February 20, 2009

The Honorable Peter Orszag
Director
Office of Management and Budget
725 17th Street, NW
Washington, DC 20503

Re: Plans to Rewrite Executive Order on OMB Regulatory Review

Dear Mr. Orszag:

We write to you today to provide preliminary comments on the *Federal Register* notice published on February 3, 2009, announcing President Obama's intention to revise the Executive Order (Executive Order 12866) that governs the Office of Management and Budget's (OMB) review of regulatory proposals. We have also provided these comments to Professor Cass Sunstein in anticipation of his appointment as OIRA Administrator.

At the outset, we urge you to establish a more formal public comment period for the revised Order, to commence after you have prepared a draft and to extend no fewer than 90 days. The *Federal Register* notice initiated a 100-day period for comments from regulatory agency heads that will end, if we are counting right, on May 14, 2009. However, as you know, many agency heads are not yet in place. Even if they were, agency leaders are likely to have different perspectives on regulatory review than the full spectrum of private sector stakeholders. Therefore, we strongly recommend that you establish a more formal public comment period for the revised Order, to commence after you have prepared a draft and to extend no less than 90 days. We are aware that you have invited some people with expertise in the area to give you comments on the not-yet-drafted Order by February 13, 2009. In our view, this truncated process will not produce the wealth of advice that you should have when reviewing these important policies.

As part of the process that the Obama Administration has initiated to receive advice on the rewriting of the Executive Order, we have sent you a separate letter inviting you to participate in a conference that the Center for Progressive Reform (CPR) (http://www.progressivereform.org/) is hosting in Washington, D.C., on Friday, May 22, 2009. This symposium will focus on the issue of regulatory review. Along with CPR's experienced team of Member Scholars that have been working on and writing about regulations, we will gather many of the most prominent advocates and critics of the existing system of centralized review of individual rules using

Rena I. Steinzor
Jacob A. France Research Professor
University of Maryland School of Law
500 W. Baltimore Street
Baltimore, MD 21201

www.progressivereform.org

410.706.0564
410.706.2184 (fax)

rsteinzor@law.umaryland.edu

traditional cost-benefit analysis. We are confident that it will provide an excellent opportunity for dialogue on these important questions, and we hope you can attend.

Summary and Overview

Our comments make two fundamental points about your efforts to revise the regulatory review process:

First, the new Executive Order should redefine the job description of the "regulatory czar." Beginning with the first Reagan Administration, the director and staff of the Office of Information and Regulatory Affairs (OIRA) have served mainly to suppress regulation thought to be excessive. This focus is hardly appropriate for the challenges confronting today's regulatory system. Instead, 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 first place to start in rescuing this failed system is to announce a fundamental re-orientation of the OIRA. Rather than chiding agencies 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), in order to produce the "smarter, better" government envisioned by President Obama. Rescuing these agencies by giving them adequate resources to fulfill their statutory mandates, helping them develop strong, proactive agendas, and ensuring they receive enhanced legal authority to take decisive action should be the first priority for the regulatory czar soon to be installed at the OMB.

Second, the new Order should implement fundamental changes in the nature and scope of OIRA review. To assist the OIRA in making the best use of its own limited resources, which include fewer than 40 staff economists, we urge you to consider eliminating the dual requirements that it (1) scrutinize individual rules and (2) enforce a rigid commitment to traditional cost-benefit analysis. Instead, the OIRA should undertake the far more manageable goals of formulating policies for pragmatic regulatory impact analyses and resolving interagency disputes. We explain further what we mean by "pragmatic regulatory impact analysis" below.

The Core Mission of the Regulatory "Czar"

The five protector agencies mentioned earlier—the CPSC, the EPA, the FDA, the NHTSA, and the OSHA—lack the resources, the legal authority, and the political will to carry out their vitally important statutory missions effectively. The ranks of their career public servants are decimated. They are overburdened by mischievous Bush Administration "midnight regulations" and illegal regulatory decisions now under challenge in the courts. Their statutes have not been reviewed or refreshed in 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.

Virtually every day, the media report on the damage these problems cause public health, worker and consumer safety, and the environment.

In 2007, for example, the 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. Congress wrote the Consumer Product Safety Improvement Act with record speed, but these new mandates remain underfunded, and the CPSC recently announced that it was delaying regulations on lead in toys for another year.

