

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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and

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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 Vandenberg interviewed 35 top EPA political appointees during the first Bush and Clinton Administrations. Lisa Schultz Bressman & Michael P. Vandenberg, “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)

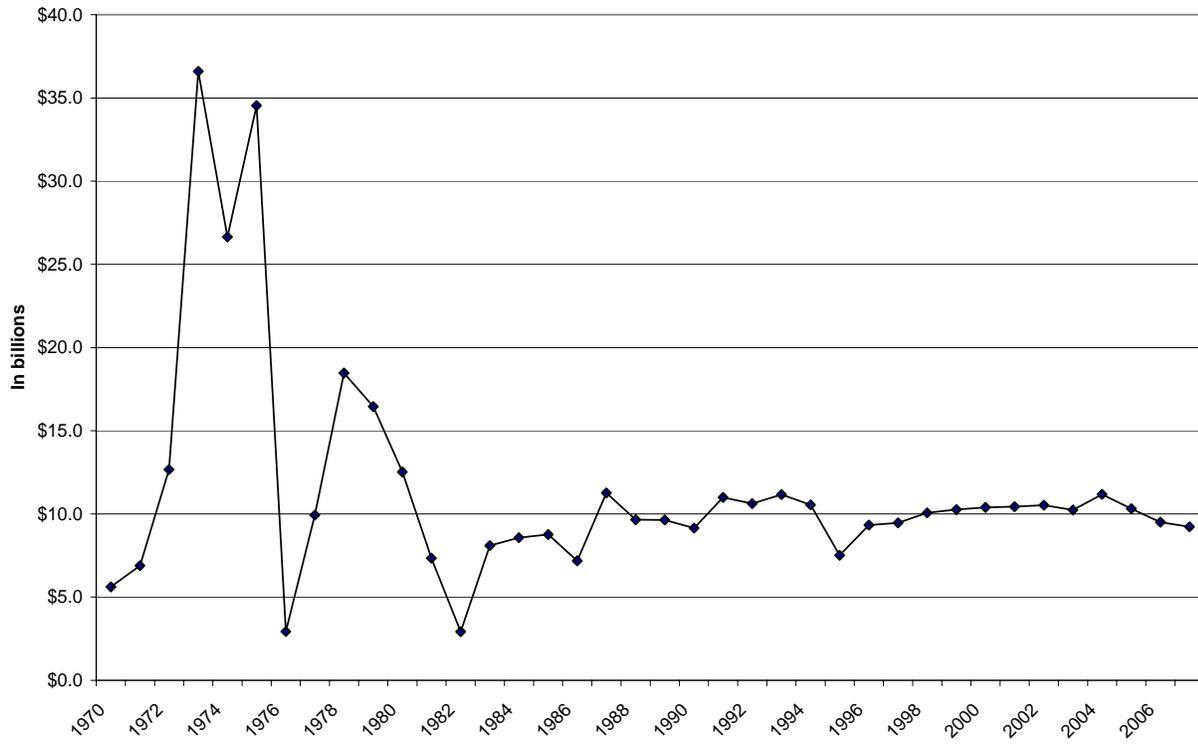
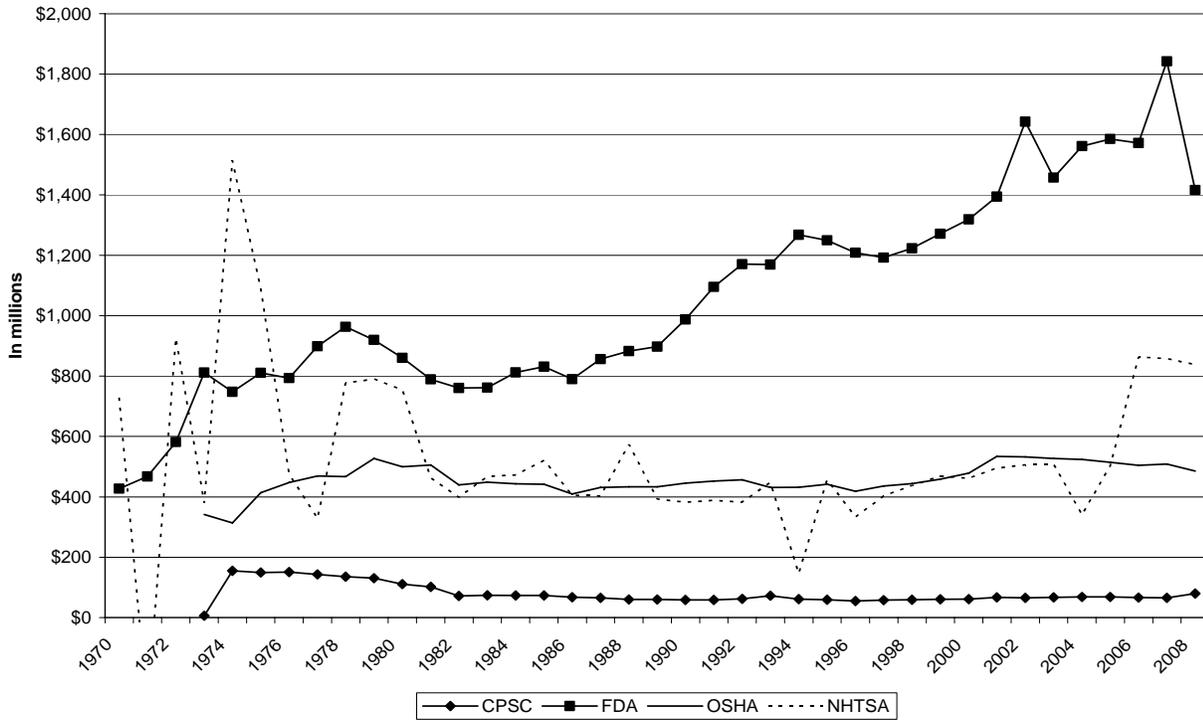


Figure 2

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

Congress of the United States
House of Representatives
Washington, DC 20515

May 5, 2006

Dr. Ralph J. Cicerone
President
National Academy of Sciences
500 5th Street, N.W.
Washington, DC 20001

Dear President Cicerone:

We are writing in regard to the National Academy of Sciences' (NAS) agreement to review the Office of Management and Budget's (OMB) Proposed Risk Assessment Bulletin (Proposed Bulletin). We are concerned that the description of NAS' review does not include important issues raised by the Proposed Bulletin. We urge NAS to define clearly the scope of its review, and either to expand the scope of its review or to articulate the issues raised by OMB's Proposed Bulletin that NAS will not address.

The Proposed Bulletin, which OMB issued on January 9, 2006, would direct agencies to comply with specified requirements when they evaluate risks to public health, safety, and the environment. OMB contracted with NAS, Contract No. 68-C-03-081, for an Ad Hoc Committee of the Board on Environmental Studies and Toxicology (Committee) to review OMB's Proposed Bulletin.

OMB's Proposed Risk Assessment Bulletin raises a number of scientific and technical issues regarding risk assessments. NAS is a logical choice to address such issues in a substantive, constructive critique of the Proposed Bulletin, given the Academy's extensive experience reviewing specific risk assessments for federal agencies and past work summarizing risk assessment techniques and best practices.

However, OMB's Proposed Bulletin also raises serious concerns about its effect on individual agencies' risk assessment practices, including whether it conflicts with statutory directives enacted by Congress. These and other important legal, policy, and budgetary questions would have to be considered in any comprehensive evaluation of OMB's Proposed Risk Assessment Bulletin.

In light of these concerns, the scope of NAS' review is very important. We are writing to inquire as to whether NAS is able and plans to address these concerns, and if not, to urge NAS to make clear in its final report the limited scope of its review. If the Committee's review does not address the full range of issues raised by the Proposed Bulletin, the NAS review cannot be considered a comprehensive review of the Proposed Bulletin.

Charge and Scope of NAS Review

OMB's charge to the NAS and the Academy's proposal produced in response to this charge are ambiguous as to the scope of the Committee's review. It is important that this ambiguity be resolved.

NAS' Plan of Action indicates the Committee will conduct a "scientific review" of the Proposed Bulletin. This suggests that the Committee will confine its review to the scientific and technical aspects of the OMB proposal. However, the specific questions to be addressed by the Committee imply that consideration will be given to issues that go beyond the scope of a scientific review.

Indeed, it appears impossible to provide a comprehensive answer to the questions without reaching beyond the scope of a scientific review. For reasons we will detail below, we believe consideration must be given to questions such as whether this guidance is necessary, and whether the imposition of a single set of rules for the performance of risk assessment across all federal agencies is appropriate.

A comprehensive review of the Proposed Bulletin must address at least the following issues:

- 1) The necessity of the Proposed Bulletin, given the risk assessment and review procedures already in place;
- 2) Potential conflicts between the Proposed Bulletin's directives and existing statutory directives;
- 3) The additional resources that would be needed for agencies to comply with the requirements of the Proposed Bulletin and the effect of these demands on agency operations; and
- 4) The potential for politicization of science created by the establishment, oversight, and enforcement of requirements for scientific and technical analyses by a White House policy office with little scientific expertise.
 - What is the precise scope of NAS' review? Will NAS address each of the issues listed above?

In addition, it is unclear whether the NAS will address the fundamental question of whether the Bulletin should be finalized, or whether the NAS will only recommend improvements to the Proposed Bulletin.

