistakes.

The FDA is struggling to come to grips with the resource imbalances and other problems that produced the Vioxx scandal and related failures to protect the public. It must completely revamp its efforts to police adverse effects in approved drugs. Its overall reputation and the morale of its staff suffered a body blow during its consideration of whether Plan B should be sold over-the-counter. All of these problems will require careful and sustained attention if we are to have any hope of restoring scientific integrity and independence to FDA new and existing drug oversight. Recent revelations regarding the apparently criminal conduct of a peanut processing company with facilities in Georgia and Texas reveal gaping holes in the food safety protection net. The company shipped salmonella-contaminated products that sickened 20,000 and caused nine deaths, provoking a recall that cost billions of dollars.

NHTSA has yet to deal effectively with the safety problems posed by Sport Utility Vehicles. Although these hazards are to some extent alleviated by the decreasing popularity of such vehicles, the economic downturn and falling price of petroleum products may well blunt these trends. As Bush appointee Jeffrey Runge, a medical doctor who was NHTSA Administrator during President George W. Bush's first term, told *The New York Times*, "The theory that I'm going to protect myself and my family even if it costs other people's lives has been the operative incentive for the design of these new vehicles, and that's just wrong." The same article described the research of Michelle White, an economist at the University of California, San Diego, whose calculations show that each accident where an SUV driver remains unhurt means four fatalities for the smaller car's occupants, pedestrians, bicyclists, and motorcyclists. Danny Hakim, "A Regulator Takes Aim at Hazards of S.U.V.s," *New York Times*, December 22, 2002, late edition, sec. 3.

OSHA is equally paralyzed on the regulatory front. As just one headline-grabbing example, the existing standard for crane safety has not been updated since 1971. OSHA staff prepared a consensus standard to update these requirements, but it has been stuck in the Secretary's office for many years. Beryllium, an extraordinarily toxic metal used in a variety of industrial applications, is regulated under a 1949 OSHA standard that is *ten times less protective* than the standard that applies to workers in facilities controlled by the Department of Energy, which updated its own protections in 1999. In fact, OSHA has issued only *two* new standards to control chemical exposures in the workplace over the last ten years. Descriptions of conditions in meat and poultry packing plants by GAO and a superb series of reports in the *Charlotte Observer* are hair-raising. GAO-05-96, *Workplace Safety and Health: Safety in the Meat and Poultry Industry, While Improving, Could be Further Strengthened*; *Charlotte Observer*, "The Cruellest Cuts, The human cost of bringing poultry to your table," <http://www.charlotteobserver.com/poultry/>. Yet this dangerous industry remains largely unregulated because OSHA lacks both the political will and the resources to attempt credible deterrence-based enforcement.

Solutions

OMB should revamp its Performance Assessment and Ratings Tool to focus on funding gaps.

Rather than view the primary job of a "regulatory czar" as stopping excessive regulation, Cass Sunstein and his OIRA staff should define as revamping the regulatory system to ensure that agencies are able to fulfill their regulatory missions in a vigorous, timely, effective, and wise manner. One critical place to start is for OMB to revamp its Performance Assessment Rating Tool (PART) used to audit the effectiveness of individual government programs to serve a much more crucial function: undertaking an analysis of the resource gap between how much it would cost to implement all of an agency's statutory mandates and the agency's individual budgets. Consider the following charts, tracking the budgets of the five health and safety agencies in *constant dollars* since they were created through 2006:

Figure 1

EPA Inflation-adjusted Budget Authority (1970-2007)