EPA Clean Air Act regulations issued by the Bush Administration were routinely overturned by judicial panels that included the most conservative Bush Administration appointees, indicating how far the Agency had strayed from implementing the laws as Congress intended. Regulation of mercury is in limbo, at least 15 years overdue. Regulation of ozone air pollution represented one of the very rare occasions when Bush's top political appointees at EPA actually recommended a more stringent pollution standard—in this case, one that was necessary to limit damage to crops, forests, and other natural resources. At the behest of political appointees at OMB, however, the President rejected their advice, and the more stringent ozone standard was never adopted. The Bush Administration OMB persuaded the President to overturn the advice of the EPA's top political appointees recommending a more stringent standard for ozone pollution, one that is necessary to limit damage to crops, forests, and other natural resources. Meanwhile, Clean Water Act protections have been 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 most common chemicals and without these values, effective regulation is impossible. The EPA also lags far behind in establishing "residual risk" standards for hazardous air pollutants.

The FDA is struggling to come to grips with the resource imbalances and other problems that produced the Vioxx scandal and related failed efforts to protect the public. The FDA must completely revamp its efforts to police adverse effects in approved drugs. Its overall reputation for scientific integrity and the morale of its staff suffered a body blow during its consideration of whether Plan B should be sold over-the-counter, and it continues to impose unjustifiable restrictions on the age of women who can gain ready access to what is a safe and efficacious drug. As illustrated by the recent revelations regarding gaping holes in the food safety net, such as the apparently criminal conduct of a peanut processing company with facilities in Georgia and Texas, the FDA needs significantly strengthened legal authority and expanded enforcement resources. And, as in the case of the CPSC and consumer products, problems with domestic food supplies pale in comparison to the hazards posed by imported food.

The NHTSA has yet to deal effectively with the safety problems posed by Sport Utility Vehicles. 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. Not to sound like a politician, but that's not compassionate conservatism."[1] Although the popularity of these vehicles are declined because of the economic decline and gas prices, these market changes, which are variable, do not relieve NHTSA of the responsibility of acting to protect the public.

Workers are killed or severely injured as cranes topple over and trenches collapse, with OSHA paralyzed on the regulatory front. 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.

Beginning with the Reagan Administration, the OIRA , in essence, has played a resource-intensive, draining, and ultimately debilitating game of "kill-a-rule" with health and safety agencies. Viewing its role primarily as the last line of defense against excessive regulatory proposals, the OIRA has deployed its small band of three dozen economists by cherry-picking regulatory proposals, often based on which rules were generating the loudest complaints from regulated industries, in order to examine their costs and their benefits with differing degrees of de-regulatory enthusiasm. It is certainly true that the OIRA under President Clinton was less militant about imposing traditional cost-benefit analysis, and therefore less controversial than its predecessors or successors. Yet the Clinton OIRA, as the other administrations, defined its role as suppressing excessive regulation.

At our conference on May 22, and in later conversations with OMB staff, we hope to convince you that the exigencies of the times demand that the OIRA's role be fundamentally redefined, bringing real change to this powerful office. Rather than view the primary job of a "regulatory czar" as prohibiting excessive regulation, we would define it as revamping the regulatory system to ensure that agencies are able to fulfill their regulatory missions in a vigorous, timely, effective, and wise manner. Instead of fine-tuning cost-benefit analysis, we recommend that the OIRA undertake an analysis of how much it would cost to increase agency budgets to the point that their statutory missions could be fulfilled. Rather than attempt to circumvent laws the OIRA thinks are economically inefficient—for example, the Clean Air Act's National Ambient Air Quality Standards (NAAQS), we urge the OIRA to make its views of the laws transparent, while at the same time following the law's instructions on how to consider regulatory costs unless and until these laws are changed.

In this vision, the OIRA would stop reviewing individual rules. Instead, it would spend its time helping agencies to explain their budgetary needs and priorities, resolving interagency disputes, and exploring important research topics of broad application, such as the seemingly chronic over-estimation of regulatory costs by regulated industries.

We hope you will join us on May 22 to discuss these and other ideas.

---

[1] Danny Hakim, "A Regulator Takes Aim at Hazards of S.U.V.s," *New York Times*, December 22, 2002, late edition, sec. 3.