The contract and the NAS proposal describing the review appear to assume that some form of this Bulletin should be finalized and that the only open questions are those pertaining to the specific guidance contained in the Bulletin. For example, in the Purpose, the charge states:

"It is recognized that a review by NAS would be beneficial and informative as OMB moves forward *to revise and finalize the Bulletin.*" (emphasis added)

It appears that, under this charge, the Committee may offer additions to the guidance, but not consider whether the Proposed Bulletin should be withdrawn. This is emphasized in the description of the task, which states:

"The NAS shall strive to develop a consensus report *that contains advice for modifications to the Bulletin*. ... The expert panel may add *additional risk assessment issues* that they determine to be of importance." (emphasis added)

Yet, in light of the issues identified in this letter, we believe that a complete evaluation must consider whether OMB should issue a risk assessment bulletin of this kind.

- Will the Committee consider the threshold question of whether OMB should finalize and issue this Bulletin?

Consistency with Congressional Intent and Existing Law

The introduction section of OMB's proposed Risk Assessment Bulletin provides a brief description of risk assessment and some examples of the agencies that perform these analyses. The introduction also includes a description of the statutes cited as the legal basis for OMB's authority to issue the guidance. There is no mention, however, of the fact that agencies, particularly regulatory agencies, often perform risk assessments in accordance with specific statutes. We also note that the charge does not include legal expertise in the list of "Expertise Required."

Our preliminary analysis of the OMB proposal indicates the analytical approach mandated in these guidelines represents a significant departure from approaches contained in the many statutes governing health, safety and the environment, and from statutory direction to federal agencies to protect human health, safety, and the environment.

We note that although there have been legislative proposals in several Congresses to mandate government-wide criteria for the use of risk assessment and cost-benefit analyses, these bills have never been enacted. Instead, Congress has continued to use a statute-by-statute approach to guide agencies' use of these analytical tools and to set standards for health and environmental protection in the context of discrete issues. OMB's Proposed Bulletin is in conflict with the approach taken in existing law.

The Proposed Bulletin appears to conflict with standard risk assessment practice by combining risk assessment and risk management analyses, and it appears to offer a risk management standard that differs considerably from numerous health, safety, and environmental statutes. The Proposed Bulletin also appears to require cost-benefit and comparative risk analyses to be performed in combination with risk assessments. Cost-benefit analyses are required to be done separately from risk assessments in a number of our health, safety, and environmental statutes, and requirements for comparative risk assessment represent a new analytical requirement that may be inappropriate for many of these statutes.

- Will the Committee undertake an analysis of the degree to which OMB's proposal conflicts or is inconsistent with existing laws?

Existing Agency Risk Assessment and Review Procedures

The ostensible goal of OMB's Proposed Bulletin is to improve the technical quality and objectivity of risk assessments prepared by federal agencies. To determine whether the Proposed Bulletin will achieve this goal requires much more than a technical analysis of the risk assessment procedures contained in the Proposed Bulletin. Among other things, such a determination requires an evaluation of the adequacy of the existing risk assessment

procedures used by federal agencies. It also requires an evaluation of whether the uniform requirements imposed by the Proposed Bulletin would improve current practices, either in some cases or across-the-board.

For a comprehensive review, the Committee must consider the current baseline level of the "technical quality and objectivity" of risk assessments performed by federal agencies. OMB's initiation of this Proposed Bulletin suggests there is some deficiency with current federal risk assessment practices. However, OMB did not provide any evidence of systemic deficiencies in federal agencies' current risk assessment practices. We urge the Committee to be clear in defining the baseline chosen as a basis for comparison and to evaluate carefully those baseline practices.

Agencies currently have numerous mechanisms for review of their risk assessments and other technical work products. Many agencies have one or more Science Advisory Committees made up of outside experts that review agency work. OMB currently mandates interagency reviews of risk assessments at its discretion and uses its authorities to review agency work products. Numerous NAS Committees have reviewed specific agency risk assessments – some of which are underway at this time. When analyses are incorporated into rulemaking procedures, there are opportunities for further review and public comment.

Agencies have traditionally had discretion to determine the type and scope of the risk assessments they need to undertake within the boundaries of their statutory directives and the purpose of the specific risk assessment. The imposition of a one-size-fits-all set of requirements for conducting risk assessments, such as those in this Proposed Bulletin, erodes agency discretion to determine the most appropriate level and type of analysis.

- Is the Committee going to consider all the existing procedures that agencies now use to ensure the technical quality of their risk assessments, including the current OMB review procedures, and then identify what, if any, additional benefits OMB's Proposed Bulletin would provide?
- Will the Committee consider the question of the appropriateness of a one-size-fits-all approach to risk assessment among agencies with very different missions, different scientific bases for analysis and testing, and different statutory directives?

Agency Resources and Timeliness of Agency Action

As procedures in the Proposed Bulletin are expected to require agencies to take additional steps and devote additional time and resources to conducting risk assessments, we have concerns regarding the overall effects of such resource diversions and delays.

It appears the Proposed Bulletin will create additional analytical requirements for agencies. To the extent the requirements of the Proposed Bulletin differ from existing risk assessment procedures, the agencies will be required to include additional information and analyses to comply with OMB's Proposed Bulletin. An estimate of the degree to which the requirements of the Proposed Bulletin will increase analytical burdens on the agencies will be possible only by a comparison between current agency risk assessment procedures and the requirements of the Proposed Bulletin.

The additional time required to comply with the procedures in the Bulletin also should be assessed. As we noted earlier, agencies are required to submit their work to numerous reviews

already. Agencies perform numerous analyses in the course of producing their risk assessments. They also produce cost-benefit analyses, regulatory impact analyses, small business impact analyses, and analyses on potential impacts of regulations on state and local governments. They perform these analyses in accordance with individual health, safety, and environmental statutes, as well as statutes and Executive Orders governing regulatory procedures of all agencies (e.g. the Paperwork Reduction Act, the Unfunded Mandates Reform Act, the Regulatory Flexibility Act, E. O. 12866, etc.).

Any additional requirements for analysis and review should produce a clear and substantial public benefit. This Proposed Bulletin should not become cover for dilatory tactics by special interests. Paralysis by analysis does not serve the interest of science or public policy.

We are also concerned about the potential for this Proposed Bulletin to increase significantly the costs to the covered agencies. Agencies have limited staff and budgets. OMB has supplied no cost estimates for this proposal, and it appears unlikely that any additional resources would be provided to agencies to fulfill their obligations under the Proposed Bulletin.

- Will the Committee assess the potential for and effects of increased costs and increased time to produce agency work products?

OMB's Role and Influence on Science and the Rulemaking Process

We assume the Committee will need to obtain information from the various federal agencies regarding their current risk assessment practices and whether OMB's proposal directs them to perform risk assessments in a manner that is not compatible with their needs, that is burdensome, or that is contrary to their statutory responsibilities.

If so, we have serious reservations about the level of candor the Committee will hear given that it will be asking agencies to offer opinions and information that might directly conflict with a policy proposal from the White House. We note this is not a problem unique to any individual Administration. The nature of the relationship between the Office of Management and Budget and federal agencies does not foster candid evaluations by career agency employees of the policies proposed by the Administration.

For example, *Inside EPA* recently reported that Dr. Nancy Beck, one of the principal OMB authors of this Proposed Bulletin, is now on detail to the Office of the Science Advisor, Dr. George Gray, at the Environmental Protection Agency (EPA). This example illustrates our concern. This Office will play a key role in providing agency comments about the Proposed Bulletin. Dr. Gray, a recent political appointee to EPA, a former colleague of Dr. John Graham, and Dr. Graham's co-author on a number of articles on risk assessment (one of which is cited by OMB in the footnotes in the Proposed Bulletin) is a proponent of the approach outlined in this Proposed Bulletin. Dr. Gray's agreement to have one of the authors of the Proposed Bulletin from OMB on detail to his office during the time period when the comments are being prepared does not give us confidence that the comments provided by EPA will reflect the concerns of EPA career practitioners of risk assessment.

The task of maintaining objectivity and delineating the boundary between science and policy is a difficult one. It is important to have safeguards to protect the integrity of scientific and technical information from political interference. We have concerns that barriers between science and politics would be eroded by involvement of a White House policy office in the establishment and

enforcement of criteria for the production of risk assessments and other scientific and technical work products by federal agencies.

Congress authorized federal agencies to implement statutes in specific areas of public health, safety, and environmental protection. OMB review is not required by any of these statutes. Technical expertise resides within the agencies, not within the Executive Office of the President. Agency actions are required by law to include public processes to ensure transparency. OMB has no such mandate, and its influence over agency actions is significant but poorly understood and documented.¹

A review that seeks to determine whether OMB's Proposed Bulletin would increase objectivity of risk assessments must consider the fact that the Executive Office of the President, of which OMB is a part, is first and foremost a policy office dedicated to implementing the policies of the President's Administration. As the Government Accountability Office (GAO) found in its 2003 report, "The Office of Information and Regulatory Analysis (OIRA) is part of the Executive Office of the President, and the President is OIRA's chief client."² OMB does not approach the review of agency work products from an unbiased perspective.

- Will the Committee address the question of whether it is feasible and desirable to have risk assessment requirements issued, overseen, and enforced by a policy office with little scientific expertise and no public accountability?