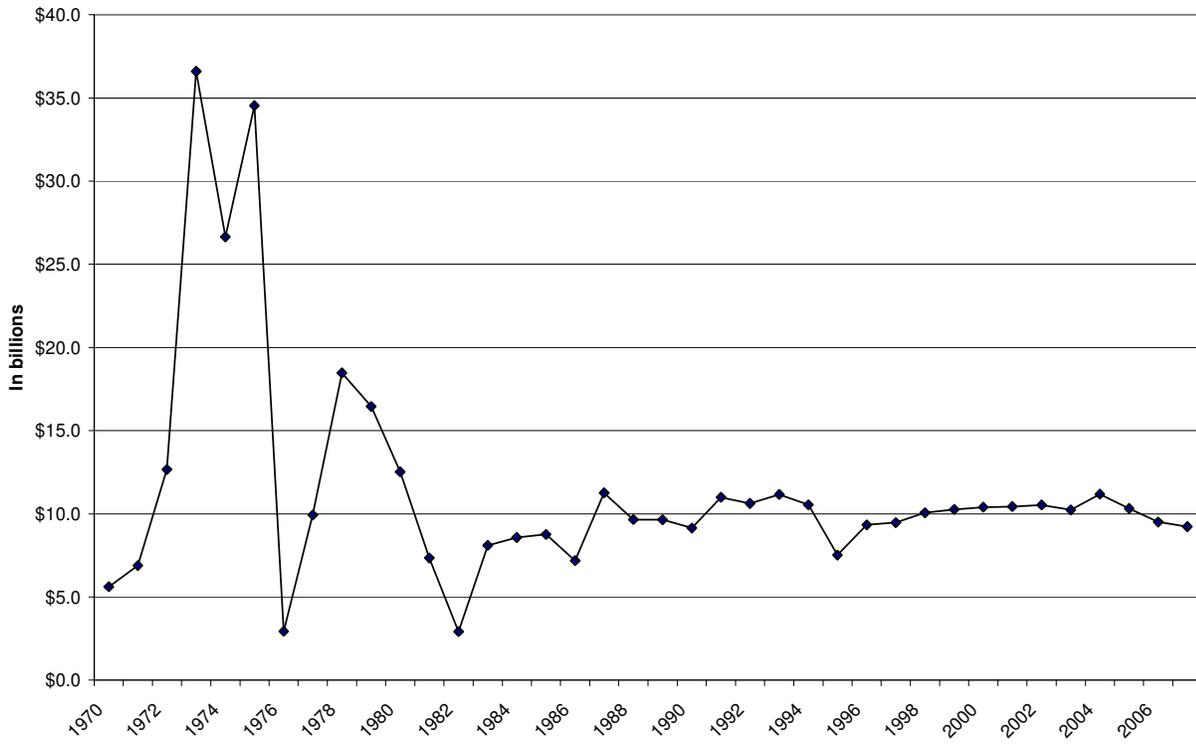
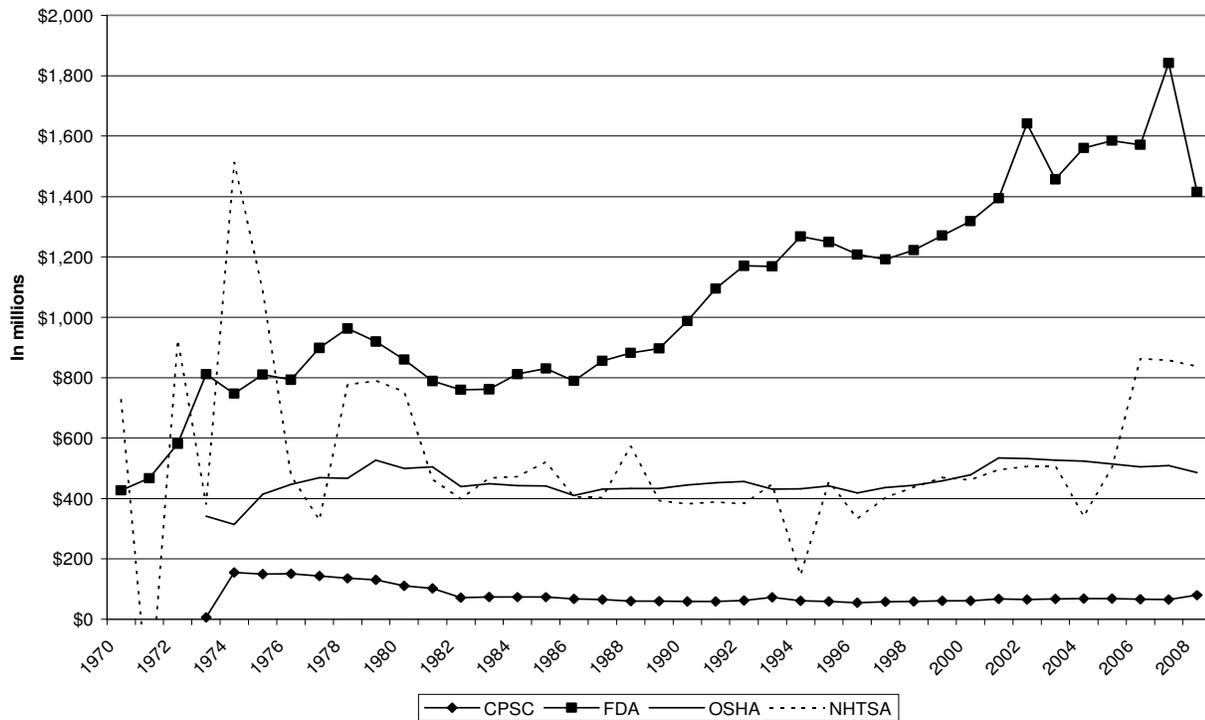


Figure 2

Inflation-adjusted Budget Authorities (1970-2008)



As these figures illustrate, with the exception of FDA, which enjoyed moderate funding increases to accelerate its process for approving new drug applications, these figures show that none of the agencies have received significant increases in their budgets since roughly 1980, approximately a decade after they were created. The EPA budget level set in 1984, which remains roughly the same amount in constant dollars as it is today, preceded passage of a series of ambitious amendments to every major environmental law, including the 1990 Clean Air Act Amendments. During this time period:

- The United States population grew 34 percent, from 227 million in 1981 to 304 million in June 2008.
- In 1975, the OSHA was responsible for policing 3.9 million workplaces, which employed 67.8 million workers; it had 2,405 inspectors to do the job. By 2006, the number of workplaces had grown to 8.7 million, worker population to 133.8 million, and the number of OSHA inspectors had fallen to 2,165.
- Between 1987 and 2006, the number of prescriptions filled in the United States came close to tripling, from 1.2 billion to 3.1 billion.
- In 1980, 155,796,000 motor vehicles were registered in the United States. By 2006, that number stood at 244,165,686.