The Problems with Cost-Benefit Analysis

Our threshold objection to traditional cost-benefit analysis is that it conflicts with the statutory standards established by Congress for health, safety, and environmental agencies. Only two of 22 major health, safety, and environmental statutes rely on a cost-benefit test to determine the level of regulation. In many cases, the OMB's insistence on superimposing this imperfect methodology trumps the considerations that must be the focus of agency decisionmaking: the criteria for decisionmaking established by the statutes themselves.

One common justification of cost-benefit methodology is that it makes decisions more "objective" and "rational." As practiced in the real world, cost-benefit analysis has proved incapable of eliminating those ambiguities and uncertainties that are of such a magnitude that they render it impossible to calculate the costs and/or benefits of a proposed regulation with sufficient specificity to allow any meaningful comparison. These flaws open up government decisionmaking to manipulation by interest groups, rather than rationalizing the process. Similarly, rather than promoting the democratic goals of transparency and public accountability, cost-benefit analysis obscures the inevitable policy choices and value judgments that underlie government decisionmaking behind a veil of numbers, and renders the decisionmaking process inaccessible to all those who lack advanced training in economics, as anyone who glances at the cost-benefit reports prepared by agencies will quickly conclude.

The indeterminacy of the methodology is the product of several factors. One of the most important sources of indeterminacy relates to the inability of cost-benefit analysis to measure the benefits produced by regulatory action. For example, cost-benefit analysts seek to divine people's "willingness to pay" for regulatory protections. But this effort is notoriously imprecise when the benefit in question is a non-market good—one that does not come with a specific price tag—the value of a child's health or clean drinking water, for example. Some monetization of benefits can often be attempted—avoided emergency room visits due to air pollution, for example, or tourist dollars generated by a wilderness area—but such valuations are often incomplete, and not all such benefits lend themselves to dollars-and-cents evaluations.

Moreover, willingness-to-pay is at least partly a function of a person's wealth, for the simple reason that wealthy people are able to pay more to attain a certain benefit or avoid a certain risk. That may not mean that the benefit is more valuable to them than to a poor person, just that they can afford it. By comparison, if regulatory benefits were monetized according to "willingness to sell"—that is, how much money people would charge to be exposed to additional safety or health risks—the value of regulatory benefits would undoubtedly be higher since this measure is not bounded by a person's wealth. So, for example, if we asked whether people were willing for their children to contract asthma for a certain amount of money, we would be applying a comparable calculation to the economists' preferred willingness-to-pay. This approach highlights how bizarre this kind of monetization would seem to the average person, and, in any case, is not used for purposes of monetizing benefits.

Another important source of indeterminacy is the absence of adequate data for calculating regulatory benefits. Even assuming that it was possible to place a monetary value of such non-market goods as lives saved or endangered species protected, it is rarely possible to predict in advance how many benefits will be achieved by a particular regulatory intervention. For example, it might be impossible to tell in advance how many lives will be saved by a particular

pollution control measure. Thus, the lack of adequate data concerning regulatory benefits, in conjunction with the inability to place an accurate measure on the monetary value on those regulatory benefits, serves only to pile indeterminacy upon indeterminacy, rendering the estimation of the monetary value of regulatory benefits to be a truly futile undertaking.

Still another source of indeterminacy is the use of discount rates to measure in current dollars the value of benefits that will not be realized until sometime in the future. For market goods, the use of a discount rate can be tricky enough, given that reasonable people can disagree about future projections of inflation and interest rates. But another layer of uncertainty is added when the discounting technique is applied to non-market goods like human life and pristine wilderness. Further, if we apply a 3- or 7-percent discount rate (as recommended by OMB) to the future benefits of, say, slowing the progress of climate change, benefits that will occur far in the future—even large ones—would virtually disappear. Rather than viewing the planet's well-being as a heritage we owe our children, this approach, taken to its logical conclusion, would justify consuming those resources until virtually nothing is left.

The indeterminacy of cost-benefit analysis severely undercuts the justification for its use—namely, that by providing a rational standard for decisionmaking, cost-benefit analysis reduces the undue influence of interest groups. In fact, its indeterminacy invites manipulation that leads to increased instances of litigation and transaction costs for the promulgation of new regulations. Accordingly, the existence of cost-benefit studies in regulatory records results in agencies spending more time in courtrooms defending their regulations and more time drafting elaborate defenses of their regulations in an effort to forestall such challenges. The end result is that these agencies will have less time and fewer resources to develop new regulations to protect people and the environment or to improve old regulations.