Conclusion

At times, risk assessment can be a useful tool to assist the government in decision-making. It is intended, however, to be a decision support tool, a means to the end of implementing laws ensuring public health, a safe workplace, a clean environment, functioning ecosystems, and robust engineered structures, among others. Agency cost and time to implement the Proposed Bulletin's requirements must be considered in light of the goals and requirements Congress has set in these areas. The Proposed Bulletin is not in the public interest if it results in undue delay in achieving the goals Congress established in our laws for public health, environmental, and workplace safety.

We value the expertise the NAS brings to policy deliberations. The Committee's findings regarding the OMB Proposed Risk Assessment Bulletin will carry great weight in this policy debate. We urge the Committee to be as clear as possible about the scope of its deliberations and the specific issues its review will and will not encompass.

¹ "Our review documented OIRA's direct influence with regard to more than two dozen rules in which it suggested significant changes that were ultimately adopted by the rulemaking agencies. OIRA's presence in the rulemaking process may also have a subtler, more indirect effect on agencies' decision making—discouraging them from submitting rules that OIRA is unlikely to find acceptable and encouraging them to make the case for the regulations that they do submit more carefully. However, the OIRA regulatory review process is not well understood or documented, and the effect that OIRA's reviews have on individual rules is not always easy to determine." P.110. General Accountability Office (GAO); "Rulemaking OMB's role in Reviews of Agencies' Draft Rules and the Transparency of those Reviews." September 2003, GAO-03-929. 217pp.

² General Accountability Office (GAO); "Rulemaking OMB's role in Reviews of Agencies' Draft Rules and the Transparency of those Reviews." September 2003, GAO-03-929. 217pp. (page 110)

Thank you for your consideration and attention to these important issues.

Sincerely,



BART GORDON
Ranking Member
Committee on Science



JOHN D. DINGELL
Ranking Member
Committee on Energy and Commerce



HENRY A. WAXMAN
Ranking Member
Committee on Government
Reform



JAMES L. OBERSTAR
Ranking Member
Committee on Transportation and
Infrastructure

Risk Policy Report

Guest Perspective

The Legacy of John Graham: Strait-Jacketing Risk Assessment

Date: May 23, 2006 -

By Rena Steinzor

Economists at Every Table

Risk assessment is the coin of the environmental realm, figuratively and literally. It is also the primary source of the most draining, counterproductive disputes preoccupying the Environmental Protection Agency (EPA). Risk assessment is not the only regulatory methodology used by EPA and other agencies assigned to protect public health, safety, and the environment. Different tools -- most notably the technology-based controls that underlie the great successes of statutes such as the Clean Water Act -- have accomplished more protection, in many cases for less money. But beginning in the mid-1980's, decision-makers have felt disgraced if they do not take a run at conducting a risk assessment on a problem, translating the results into numbers that are deceptively precise. Curtailing this trend is not in the cards for the foreseeable future.

Given its importance, it was no surprise when John Graham's parting salvo as the director of the Office of Management and Budget's (OMB) Office of Information and Regulatory Affairs (OIRA) was a *Proposed Risk Assessment Bulletin* (bulletin) that was intended to be the most prominent aspect of his legacy.¹⁷ The 26-page document would establish uniform, government-wide standards for risk assessments regarding human health, safety, or the environment.¹⁸ OMB will accept comments until June 15, 2006 and a National Academy of Sciences (NAS) panel is conducting a review of the proposal.¹⁹

Graham's assertion that OMB is qualified to define what constitutes an acceptable risk assessment displays misplaced confidence of the first order. Despite his aspiration to enlarge OIRA's role in science policy, Graham cannot possibly have added more than a handful of scientists to a staff overwhelmingly dominated by economists and budget analysts. If OIRA succeeds in this remarkable power grab, unqualified economists will take their seats beside toxicologists, epidemiologists, pediatricians, neurologists, engineers, statisticians, and other qualified experts as the complex implications of scientific uncertainty are debated.

By raising the "expertise" question, I do not mean to pick a shop-worn, counterproductive fight about whether OMB is entitled to conduct regulatory oversight on behalf of the president. Risk assessment is a cornerstone of many important decisions that OIRA reviews. Yet this effort to control every form of risk assessment *pre-*

rulemaking goes far beyond that basic function, even assuming that the polarized spectrum of OIRA's constituencies could agree on its appropriate oversight role.

Under the bulletin, any assessment, no matter what its nature or scope, must estimate the "central" risk likely to result from exposure, using a formula for "weighting" model results that is as vague as it is pseudo-scientific. Agencies will be compelled to fast forward to the end of their decision-making process, determining all available options for managing risk before they complete assessments. Risk assessments will be rejected unless they are based on research determining "No Observed *Adverse* Effects Levels" (NOAELs), as opposed to the long-standing practice of determining "No Observed Effect Levels" (NOEL). And any perceived misstep along the way could trigger challenges to agencies' compliance with the Information Quality Act (IQA) (or Data Quality Act), one of the worst appropriations riders enacted by Congress. OMB claims legal authority to interfere with the scientific process in this aggressive and inappropriate manner under the IQA, although the one-page law says nothing specific about its authority in this arena.

Tobacco for Everything

The IQA says that information "disseminated" by the government must be "correct" and of high "quality, objectivity, utility and integrity."²⁰ The concept for such a mandate originated with EPA's report on second-hand smoke.²¹ Philip Morris Inc. was fighting a rear-guard battle against further controls of tobacco and was heavily invested in picking apart every detail of the report. The company hired Jim Tozzi, a Reagan-era OIRA veteran, to persuade his former colleagues to accomplish this charmingly over-simplistic mandate administratively. After all, who could oppose the idea that government should establish a process for outside parties to challenge its dissemination of incorrect information?

As it turned out, seasoned bureaucrats could easily harbor misgivings about this new approach to obstruction and Clinton-era OMB officials were no exception. Frustrated by their indifference, Tozzi went to Capitol Hill where he achieved relief via a rider on 2001 "must pass" appropriations legislation. From these modest origins, the IQA has spawned guidance from every federal agency and department for how they will consider requests for correction of a wide variety of information.

Of course, "truth" and "correctness" are elusive concepts when the science, technology, and economics underlying such decisions become ever more complex. As the tobacco industry well understood, challenging any debatable assertion, no matter how minor, contained in every piece of unfavorable research is the best way to muddy the waters to confound regulators, stalling decisions until the tide of research turns completely and washes away these last outposts of resistance.

Enforcing the Bulletin

This "corpusecularization" of science, to use the term coined by Professor Thomas McGarity,²² is the foundation of the "sound science" movement that is in full swing both

in the U.S. and internationally. Its central tactic is the flyspecking of scientific studies to find individual “errors” of three distinct kinds: (1) clear misstatements of fact; (2) decisions that could have been made differently; and (3) science policy judgments that are unpopular with special interests.

The problem with the discovery of factual mistakes is that corpuscularists demand the exclusion of an entire study whether the error is major or minor, preventing scientists from using their expertise in a “weight of evidence” evaluation that takes mistakes into account in evaluating -- but nevertheless using -- such research. As for the second and third categories, the sound science movement’s has achieved great, if undeserved, rhetorical success by labeling as “incorrect” scientific judgments regulated industries do not like, regardless of whether such judgments are legitimate, common, and transparent. Scientists adopt assumptions all the time in order to proceed with their work. They may decide to use groups of 25, not 40, rats in a bioassay. By challenging such judgments as mistakes that should discredit a study, corpuscularists put everyone on a treadmill of controversy with no easy escape. Similarly, such science policy judgments as the use of “safety factors” to compensate for uncertainties in animal testing may be a legitimate concern in deciding how to evaluate a study but are not a sensible reason to ignore it entirely.

The campaign to deconstruct science in order to gain the upper hand in regulatory decisionmaking has continued at a rapidly quickening pace in all arenas -- from rulemaking to judicial proceedings to the scientific literature. Thus far, the IQA has played only a supporting role. Government-wide, IQA “Requests for Correction” number in the hundreds, not thousands, and agencies have rejected most of them in short order. All that could change, however, if the IQA provides a route to judicial review, especially for studies, reports, toxicological profiles, and risk assessments issued before or apart from rulemaking. Whether or not regulated industries win such appeals, opportunities to undermine the validity of adverse information and delay decision-making could well be worth the litigation costs.

A few weeks ago, the U.S. Court of Appeals for the Fourth Circuit made short shrift of a bid to obtain judicial review of agency IQA decisions under existing language. Judge J. Michael Luttig wrote that the IQA does not create a cause of action for any particular person or group to challenge the correctness of information in court because Congress did not specify who would have standing in such circumstances.²³ Of course, Congress could fix this problem and the Chamber of Commerce has pledged to go this route. If the matter is debated fully, and industry lobbying does not win out over the long-standing concerns of the House and Senate judiciary committees about acute docket overload in the federal courts, the IQA could be transformed from nuisance to major wrench in the works of health and safety regulation. In effect, it would then amount to a codification of corpuscularization, especially with respect to documents such as risk assessments covered by the bulletin, which was supposedly written to implement the IQA.

One Small Size Does Not Fit All

The threshold problem with the bulletin is that it reflects the naïve belief that uniform, government-wide standards would improve a process that has almost as many iterations as it does results. The bulletin requires agencies to include a “central or expected” risk estimate whenever a “quantitative characterization of risk” is made available, and mandates that quantitative estimates should be done “whenever possible.”²⁴ Just how would one calculate this central estimate?