The President should suspend OIRA review of individual rules.

A second crucial reform is to terminate OIRA's responsibility for spot-checking individual regulatory impact analyses. As explained above, this review is far from comprehensive because OIRA has such a small staff. Instead, under Republican presidents, the historical purpose of such reviews was to intimidate agencies into reducing the protectiveness of their own rules in anticipation of potential OIRA disapproval. Apparently, these administrations did not have confidence that their appointees to head the agencies could exert enough control over career staffs to accomplish presidential goals. Ironically, this fear that agency administrators would "go native" did not really materialize, especially under the Bush II Administration. Furthermore, all of the agencies have ample expertise to prepare such documents, under the supervision of political appointees who have expertise in the matter, and OIRA review is duplicative.

Instead of bogging itself down in the micromanagement of specific rulemaking, OIRA should spend its time doing work that no other unit of government is set up to accomplish:

- **Resolving interagency disputes over cross-cutting policies.** OIRA should play a central role in convening the principals of warring agencies to resolve disputes over regulatory policy. In this role, OIRA must avoid the pitfall of hauling one agency (e.g., EPA) before a panel of other agencies and departments that it is assigned to regulate (e.g., the military) to answer for its sins. Instead, OIRA should serve as a neutral broker, well-informed on the legal constraints, especially the requirements of agency statutory mandates that affect the resolution of the dispute, obtaining the assistance of Justice Department experts as necessary.
- **Conducting original research on cross-cutting regulatory issues.** OIRA should spend a significant part of its time exploring important research topics of broad application. For example, as I mentioned earlier, limited research by academics shows that regulatory costs are chronically over-estimated by industries attempting to avoid or weaken regulatory proposals. OIRA's economists, who have at their disposal considerable retrospective data on the government's experience with regulation, could assist greatly in the development of more reliable methodologies for such estimates. Other cross-cutting issues include the efficacy of deterrence-based enforcement, as opposed to compliance counseling and the development of more meaningful "accountability metrics" to ensure that agencies are performing their statutory missions effectively.

OIRA and Science

At various bitter moments in the past, the present, and—I fear—the future, the legal profession is subjected to impassioned attacks for attempting to dominate the nation's civic affairs. More than once, we have heard the accusation that a piece of legislation is a "lawyers' full employment act" drafted for the primary purpose of making sure that we attorneys always have jobs meddling in other people's affairs. Yet I am afraid that as appropriate as this taunt may be in certain contexts, another profession—namely, economists—has provided the legal profession with serious competition on the power-grabbing front.

Under John Graham, OIRA embarked on two fundamentally misguided projects to change the way regulatory science is analyzed and used. The first involved the peer review of studies used by federal agencies to make such decisions. The second purported to announce a “one-size-fits-all” risk assessment policy for the entire government. These proposals were drafted by a tiny group of scientists hired by Graham to expand his reach into science policy. The documents were so poorly informed and extreme that they provoked a backlash of opposition from the scientific community, the public interest community, and this Committee. A panel convened by the National Research Council condemned the risk assessment bulletin in no uncertain terms. National Research Council, *Scientific Review of the Proposed Risk Assessment Bulletin from the Office of Management and Budget*, available at http://www.nap.edu/catalog.php?record_id=11811. In the end, OIRA was compelled to drastically revise the peer review bulletin, cutting back severely on its scope. It withdrew the risk assessment guidance.

To give you some sense of these proposals, their flaws, and the trouble they caused, I have attached three documents to this testimony: a May 5, 2006 letter from Chairmen Bart Gordon, John Dingell, Henry Waxman, and James Oberstar to Ralph Cicerone, the president of the National Academy of Sciences regarding the risk assessment proposal; a May 23, 2006 article I wrote about the risk assessment proposal for *Risk Policy Alert*; and the Center for Progressive Reform’s December 7, 2003 comments on the peer review proposal .

Given this unfortunate track record, it is vitally important that OIRA under the Obama Administration confine its supervision of government to areas within its expertise, leaving to experts such as White House science policy adviser John Holdren the difficult job of restoring the independence and integrity of regulatory and other science policy issues throughout the government.

Conclusion

When Barack Obama ran for president, he defined the role of government as helping people when they cannot help themselves:

Now, understand, I don't believe that government can or should try to solve all our problems. You don't believe that either. But I do believe that government should do that which we cannot do for ourselves--protect us from harm; provide a decent education for all children--invest in new roads and new bridges, in new science and technology. ... Look, if we want get through this crisis, we need to get beyond the old ideological debates and divides between the left and the right. We don't need bigger government or smaller government. We need better government. We need a more competent government. We need a government that upholds the values we hold in common as Americans.

To deliver real change, OIRA must embrace this mandate, and not the false premise that its most important mission is to prevent regulatory agencies from interfering with business.

ATTACHMENTS:

- 1 Congressional Letter to NAS President
- 2 Steinzor Article on Proposed Risk Assessment Guidance
- 3 CPR Comments on Peer Review Proposal