An Alternative Approach: Pragmatic Regulatory Impact Analysis

As outlined in a recent article, "Beyond Cost-Benefit Analysis: A Pragmatic Reorientation,"[2] by CPR Member Scholars Sidney Shapiro and Christopher Schroeder, we urge you to consider replacing traditional cost-benefit analysis with "pragmatic regulatory impact analysis," an approach that is far more consistent with the statutory mandates that apply to the five protector agencies. Under those statutes, health, safety, and environmental regulation proceeds in two steps. First, agencies determine whether a "risk trigger" has been met. The trigger specifies when risk is sufficiently serious to warrant regulation under the applicable statute. Although agencies must demonstrate that the risk to the public or the environment exceeds some threshold, regulators are authorized to act on the basis of anticipated harm. Second, agencies must determine the level of regulation by using whatever standard the statute applies to those determinations. For example, the Clean Air Act mandates the setting of NAAQS with "an adequate margin of safety," while the Clean Water Act instructs the EPA to use various forms of "best" pollution control technologies.

[2] Sidney A. Shapiro & Christopher H. Schroeder, *Beyond Cost-Benefit Analysis: A Pragmatic Reorientation*, 32 HARV. ENV. L. REV. 433 (2008).

A pragmatic regulatory impact analysis focuses on the issues generated by the statutory standard under which the agency operates. Technology-based standard setting is the most common method of establishing the level of regulation. In this type of statute, Congress requires an agency to choose the level of risk reduction by identifying and patterning regulatory objectives upon some model technology. Regulated entities are required to achieve the same degree or extent of protection as the model technology. For example, the Occupational Safety and Health Act requires employers to provide the maximum level of protection that can be achieved by available technologies unless the cost of this level of protection will threaten the financial integrity of the industry being regulated. Traditional cost-benefit analysis is superfluous to the resolution of the issues raised by implementation of this standard.

Open-ended balancing is the second most common method of establishing the level of regulation among the surveyed statutes. No statute relying on open-ended balancing (*e.g.*, NAAQSs under the Clean Air Act) requires the use of a cost-benefit criterion for establishing the level of regulation. Instead, agencies take cost into consideration, and then adopt the level of protection justified by other factors. Statutes with an open-ended balancing standard require an agency to consider a variety of factors, but the statutes do not indicate what weight an agency is to give each factor. A pragmatic regulatory impact analysis would discuss the potential impact of regulatory options according to each criterion in the statute, and it would identify arguments for how those criteria should be balanced.

Pragmatic regulatory impact analysis also provides an opportunity to offer a transparent accounting of the issues relating to risk assessment that the agency is considering. Such analyses should clearly describe the nature and extent of the potential harm and convey a sense of the uncertainties that surround any quantitative statements. Agencies would be required to identify the assumptions or inferences they have employed, as well as the scientific and policy bases for those inferences. If scientific and policy experts cannot reach consensus about an issue, the agency should present both sides of debate, explaining how it intends to resolve these disagreements.

This alternative methodology is more useful than a traditional cost-benefit analysis for assessing risk triggers for three reasons. First, pragmatic regulatory impact analyses would focus on the issues of reliability and acceptability in order to arrive at a characterization of risk that is useful for making the decisions required by the statute, while the discussion of risk data in a traditional cost-benefit analysis is typically divorced from such statutorily mandated concerns. Instead, traditional cost-benefit analysis focuses on risk information to generate monetary estimates of the benefits of a proposed rule. This orientation deflects the analysis into a discussion of monetization rather than a consideration of the risk issues relevant under the risk trigger. Second, a cost-benefit dominated analysis is not structured to conduct a discursive inquiry into the risk evidence, and such a discussion would likely be beyond the expertise of the economists who are responsible for conducting it. Finally, the emphasis on pinpoint benefit estimates in a cost-benefit dominated analysis has the effect of hiding the underlying uncertainties in the risk evidence.

Under existing practice, the first time that the public usually becomes aware of how an agency has sorted out the issues relating to the risk trigger and the statutory standard is in the Notice of Proposed Rulemaking. The pragmatic regulatory analysis described above would in effect be a discussion draft of that document. A pragmatic regulatory impact analysis would

therefore not only assist decisionmakers in formulating rulemaking proposals, it would provide the public with the background information concerning the issues to be resolved in formulating these proposals in a form that should be accessible and understandable.

Once again, we hope you will join us on May 22 to explore these proposals.

Sincerely,

Rena Steinzor
President
Center for Progressive Reform