This bulletin uses the terms ‘*central*’ and ‘*expected*’ estimates synonymously. When the model used by assessors is well established, the central or expected estimate may be computed using *standard statistical tools*. When model uncertainty is substantial, the central or expected estimate may be a *weighted average of results* from alternative models. *Formal probability assessments* supplied by qualified experts can help assessors obtain central or expected estimates of risk in the face of model uncertainty.²⁵

Suppose we must conduct a risk assessment of a single toxic substance (think arsenic, dioxin, perchlorate, mercury, or vinyl chloride) and have available chemical structure analyses, animal and epidemiological studies, and fate and transport models. Each piece of research has its strengths and weaknesses, including the inevitable policy-laden, default assumptions about the shape of the dose response curve, the level of exposure of both animal and human populations, and the pharmacokinetics of what happens to the chemical once it enters the body.

The bulletin appears to require that the numeric results of specific subgroups of models be averaged together. One example is the hotly contested area of dose-response curve models that use either traditional, “no threshold” assumptions or assume that low doses of specific chemicals are “acceptable.” But the bulletin does not stop there. Instead, it appears to require that the numeric results of the full range of “apples and oranges” models somehow be subject to number crunching, also yielding a single estimate of risk.

Given the right, balanced, and suitably skillful risk assessor, a reference dose (RfD) for a single chemical can be calculated, although the calculation will require a series of scientific findings *and* science policy judgments that must remain fully transparent so that they can be debated fully. These difficulties are the reason why NAS panels routinely wring their hands over such numbers and either add a series of safety factors to hedge their bets²⁶ or pronounce the EPA RfD “justifiable,”²⁷ as they did with EPA’s mercury and arsenic reviews.

Now suppose that we are doing a risk assessment that has considerably more dimensions: an assessment of the risks posed by a substantial expansion of nuclear energy or the implications of a terrorist attack on the chemical industry. Anyone familiar with the practice of risk assessment in this broader context would recognize the foolishness of attempting to calculate a central number that reflects the wide variety of models and other methodologies used by multi-disciplinary approaches. Reducing such disparate pieces of data to one number can only produce the “junk” science that sound science advocates assure us they are determined to eradicate. Even constructing a meaningful *qualitative* statement summarizing central risk poses substantial challenges.

The Great Conflation

The fact is that risk assessments come in all shapes and sizes. They can take weeks, months, years, or decades. The perceived magnitude of the risk inevitably plays a crucial role in determining an assessment's nature and scope, and OMB wisely advises risk assessors to be transparent about these decisions.²⁸ But it is one thing to acknowledge that science policymakers cannot help but think about the importance of a problem and what they might be able to do about it when they design an assessment and quite another to say that they must identify and assess those solutions *before* the nature of the risk is established. And yet the bulletin demands that they undertake exactly this task:

“[R]isk assessments that will be used for regulatory analysis ... shall include ... an evaluation of alternative options, clearly establishing the baseline risk, as well as the risk reduction alternatives that will be evaluated [and] a *comparison of the baseline risk against the risk associated with the alternative mitigation measures being considered.*”²⁹ (italics added)

Distinctions between risk *assessment* and risk *management* have provoked many a lengthy and esoteric argument in the rarified circles that undertake this troublesome work. Across the political spectrum, many believe that there is no clear line between the two, especially in the sense that policymaking, as opposed to “pure” science, infects both aspects of any problem. “Hard” science informs the design of experiments and determines the results, while “trans-science” permeates everything that happens to those results before they affect human affairs.

Acknowledging this reality is not the same thing as accepting the very large stride that is necessary to get to the idea that risk assessors must worry about the difficulty of finding a remedy before they have assessed the risk. One especially pungent example is testimony by Colonel Dan Rogers, a lawyer by training and Department of Defense's point person on perchlorate, before the NAS panel reviewing EPA's RfD on perchlorate:

Thousands of men and women in the uniformed services of the United States of America eagerly await the results of your careful and considered and objective deliberations, for what you decide will have a greater impact on their lives than on any others. ... [T]here is no room for reliance on science *policy* precaution for its own sake ... Every layer of science *policy* precaution inhibits our ability to train ... *[putting] our combat forces and, ultimately, our nation at risk.* (italics added) Colonel Daniel Rogers, U.S. Air Force³⁰

Or, in other words, the bulletin supports Colonel Rogers' demands that the panel consider his dire warnings about diminution of national security at the same time that it grapples with how perchlorate might pose a risk to public health.

Prove Rather Than Prevent Harm

One of the well-established practices used to both simplify and ensure the protectiveness of risk assessments is to apply the “No Observed Effect Level” (NOEL) as a starting point for dose-response analysis. The reasoning is that since we do not have a firm handle on why certain chemicals cause disease, or how diseases like cancer are initiated and spread, *any* change detected in an organism following exposure is the right place to begin charting whether additional exposure will cause harm. However, science has evolved in some cases to allow us to consider that some organisms can endure such changes without suffering damage. In those instances, it may well be appropriate to begin charting a dose-response curve at the “No Observed *Adverse* Effect Level” (NOAEL).

Rather than allow this approach to evolve at the same pace as the science, however, OMB waves a wand and transforms it to the default assumption in all risk assessments.³¹ With respect to human health effects, measuring the concentration of a chemical metabolite in a target tissue is “not a demonstration of an adverse effect” although it does indicate exposure.³² Nor does measurement of a “biological event in the human body” demonstrate an adverse effect.³³ Instead, “adversity typically implies some functional impairment or pathologic lesion that affects the performance of the whole organism or reduces an organism’s ability to withstand or respond to additional environmental challenges.”³⁴

At least two things are notable about these stark instructions. First, this aspect makes it clear, if there was any doubt, that the bulletin is not a summary of consensus risk assessment principles, however carefully OMB hedges the language in most sections. If OMB actually uses this language to ride herd over assessments, much less if the courts become involved, the bulletin will skew risk assessments in the direction favored by regulated industries.

Second, OMB is obviously preoccupied with *EPA* risk assessments dealing with toxic chemicals where NOELs and NOAELs are relevant to decisions whether to control exposure. Rather than simply pursue this narrow, albeit controversial, goal, OMB does its best to camouflage its intentions with lofty expressions of overall concerns about improving the quality of assessments government-wide.

Politicized Double Standard

As added evidence that OMB is pursuing a political, as opposed to a scientific or even objective agenda, the bulletin *exempts* from coverage risk assessments prepared by regulated industries, including new drug approvals, pesticide registrations, and the licensing of individual (e.g., nuclear or chemical) plants. In these contexts, risk assessments are used to determine whether to allow activities to occur, from the marketing of Vioxx to the use of pesticides to the operation of Three Mile Island. If OMB sincerely perceives a problem with risk assessment used in a regulatory context, and believes it has the legal authority and scientific expertise to define and police the preparation of such analyses, this double standard is as unwarranted as it is unexplained.

Conclusion

OMB's foray into peer review was a misadventure of sizeable proportions. The bulletin shows that OMB learned little from that experience, although it is also possible that OMB is cheerfully immune to such controversy and expects to be barraged by the same wide variety of stakeholders as those that attacked its peer review proposal. Given the relative importance of the bulletin, we can only hope that it is not disappointed.

Footnotes

¹ Rena Steinzor is the Jacob A. France Research Professor at the University of Maryland Law School. She is also a founder and board member of the Center for Progressive Reform (CPR) (www.progressivereform.org).

² OMB, Proposed Risk Assessment Bulletin, posted at <http://www.whitehouse.gov/omb/inforeg/infopoltech.html#iq>. A *Federal Register Notice* regarding the Bulletin appeared at 71 FR 2600 (Jan. 17, 2006) [hereinafter *Bulletin*].

³ *Id.* at 23 (definition of "risk assessment").

⁴ Information on the NAS panel appears at <http://www8.nationalacademies.org/cp/CommitteeView.aspx?key=34282>.

⁵ Section 515 of the FY 2001 Appropriations Act, P.L.106-554, 114 Stat. 2763A-153-154 (December 21, 2000).

⁶ For a complete account of this history, see Thomas O. McGarity et. al, *Truth and Science Betrayed: The Case Against the Information Quality Act* (March 2005), available at <http://www.progressivereform.org/articles/iqa.pdf>; Sidney A. Shapiro, et al., *Ossifying Ossification: Why the Information Quality Act Should Not Provide for Judicial Review* (February 2006), available at http://www.progressivereform.org/articles/CPR_IQA_601.pdf.

⁷ For an explanation, see Thomas O. McGarity, *Our Science Is Good Science and Their Science Is Junk Science: Science-based Strategies for Avoiding Accountability and Responsibility for Risk-producing Products and Activities*, 52 Kan. L. Rev. 897 (2004).

⁸ *Salt Institute v. Thompson*, 440 F. 3d 156 (4th Cir. 2006).

⁹ *Bulletin* at 23-24

¹⁰ *Id.* at 17 (emphasis added).

¹¹ See, e.g., National Research Council, *Health Implications of Perchlorate Ingestion* (Washington, D.C.: National Academy Press, 2005).

¹² See, e.g., National Research Council, *Toxicological Effects of Methyl Mercury* (Washington, D.C.: National Academy Press, 2000), available at <http://books.nap.edu/openbook/0309071402/html/index.html> (bet hedging)

¹³ *Bulletin* at 12.

