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Re: Comments Regarding Executive Order on OMB Regulatory Review

Dear Sir/Madam:

We write to you today to submit comments regarding the new Executive Order on Regulatory Review. We submit these comments in response to the invitation for public comments announced in the *Federal Register* notice published on February 26, 2009.

I. INTRODUCTION

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. Whether it involves protecting consumers from peanut-butter that makes them ill, preventing the importation of toys that can kill and injure children, protecting workers in plants that manufacture microwave popcorn from a fatal lung disease, or beginning to address global warming, over the last eight years, the regulatory structure has time and again demonstrated its inability to keep up with the range of potential harms confronting Americans.

The institution of centralized regulatory review, conducted through the lens of cost-benefit analysis, has played a prominent role in contributing to the dysfunctional state of the regulatory system. To correct this situation, and to rescue agencies from their dysfunctional state, nothing less than a fundamental redesign of the institution of regulatory review is required. In particular, we recommend two major changes to Executive Order 12866.

First, the Office of Information of Regulatory Affairs (OIRA) must abandon its role of conducting centralized regulatory review. During the Bush Administration, OIRA's mission was defined exclusively as controlling excessive regulation by agencies through review of individual rules and the threat that any one may be held up as its economists question an agency's cost-benefit analysis. OIRA's role should be fundamentally reoriented. It should work with agencies to improve their ability to fulfill their regulatory missions, helping agencies to calculate and document their true budgetary needs, develop better and more proactive regulatory agendas, resolve interagency disputes, and ensure they have the necessary legal authority to truly protect individuals and the environment. Not only would this broader role for OIRA help agencies to carry out their regulatory missions far more effectively, it would also feature OIRA's unique institutional strengths. With just 35-40 staff economists, OIRA is ill-suited to conduct any meaningful review of the complex issues at stake in highly complex rulemakings. Instead, OIRA inevitably ends up cherry-picking the rulemakings that are targeted by the most vociferous industries.

Second, the new Executive Order must replace cost-benefit analysis as a determinative factor in regulatory decision-making for two reasons: (1) it is inconsistent with the law in most cases and (2) it has failed as a tool of regulatory analysis. In the vast majority of public health, safety, and environmental statutes, Congress has not chosen to incorporate cost-benefit analysis. It has instead directed agencies to use a variety of well-established alternative methods for setting standards. These include technology-based standard-setting, effects-based standard-setting, and multi-factor balancing. As a result, OIRA's review of individual rules through the lens of cost-benefit analysis is almost always at odds with the agency's congressionally delegated rule-making authority.

Moreover, cost-benefit analysis is a failed approach to regulatory analysis, producing reliably unreliable results. To be clear, cost-benefit analysis is not in need of mere tweaking. It is inherently flawed. Over a quarter century of use by administrations of both parties, it has failed to accurately or adequately capture the benefits of proposed regulations, and it has even ignored some benefits altogether because they defied monetization. At the same time, it has frequently overstated the costs to industry of compliance. As a result, cost-benefit analysis is a truly distorted approach to regulatory decision-making that is tilted heavily against new regulations.

One reason that some past administrations have continued to use cost-benefit even though it is unsupported by statute is that it perfectly suited their ideological purposes, slanting regulatory analysis in opposition to protective regulations, so as to benefit industry. The current administration, concerned as it is about protecting health, safety, and the environment should not fall back on cost-benefit analysis, or be cowed into using it, simply because it has been in use a long time. It was introduced despite the lack of a statutory basis, it has continued in use despite its manifest failings, and the only argument for its continuation is that it has grown familiar to Washington insiders. It is "the way we've always done things." But it has failed the public. It has been an impediment to the enforcement of the law. It has foiled congressional intent. It has become a tool for opponents of meaningful environmental, health and safety protections. Its time has passed.

In order to assure the quality of agency rulemaking, we describe below a new approach to regulatory decision-making: “Pragmatic Regulatory Impact Analysis” (PRIA). This methodology starts from the premise that the agency should employ the particular standard-setting method that Congress specified in the relevant statute. Rather than sweeping aside those congressionally mandated standard setting methods, PRIA provides a framework designed to help agencies work through the difficult policy and science issues that must be resolved in order to apply those methods.

PRIA preserves the regulatory agency as the primary locus of rulemaking authority. Individual agencies would conduct such analyses and issue them as discussion drafts for Notices of Proposed Rulemaking. The key characteristics of a pragmatic regulatory impact analysis are its emphasis on all the factors specified by the statutes, and its reliance on informed judgments by a full range of scientific, technical, legal, and managerial experts at agencies with respect to those central issues. These characteristics make for a decision-making process that is more transparent, inclusive, and effective. Allowing agencies to focus on PRIA, a process that is required by their authorizing statutes, rather than sidetracking them into the far more constrained and myopic performance of cost-benefit analyses would produce far better regulatory decisions.