¹⁴ *Id.* at 24. (emphasis added)

¹⁵ Col. Daniel Rogers, United States Air Force, Presentation to the National Academy of Sciences Committee to Assess the Health Implications of Perchlorate Ingestion (Oct. 27, 2003) (on file with author) (emphasis added), at 2-3.

¹⁶ *Bulletin* at 20.

¹⁷ *Id.*

¹⁸ *Id.*

¹⁹ *Id.*

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December 7, 2003

Dr. Margo Schwab
Office of Information and Regulatory Affairs
Office of Management and Budget
725 17th Street, N.W.
New Executive Office Bldg., Room 10201
Washington, D.C.

Re: Proposed Bulletin on Peer Review and Information Quality

Dear Dr. Schwab:

OMB has proposed a Bulletin that would supplement existing procedures under the Information Quality Act (IQA)¹ by requiring peer review of regulatory information and by specifying the procedures under which that review would take place.² OMB has also proposed to become intimately involved in the resolution of information quality complaints.³ The scope of matters covered Bulletin is overbroad and therefore exceeds OMB's legal authority. For the same reasons, the Bulletin will result in duplicative and costly peer review. In its preoccupation with agency-funded scientists, and its omission of comparable rules for industry scientists, the Bulletin will not accomplish the most important reform that could justify its issuance: ensuring that peer review is balanced for bias and therefore is not dominated by regulated industries to the extent it is today.

The Center for Progressive Regulation (CPR) appreciates the opportunity to comment on these proposals. CPR is an organization of academics specializing in the legal, economic, and scientific issues that surround health, safety, and environmental regulation. As our website indicates, www.progressiveregulation.org, CPR's mission is to advance the public's understanding of the issues addressed by the country's health, safety and environmental laws and to make the nation's response to health, safety, and environmental threats as effective as possible. The Center is committed to developing and sharing knowledge and information, with the ultimate aim of preserving the fundamental value of the life and health of human beings and the natural environment. CPR circulates academic papers, studies, and other analyses that

¹ Treasury and General Appropriations Act for Fiscal Year 2001, Pub. L. No. 106, § 515 (2001).

² Proposed Bulletin on Peer Review and Information Quality, 68 Fed. Reg. 54023 (2003).

³ Id.

promote public policy based on the multiple social values that motivated the enactment of our nation's health, safety and environmental laws. CPR seeks 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.

The Center also seeks to provoke debate on how the government's authority and resources may best be used to preserve collective values and to hold accountable those who ignore or trivialize them. We seek to inform the public about ideas to expand and strengthen public decision-making by facilitating the participation of groups representing the public interest that must struggle with limited information and access to technical expertise.

SUMMARY

OMB proposes mandatory peer review even though the IQA says nothing about peer review and contains no directive that agencies must use it before disseminating information. Moreover, OMB proposes to require peer review even though Congress rejected legislation mandating similar peer review procedures just a few years ago.⁴ In light of the lack of statutory authority for its proposal, OMB seeks to justify its peer review requirements by noting that scientists and government officials have recognized the importance of peer review in regulatory processes.⁵ There is a difference, however, between recognizing in the abstract that peer review can aid regulatory decision-making and developing specific proposals for making peer review useful. When OMB fills in the details, it fails to limit peer review to circumstances where it is best utilized, and it does not provide for an accountable and balanced peer review process in those circumstances.

More specifically, CPR asks that OMB consider the following objections to its proposal:

- OMB's assertion of jurisdiction to require agencies to use peer review regarding the dissemination of information is doubtful. Even if OMB has authority to require peer review for information that the government disseminates in reports and on the Web, it lacks the authority to require peer review in rulemaking because the IQA does not apply to rulemaking. OMB should delete the requirement that agencies undertake peer review with respect to scientific information that is already subject to extensive notice and comment in the context of a rulemaking covered by the Administrative Procedure Act (APA).
- OMB fails to target peer review to those situations in which it might be most useful. In light of the considerable costs of peer review, OMB should limit peer review to circumstances in which the information to be disseminated sets a new precedent or is reasonably controvertible.
- OMB's effort to avoid the Federal Advisory Committee Act (FACA) does not serve its purpose of increasing public confidence in the information that government disseminates.

⁴ See, e.g., H.R. 9 (1995).

⁵ Proposed Bulletin, *supra* note 2, at 54024.

Contrary to OMB's legal analysis, FACA would apply to any peer review committee mandated by an OMB Bulletin. Even when FACA does not legally apply, OMB should require that agencies comply with the requirements in FACA for balanced peer review committees and a public peer review process when agencies seek peer review of especially significant information.

- OMB's assumption that scientists who receive public funding are more likely to be biased than scientists who receive industry funding is simply wrong, and its plan for appointing scientists with offsetting biases is unworkable. To address potential bias, OMB should require peer review committees to be "fairly balanced," as FACA requires, and should require public disclosures by scientists undertaking peer review of their historical affiliations and sources of research funding. OMB should make explicit its intent to leave in place federal laws and regulations that bar the participation of scientists with demonstrable financial "conflicts of interest," and should encourage agencies to disclose any waivers granted such reviewers.
- OMB rightfully rejected the centralized appointment of peer reviewers, although the reasons expressed by OMB for doing so significantly understate the difficulty of such a process, including the lack of coordination and accountability.
- OMB's decision to exempt information disseminated in adjudication and permit proceedings from its peer review procedures lacks any apparent justification, raising the suspicion that OMB's exemption is based on the fact that the information disseminated in adjudications and permit proceedings is largely information submitted by industry. OMB should require peer review of such studies under the circumstances recommended above.
- OMB's proposal to review each and every request for information correction creates the potential for backroom deals between OMB and the complaining party or other interested parties. To ensure accountability, OMB should issue a concise written explanation for public disclosure indicating that it recommended that an agency modify existing information in light of a complaint, and it should reveal for public disclosure any written communications, and a summary of any oral communications, pertaining to the substance of an information quality complaint received from members of Congress or their staffs or from persons outside of government.

AUTHORITY TO REQUIRE PEER REVIEW

OMB claims the IQA provides authority for its Bulletin, but the text of the Act does not support this claim. The Act does not explicitly require, or even authorize, peer review. Moreover, although the Act imposes a number of duties on OMB, Congress did not include among these duties setting up guidelines for peer review. Further, Congress explicitly rejected the imposition of peer review a few years ago after due consideration and debate,⁶ and it is difficult to believe that Congress changed its mind when it passed the IQA. After all, the IQA was a rider hidden in an appropriations bill that no one in Congress other than the sponsor knew was there.

⁶ Note 4 & accompanying text.

Moreover, OMB cannot claim other sections of the Paperwork Reduction Act (PRA) as authority for requiring peer review. Although the Act was passed in 1980, OMB has never previously interpreted PRA to authorize the imposition of peer review, and the fact that Congress has several times considered legislation that would expressly require peer review confirms that OMB lacks this power. Although PRA gives OMB authority to “develop and oversee the implementation of policies, principles, and standards to apply to Federal agency dissemination of public information ...,”⁷ this authority extends only to overseeing how the government “manages” the information that it collects.⁸

Even if the courts hold that OMB can impose a peer review requirement on agencies, this authority does not extend to the dissemination of information in rulemaking because the IQA simply does not apply to rulemaking. Congress indicated that the IQA does not apply to rulemaking when it required that agencies create a new “administrative mechanism” to hear and resolve complaints about information quality.⁹ This means Congress intended the rider to apply to contexts where the dissemination of information is not already subject to an administrative mechanism to correct problems. This would not include rulemaking because such a process already exists in rulemaking. Since setting up another process would be superfluous or redundant, it has to be assumed that Congress had no such intention.¹⁰

SCOPE OF PEER REVIEW

While peer review has a role to play in the regulatory process, OMB’s proposal for peer review is too broad in light of the potential benefits that it is likely to generate. OMB errs in assuming that peer review is appropriate or even necessary for all “significant” information because it is likely to have or will have a substantial impact on public policy or private initiatives.¹¹ Although information may have such an impact, it does not follow that the information is likely to be unreliable or that peer review is necessary to ensure its objectivity. OMB should therefore limit peer review to circumstances where the information to be disseminated sets a new precedent or is reasonably controvertible.¹² In any other circumstance, peer review is wasteful and will unnecessarily delay the dissemination of important information.

⁷ 44 U.S.C. §§3504(d)(1).

⁸ See OMB Circular No. A-130 Revised (“The PRA establishes a broad mandate for agencies to perform their information resources management activities in an efficient, effective, and economical manner.”), available at <http://www.whitehouse.gov/omb/circulars/a130/a130trans4.html#8>.

⁹ Information Quality Act, *supra* note 1, §515(b)(2).

¹⁰ The background of the Act also confirms that Congress intended the Act to apply outside the context of rulemaking. Prior to enactment of the Information Quality Act, there was a discussion and debate over how to provide for public input before agencies produce reports or put information on their web sites. See, e.g., 23 Administrative & Regulatory Law News #3 (Spring 2000), at 10 (describing program held by the ABA on the dissemination of reports and information on the Web); White Paper From Industry Coalition to EPA Over Concerns Over Information Programs Submitted May 4, 1999, Daily Env. Rep. (May 4, 1999), at E-1 (discussing the dissemination of reports and information on the Web). There was no discussion, however, of the need to provide mechanisms to improve information quality in the context of rulemaking.

¹¹ Proposed Bulletin, *supra* note 2, at 54028, §§1-2.

¹² This argument is supported by a formal policy position of the American Bar Association concerning risk assessment. The ABA has recommended that the “nature, significance, and complexity” of a risk assessment should determine “when” agencies use peer review, as well as determining the “nature and scope” of peer review. ABA Resolution on Risk Assessment (October 1999), available at <http://www.abanet.org/adminlaw/risk02.pdf>. The report accompanying the recommendation, which was not officially adopted by the ABA, explains that peer review

OMB partially concedes this point. Regarding “significant” information, it permits agencies to “select an appropriate peer review mechanism based on the novelty and complexity of the science to be reviewed, the benefit and cost implications, and any controversy regarding the science.”¹³ The government, however, distributes a wide variety of information, much of which occurs outside of the context of rulemaking, for which peer review may be unnecessary, even though the information has not been previously subjected to peer review. While OMB’s flexibility regarding such information may minimize the government’s burden in individual situations, the collective time and expense to the government of having universal peer review for significant information is likely to be substantial. Moreover, agencies are not permitted to vary the additional procedures they must use concerning “especially significant” regulatory information,¹⁴ regardless whether the additional procedures are useful and necessary.

FACA

OMB suggests to agencies that they can avoid complying with the Federal Advisory Committee Act (FACA) when they undertake peer review. Congress passed FACA “in large part to promote good-government values such as openness, accountability, and balance of viewpoints.”¹⁵ Because these values are vital to ensuring the legitimacy of peer review, OMB should require that agencies conduct peer review of “especially significant information” under FACA.

FACA offers two essential protections necessary to legitimize peer review. First, it mandates a peer review process that is open to the public.¹⁶ OMB does require that an agency provide an opportunity for public comment and that such comments should be furnished to peer reviewers in sufficient time that they can take the comments into account.¹⁷ OMB presumably intends that the comments also be made public, although it does not explicitly so provide. OMB also provides that the report of the peer reviewers and the agency’s responses to that report be made public.¹⁸ It is difficult to see why the public should trust a peer review process that operates behind a veil of secrecy. If OMB’s goal is to increase public confidence in the information that

should be “limited to situations in which it is most likely to improve the analysis, such as complex or novel problems, or add authority, such as highly controversial situations.” American Bar Association, Section of Administrative Law and Regulatory Practice, Report (August 1999), at 9, available at <http://www.abanet.org/adminlaw/risk02.pdf>.

¹³ Proposed Bulletin, *supra* note 2, at 54028, §2.

¹⁴ *Id.* at 54028, §3.

¹⁵ Steven P. Croley, *Practical Guidance on the Applicability of the Federal Advisory Committee Act*, 10 AD. L.J. 111, 117 (1996); *see also* Jay S. Bybee, *Advising the President: Separation of Powers and the Federal Advisory Committee Act*, 104 YALE L.J. 51, 73 (1994) (noting that Congressional hearings on FACA “focused on the non-representative nature of the advisory committees, and the need to open their proceedings and reports to the President).

¹⁶ FACA requires that peer review minutes are open to the public, 5 U.S.C. App. II §10(a)(1), interested persons are entitled to “attend, appear before, or file statements with any advisory committee,” *id.* §10(a)(3), detailed minutes must be kept, *id.* §10(c), and any records or documents made available to the committee be made available to the public unless the records can be withheld according to one of the exceptions for public disclosure under the Freedom of Information Act (FOIA), *id.* §10(b). An agency can close a meeting only if it determines that one of the exceptions to the Sunshine Act applies. *Id.* §10(d).

¹⁷ Proposed Bulletin, *supra* note 2, at 54029, §3.

¹⁸ *Id.*

the government disseminates, closing the peer review meetings and hiding peer review documents does not serve its purpose.

Second, FACA requires agencies to ensure that their advisory committees are “fairly balanced in its membership in terms of the points of view represented and the functions to be performed.”¹⁹ This safeguard is important because it recognizes that peer review inevitably involves matters of judgment about which reasonable scientists can disagree. This is the situation for two reasons. First, although OMB correctly asks that agencies refer only “scientific and technical matters to agencies, leaving policy determinations for the agency,” it is virtually impossible to separate scientific and policy issues.²⁰ Second, even within the realm of “scientific issues,” peer reviews will confront issues for which there are no objective answers, requiring them to use their best judgment.²¹ Furthermore, allowing an agency to pick peer reviewers without regard to balance invites an agency to tilt peer review to its preferred outcome. This has long been a problem with peer review,²² and OMB’s failure to require the use of FACA will continue the problem.

OMB seeks to avoid FACA by authorizing agencies to “direct peer reviewers of regulatory information – individually or in a group – to issue a final report detailing the nature of their review and their findings and conclusions.”²³ Although FACA may not apply to convening a number of people to obtain the advice of each individually (rather than collectively),²⁴ individual review is a bad idea. The advantage of conducting peer review by committee is that “each committee member has the opportunity to observe the demeanor of the others and to challenge their evaluations.”²⁵ As a result, “bringing all reviewers together to discuss their opinions can be a powerful shield against favoritism and animus.”²⁶ This shield becomes even more important if OMB succeeds in closing peer review meetings to the public by permitting agencies to avoid FACA by hiring contractors to conduct the peer review.

¹⁹ 41 C.F.R. §102-3.30(c) (2003).

²⁰ See Wendy E. Wagner, *Congress, Science, and Environmental Policy*, 1999 U. ILL. L. REV. 181, 214 (1999) (“Although these advisory panels have proved helpful in ensuring that the agencies use positive scientific knowledge accurately, these panels often find themselves reviewing the agency’s policy choices under the auspices of peer review.”); Joel Yellin, *Science, Technology, and Administrative Government: Institutional Designs for Environmental Decisionmaking*, 92 YALE L.J. 1300, 1305-06 (1983) (“If it were possible to separate the technical from the political, ethical, and legal, ... environmental decisions could be made in a simple two step process. ... The history of unsuccessful attempts to distinguish fact from law suggests that separation may be an unattainable goal.”)

²¹ See Holly Doremus, *Listing Decisions Under the Endangered Species Act: Why Better Science Isn’t Always Better Policy*, 75 WASH. U.L.Q. 1029, 1064 (1997) (Reliance on science must, by necessity, include reliance on some hunches.)

²² See Bybee, *supra* note 15, at 58-59 (discussing the uses and abuses of advisory committees); THOMAS O. MCGARITY & SIDNEY A. SHAPIRO, *WORKERS AT RISK: THE FAILED PROMISE OF THE OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION* 196 (1993) (discussing the potential of stacking advisory committees to obtain an agency-favored preordained outcome).

²³ Proposed Bulletin, *supra* note 2, at 54027, §3. This interpretation is open to challenge. See Steven P. Croley & William F. Funk, *The Federal Advisory Committee Act and Good Government*, 14 YALE J. REG. 451, 472-78 (1997) (questioning the conclusion that FACA does not apply to individual reviewers).

²⁴ 41 C.F.R. §102-3.40(e) (2003).

²⁵ Thomas O. McGarity, *Peer Review in Awarding Federal Grants in the Arts and Sciences*, 9 HIGH TECHN. L.J. 1, 64 (1994).

²⁶ *Id.*

Based on *Byrd v. EPA*,²⁷ OMB also claims that an agency can avoid complying with FACA if it hires a contractor or consultant, who in turn organizes the peer review.²⁸ In *Byrd*, the Environmental Protection Agency (EPA) hired a private contractor to select and manage a peer review panel and submit a report to the agency.²⁹ A majority of the panel held that FACA did not apply because, although EPA had reserved authority to control the contractor's choice of peer reviewers, it did not exercise this power. In their words, the decision was based "on what EPA in fact did, rather than on what it could have done."³⁰

The *Byrd* case has not been followed by any other circuit. More importantly, it does not help OMB because OMB requires agencies to ensure that peer review of especially significant regulatory information meets a number of requirements, including that peer reviewers "shall be selected primarily on the basis of necessary scientific and technical expertise."³¹ In order to meet this requirement, agencies must actively review the choice of peer reviewers by a contractor and veto any peer reviewer that does not meet this condition. Likewise, agencies have a legal duty to ensure that the other conditions that OMB has established for peer review of especially significant information are met. Thus, unlike the situation in *Byrd*, an agency will have to control the peer review process, which EPA did not do in *Byrd*, according to the majority opinion.

Of course, it is not necessary for OMB to require the formal use of FACA, although that would be a good idea, in order to ensure an open peer review process and balanced peer review. OMB could simply require agencies to comply with the fair balance and open government provisions of FACA without formally chartering peer review committees.

CONFLICTS OF INTEREST VERSUS BIAS

A fundamental flaw in the proposed Bulletin is its failure to distinguish between conflicts of interest that disqualify prospective scientists from serving on peer review panels under existing law and the bias that scientists may exhibit when they have formulated a position on a scientific issue through their work in the same or related areas. A full range of statutory and regulatory requirements, most notably the Ethics in Government Act,³² bar scientists who have a direct financial interest in the outcome of an administrative decision from serving on government peer review panels established to review scientific studies that affect such deliberations. Agencies may waive these requirements, but must go through a formal process to do so. The proposed Bulletin uses the phrase "real or perceived conflicts of interest" but does not otherwise recognize

²⁷ 174 F.3d 239 (D.C. Cir. 1999).

²⁸ Proposed Bulletin, *supra* note 2, at 54028, §4a.

²⁹ 174 F.3d at 241.

³⁰ *Id.* at 247. In his dissent, Judge Williams held that FACA applied because the panel was "so closely" controlled "in membership and purpose." *Id.* at 249. For Judge Williams, the key was EPA's "veto power," and the fact that "it was not used" did not matter because EPA might "exercise it in future applications" and "the contractor was and is quite likely to take the fact of the veto into account in its selection decisions." *Id.*

³¹ Proposed Bulletin, *supra* note 2, at 54027. Further, the proposed guidelines require an agency to "provide to peer reviewers an explicit written charge statement describing the purpose and scope of the review." *Id.* at 54028. In addition, the "agency shall provide an opportunity [for public comment]," and it "shall direct peer reviewers ... to issue a final report," and OMB specifies the specific nature of the report. *Id.*

³² 5 U.S.C. §§ 201 et. seq.

that this term has a legal meaning under existing law.³³ It should be revised to make explicit OMB's recognition that existing legal requirements regarding conflicts of interest remain in force with respect to any peer review panels established under the Bulletin.

Even if scientists possess indirect financial interests (e.g., continued employment with a broadly-based industry trade association) that are not covered by federal conflict of interest rules, such interests may lead to an appearance that they are biased with respect to the outcome of a peer review. Despite its apparently exhaustive review of prominent literature on peer review, including reports by the General Accounting Office (GAO) and the EPA Inspector General, OMB conspicuously omits a recent GAO report documenting EPA's persistent tendency to ignore such financial interests in assembling peer review panels, with the result that scientists who were paid by manufacturers of chemicals under consideration by the EPA Science Advisory Board were actually permitted to serve on such panels.³⁴ To remedy its apparent insensitivity to this important problem, OMB should consider describing these interests without reference to the legal term of art "conflict of interest," while simultaneously strengthening its exhortations to agencies to avoid choosing such compromised candidates.

OMB advises agencies to consider disqualifying scientists who have or may do research supported by the government,³⁵ but it does not recommend a parallel rule to disqualify a scientist who has received, or is attempting to receive, research funding from regulated industries.³⁶ OMB, however, has the situation exactly backwards. If anything, agencies should exhibit more care in their selection of scientists whose research is funded by industry.

OMB is concerned that scientists funded by agencies, or who would seek such funding, could feel pressured to bend their advice to an agency in order to secure present or future funding. Public financing of science, however, occurs under procedures that protect and promote the independence of the scientists doing the research. By comparison, private research occurs under conditions that make it more likely that scientists will lose their funding if they do not produce results that are satisfactory to the industrial source of funding.³⁷

³³ Proposed Bulletin, *supra* note 2, at 54027, § 2.

³⁴ GENERAL ACCOUNTING OFFICE, EPA'S SCIENCE ADVISORY BOARD: IMPROVED PROCEDURES NEEDED TO ENSURE INDEPENDENCE AND BALANCE 18 (2001) (Report No. GAO-01-536) (describing the impropriety of EPA's appointment of industry-dominated panels) [GAO EPA Report].

³⁵ *Id.*

³⁶ OMB apparently does not think that latter situation is a problem unless a scientist has an actual financial interest in the outcome of the study. Proposed Bulletin, *supra* note 2, at 54024. Perhaps OMB anticipates that scientists who undertake research funded by industry will also have a financial stake in the outcome of the research. While this is a growing problem, not all industry-funded scientists are in this situation. OMB's position on this issue, however, is not entirely clear. In its proposed rules, OMB lists as possibly disqualifying the receipt of "substantial funding" from an agency or the application for such funding from an agency. *Id.* at 54027. There is no similar proposed disqualification for scientists who receive, or are seeking to receive, funding from industry, although OMB does propose that agencies consider as potentially disqualifying that a person has "financial interests in the matter at issue." *Id.* OMB's preamble informally defines "financial interest in the subject matter" as "(e.g., ties to a regulated business)." *Id.* at 54024. This seems to suggest an implicit acknowledgment by OMB that ties to a regulated business should be a negative factor in the selection process.

³⁷ Professor Sheldon Krinsky explains:

When government funds basic science, it does not have a vested interest in a particular outcome. Given the transparency of the funding and the peer-review process, government agencies have to be very careful

Finally, OMB proposes that an agency can appoint a “biased” reviewer if necessary to gain needed expertise if it appoints someone who has a contrary bias.³⁸ This proposal reflects OMB’s assumption that agencies can generally create a neutral peer review process, which is not actually possible in light of the factors discussed earlier. Moreover, it is unlikely that an agency can match up offsetting biases in the manner that OMB anticipates. What type of person, for example, has a “contrary bias” to a person who has an unrelated contract with the agency? The general prophylactic of requiring a “broadly representative” and “fairly balanced” review group is a more effective protection against biased peer review outcomes and is more manageable.

DISCLOSURE OF AFFILIATIONS

OMB requires that a peer review report shall “disclose the names, organizational affiliations, and qualifications of all peer reviewers, as well as any current or previous involvement by a peer reviewer with the agency or issue under peer review consideration.”³⁹ Once again OMB draws a distinction between agency and industry affiliation that is unwarranted. Whereas a peer review report must disclose the involvement of peer reviewers with an agency, there is no similar disclosure requirement for scientists who are involved with the regulated industry. Further, although OMB suggests that an agency may wish to require peer reviewers to disclose “sources of personal or institutional funding,”⁴⁰ it is not clear whether OMB is referring to industry funding of research.

OMB should require that a peer review report disclose the historical affiliations of peer reviewers (both agency and industry related) and the sources of funding that a scientist has received. As the General Accounting Office (GAO) has observed, this approach gives the public information that can be used to evaluate the legitimacy of the advice being received because it indicates the degree of balance that the agency has obtained in its appointment of peer reviewers.⁴¹ Moreover, this approach permits an agency to hear from a diverse group of scientists and not disqualify certain scientists because of their previous sources of funding, while assuring the public of the legitimacy of the peer evaluation process.⁴² Finally, an agency should gather this information at

of not appearing to tease out or share scientific results that meet a political perspective, even in areas of applied research... .

Private funded science is not transparent. There are unstated agendas. Many scientists who are funded by private companies understand what results would please the company and what results would benefit the company’s bottom line. If a scientist is tethered to a company’s research program, then the company is likely pleased with the outcome of the research and therefore would benefit by continuing to fund it. It is not unusual for investigators to internalize the interests of the company... .

SHELDON KRIMSKY, SCIENCE IN THE PRIVATE INTEREST: HAS THE LURE OF PROFITS CORRUPTED BIOMEDICAL RESEARCH? 143-44 (2003).

³⁸ Proposed Bulletin, *supra* note 2, at 54027, §3,

³⁹ *Id.* at 54028, §3.

⁴⁰ *Id.*

⁴¹ GAO Report, *supra* note 34, at 18.

⁴² Disclosures might implicate some protections under the Privacy Act, but the Act permits individuals to waive any privacy protections that they might have. See 5 U.S.C. § 552a(b) (permitting written waivers). It is reasonable for an agency to require such waivers as a condition of serving as a peer reviewer.

the beginning of the peer review process when the agency can use it to ensure that peer review is a balanced process.⁴³

CENTRALIZED APPOINTMENT OF REVIEWERS

In its proposed guidelines, OMB declines to propose the centralized appointment of reviewers because it “could be unduly inefficient and raise other concerns.”⁴⁴ OMB understates the difficulties with centralized appointment of reviewers.

First, OMB does not suggest what entity might serve this function, but it is clear that the selection of OMB for this function is unlikely to “lend the appearance of greater integrity to the peer review process.” There has been significant concern over the years concerning the accountability of presidential supervision of rulemaking,⁴⁵ and OMB’s control over peer review would raise the same legitimate concerns.

Second, putting an entity in charge of peer review which has no responsibility for the implementation of a statutory scheme invites the appointing agency to pursue its own political and substantive agenda, regardless of whether it is appropriate for the implementation of the statutory scheme.⁴⁶ The risk that a centralized agency would pursue its own agenda is particularly acute to the extent that it is not publicly accountable for its actions. Yet, as indicated above, there is no assurance that the agency that appoints the peer reviewers, whether it is OMB or some other entity, will do so in an accountable way. The lack of accountability invites capture by vested interests. This is particularly a problem because OMB fails to require that peer review be a balanced process.

Finally, peer review is less likely to inform and improve regulatory decision-making when agency employees regard it as a bureaucratic burden imposed on an agency rather than a tool for improving the quality of decision-making.⁴⁷ Agency personnel are more likely to regard peer review as a bureaucratic requirement, as opposed to an integral part of the agency’s decision-making process, when it is imposed on the agency by OMB and implemented by another entity, be it OMB or some other agency.

⁴³ See GAO Report, *supra* note 34, at 20 (recommending that EPA collect background information about potential peer reviewers before their appointment to a peer review committee).

⁴⁴ *Id.*

⁴⁵ See, e.g., GLEN ROBINSON, *AMERICAN BUREAUCRACY: PUBLIC CHOICE & PUBLIC LAW* 102 (1991), Sidney A. Shapiro, *Presidential Oversight and the Deterioration of Regulatory Policy*, 46 AD. L. REV. 1, 21-23 (1994) (discussing the debate of White House accountability in rulemaking oversight).

⁴⁶ This is what happened when Congress located the Occupational Safety and Health Administration (OSHA) and the National Institute of Occupational Health (NIOSH) in two different cabinet departments. Although Congress created NIOSH to serve as the scientific arm of OSHA, NIOSH at times has pursued this mission according to its agenda and has not always pursued projects helpful or appropriate to OSHA. Sidney A. Shapiro & Thomas O. McGarity, *Reorienting OSHA: Regulatory Alternatives and Legislative Reform*, 6 YALE J. ON REG. 1, 57-59 (1989).

⁴⁷ According to the National Academy report, peer review “must become accepted as part of the agency’s culture, not merely a bureaucratic requirement.” National Academy of Sciences, *Strengthening Science as the US Environmental Protection Agency: Research Management and Peer Review Practices* 115 (2000). Professor Lars Noah makes a similar point when he observes that peer review works best when it is peer reviewers interact with agency scientists in an ongoing dialogue. Lars Noah, *Scientific “Republicanism”: Expert Peer Review and the Question for Regulatory Deliberation*, 49 EMORY L.J. 1033, 1059-60 (2000)

UNEQUAL TREATMENT OF INDUSTRY INFORMATION

The proposed Bulletin seeks to assure the objectivity of information disseminated by the government by subjecting it to peer review, but the Bulletin exempts an important category of information generated by industry from this procedure. According to the proposal, “agencies need not have peer review conducted on significant regulatory information that ... is disseminated in the course of an individual agency adjudication or proceeding on a permit application.”⁴⁸ The lack of any apparent justification for these exceptions leads to the conclusion that OMB is protecting industry information from peer review.

OMB presumably exempted information disseminated in adjudications because its Information Quality Guidelines exempted adjudication from the Act altogether,⁴⁹ but it is not clear why information disseminated in adjudication is not subject to the Act. Maybe OMB believed that the adjudicatory process is sufficient to vet the accuracy of the information involved, but there are two difficulties with this position. First, the procedures in an adjudication vary widely depending on whether the adjudication is formal or not, and if not, what procedures are required by the statutory mandate under which the agency is operating.⁵⁰ Many informal adjudications are conducted with no procedures whatsoever. Second, if this is OMB’s position, it is difficult to understand why OMB does not also exempt information disseminated in a rulemaking because the procedures are adequate to vet the information that is disseminated.

OMB also offers no reason why it exempts information disseminated in a proceeding on a permit application. Since these proceedings involve adjudication, OMB’s exemption might have been based on the prior reason. Or OMB may have concluded that permit applications were not important enough to deserve peer review. But OMB subjects other types of significant regulatory information to peer review, and there is no indication by OMB why information disseminated in a permit proceeding, if it is significant regulatory information, should not be subject to peer review.

OMB’s exemption for permit proceedings may be an attempt to protect propriety or trade secret industry information, but this is an invalid reason for not subjecting this information to peer review. An agency can follow the practice of FDA, which regularly protects such information and still subjects it to peer review.⁵¹

⁴⁸ Proposed Bulletin, *supra* note 2, at 54027, §2.

⁴⁹ In the Guidelines, OMB defines “dissemination” as not including “distribution ... limited to adjudicative processes. Office of Management and Budget, Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility and Integrity of Information Disseminated By Federal Agencies, 67 Fed. Reg. 8452, 8460 (2002).

⁵⁰ See RICHARD J. PIERCE, SIDNEY A. SHAPIRO & PAUL R. VERKUIL, ADMINISTRATIVE LAW & PROCEDURE §§ 6.4.3, 6.4.10 (3d ed. 1999) (explaining the variability of procedures used in adjudication).

⁵¹ FDA advisory committees are composed of scientists who are hired as special government employees, which makes it possible for FDA to reveal the information to them and which imposes on the scientists a legal obligation to keep the information confidential. See 21 C.F.R. §14.80 (members of FDA advisory committees serve as special government employees).

The lack of any apparent justification for these exceptions leads one to the suspicion that OMB's exemption is based on the fact that the information disseminated in adjudications and permit proceedings is largely information that is submitted by regulated industries. But there is no apparent reason why industry information should be exempted from peer review, except when the nature of the information does not warrant the cost and delay created by peer review. As noted earlier, peer review should be reserved for the dissemination of information that sets a new precedent or is reasonably controvertible. If industry information meets this test, it is not possible to distinguish it from information that arises in other contexts.

OMB's solicitude for industry information is particularly puzzling because such information is usually not subjected to the same level of scrutiny as information that is the result of public funding.⁵² Moreover, since industry often regards information submitted to agencies to obtain permits or licenses as propriety or trade secret, it is far more likely to have received little or no independent scrutiny that information produced by scientists as the result of public funding.

OMB AND CORRECTION REQUESTS

OMB's proposed Bulletin ends with a proposal that agencies provide to it within seven days a copy of each non-frivolous request for information quality correction unless the agency posts the complaint on its web site, and that an agency consult with OMB before it responds to the complaint.⁵³ In light of the public interest in the outcome of complaints concerning "especially significant regulatory information," it is important that OMB be accountable for its participation in the resolution of information quality complaints, but OMB has proposed nothing in the way of accountability procedures.

OMB should take two steps to promote accountability concerning complaints about "especially significant regulatory information." It should issue a concise written explanation for public disclosure indicating that it recommended that an agency modify existing information in light of a complaint, and it should reveal for public disclosure any written communications, and a summary of any oral communications, pertaining to the substance of an information quality complaint from members of Congress or their staffs or from persons outside of the government.⁵⁴

⁵² For example, regarding privately funded research in the life sciences, empirical studies have found a "greater secrecy among colleagues, a significant failure of scientific exchange in the community, and a pattern of delayed publication." KRIMSKY, *supra* note 37, at 84.

⁵³ §7, Proposed Bulletin, *supra* note 2, at 54029.

⁵⁴ These recommendations reflect a formal policy adopted by the American Bar Association concerning the accountability of White House oversight in the context of rulemaking. See Recommendation on Presidential Oversight (Feb. 1993), available at <http://www.abanet.org/adminlaw/policy.html>, The ABA has recommended that government entities designated by the President to engage in a continuing process of oversight of the rulemaking process should issue a written explanation of changes it has requested agencies to make in proposed and final rules. The ABA has also recommended that the entity reveal conduit communications that it has received concerning the matter it is reviewing from members of Congress, their staffs, or from persons outside of the government concerning such proposed or final rules. The former Administrative Conference of the United States (ACUS) has made a similar recommendation of. Presidential Review of Agency Rulemaking (Recommendation 88-9), 1 C.F.R. §305.88-9 (1992).

Sincerely yours,

Sidney A. Shapiro
Board Member and Treasurer

Rena Steinzor

Rena Steinzor is a Professor at the University of Maryland School of Law, where she teaches courses in administrative law, risk assessment, critical issues in law and science, contracts and legal method, and a survey of environmental law. She has a secondary appointment at the University of Maryland Medical School.

During the course of her academic career, Professor Steinzor has written extensively on efforts to reinvent environmental regulation in the United States, the use and misuse of science in environmental policy making, and the devolution of legal and administrative authority to the states. She edited *A New Progressive Agenda for Public Health and the Environment* (Carolina Academic Press 2005) with Professor Christopher Schroeder of the Duke Law School. The book proposes an alternative set of values and principles that should guide efforts to reform environmental law.

Steinzor worked with Professor Wendy Wagner of the University of Texas School of Law, to edit a book of essays by prominent academics entitled *Rescuing Science from Politics* (Cambridge University Press, 2005) writing an introduction and conclusion summarizing the issues and recommendations suggested by the book. Professor Steinzor has completed work on a book entitled *Mother Earth and Uncle Sam: How Pollution and Hollow Government Hurt Our Kids*, which was published by the University of Texas Press in December 2007.

Professor Steinzor is the president of the Center for Progressive Reform (CPR) (www.progressivereform.org), a virtual think tank comprised of some 45 member scholars from universities across the United States. CPR is committed to developing and sharing knowledge and information, with the ultimate aim of preserving the fundamental value of the life and health of human beings and the natural environment. One component of CPR'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. CPR seeks to inform the public about scholarship that envisions government as an arena where members of society choose and preserve their collective values. CPR rejects the idea that government's only function is to increase the economic efficiency of private markets.

Before joining the law school faculty, Professor Steinzor was the partner in charge of the environmental practice at Spiegel & McDiarmid, a Washington D.C. law firm specializing in the representation of state and local government entities in the energy and environmental areas. Prior to joining the firm, Professor Steinzor was counsel to the Subcommittee on Commerce, Transportation & Tourism of the House Energy & Commerce Committee, which was then chaired by James J. Florio (D-N.J.). She advised the Subcommittee during its consideration of the Superfund Amendments and Reauthorization Act of 1986 and the Asbestos Hazard Emergency Response Act of 1986. She also served as an attorney advisor to Commissioner Patricia P. Bailey of the Federal Trade Commission and worked as a consumer protection attorney at the FTC in various staff positions.

Professor Steinzor is a 1976 graduate of Columbia Law School and a 1971 graduate of the University of Wisconsin.