The comments that follow begin in Part II by examining the current dysfunctional state of public health, safety, and environmental agencies. Parts III, IV, and V explain how the two proposals for reform outlined above—a reoriented role for OIRA and the replacement of cost-benefit analysis with pragmatic regulatory impact analysis—will ultimately improve the regulatory system, by supporting the efforts of regulatory agencies to fulfill their regulatory missions of protecting individuals and the environment. Finally, Parts VI, VII, and VIII then explain how the current institution of centralized regulatory review, conducted through the lens of cost-benefit analysis, has contributed to the current dysfunctional state of the regulatory agencies.

II. HEALTH, SAFETY, AND ENVIRONMENTAL AGENCIES SUFFER FROM FUNDING SHORTFALLS, INADEQUATE LEGAL AUTHORITY AND EXTENSIVE POLITICIZATION.

The federal agencies charged with protecting public health and the environment—the Consumer Product Safety Commission (CPSC), the Environmental Protection Agency (EPA), the Food and Drug Administration (FDA), and the Occupational Safety and Health Administration (OSHA), to name a few—lack the resources, the legal authority, and the political will to carry out effectively their vitally important statutory missions. 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. Yet, 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. 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. 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 of 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 medically 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.

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.

III. CONGRESS DIRECTED HEALTH, SAFETY, AND ENVIRONMENTAL AGENCIES TO USE A MULTI-FACTORIAL ANALYSIS THAT EXTENDS FAR BEYOND THE CRABBED AND MYOPIC CONSIDERATIONS INVOLVED IN TRADITIONAL COST-BENEFIT ANALYSIS.

Only two of the 31 statutory mandates that apply to health, safety, and environmental agencies specifically call for a balancing of costs against benefits as part of the judgments agencies must make in formulating regulations. Instead, as illustrated by the table on the next page, in 29 out of 31 of these provisions, Congress directed agencies to use one of several, well-established alternatives to cost-benefits analysis including the formulation of technology-based or effects-based standards, phased bans, or the balancing of multiple factors.

A. Technology-Based Standards

The most common of the standard setting methods employed by Congress is technology-based standards, sometimes also referred to as feasibility standards. Technology-based standards are called for extensively throughout the Clean Air Act and the Clean Water Act, among many others. These standards set pollution limits at the lowest level technologically and economically feasible, assuming that such pollution reductions will deliver sufficient health and environmental benefits to be worth the costs. This requires the agency to evaluate the likely costs of a proposed standard in order to determine whether it is economically feasible (*i.e.*, “available”). But it does not require agencies to delve into the far more problematic task of attempting to quantify and monetize the environmental benefits of regulation in order to compare them to costs.

Congress’ rejection of cost-benefit analysis was grounded in experience with the kind of regulatory paralysis that can result when decision-making standards impose unrealistic information burdens on agencies. Congress’ adoption of technology-based standards in the Clean Water Act, for example, was in response to just such a failure. Previous versions of the Act had required standard-setting and enforcement to be based on an evaluation of the benefits of regulation—*i.e.*, on assessments of the quality of the receiving waters. This approach proved to be entirely unworkable—in the words of the Senate Committee on Public Works—“inadequate in every vital aspect.”¹ Evaluating the benefits of water pollution reduction required tedious and costly site-specific measurements, as well as assessments of complicated and inadequately understood ecological chains of causation. Technology-based standard-setting, on the other hand, allows the EPA to set uniform national standards for each industry based on the maximum technologically achievable level of pollution reduction.² This only requires the agency to evaluate technologies and costs, without delving into the problematic realm of precisely quantifying environmental benefits.

B. Effects-Based Standards

In a number of statutes, Congress has directed agencies to use effects-based standards that consider only the human health or environmental effects of a regulation without regard to economic costs. The most prominent examples of these are the National Ambient Air Quality Standards under the Clean Air Act and the stringent standards for the protection of imperiled species under the Endangered Species Act. In the case of the Clean Air Act, these effects-based standards reflect Congress’ concern with the paramount importance of protecting human life as

Only Two Statutory Provisions Protecting Health, Safety, and the Environment Call for Cost-Benefit Analysis

Reliance on Cost-Benefit Analysis?	Statutory Standard	Provisions in Environmental, Health and Safety Statutes	Number of Provisions
Prohibited by statute: 23	<i>Technology-Based</i>	<ul style="list-style-type: none"> • Clean Water Act (existing sources standard) • Clean Water Act (new sources standard) • Clean Air Act (non-attainment areas standard) • Clean Air Act (prevention of significant deterioration standard) • Clean Air Act (national emissions standards for hazardous air pollutants) • Clean Air Act (mobile sources standard) • Clean Air Act (new sources standard) • Occupational Safety and Health Act • Resource Conservation and Recovery Act (land disposal restrictions) • National Traffic and Motor Vehicle Safety Act • Surface Mining Control and Reclamation Act 	11
	<i>Effects-Based</i>	<ul style="list-style-type: none"> • Clean Water Act (ambient water quality standards and anti-degradation policy) • Clean Air Act (national ambient air quality standards) • Food, Drug, and Cosmetic Act (Delaney Clause) • Food, Drug, and Cosmetic Act (pesticide residues standard) • National Forest Management Act (diversity protection provision) • Endangered Species Act (species listing, take, and jeopardy standards) • Wilderness Act • Wild and Scenic Rivers Act • National Wildlife Refuge Administration Act • National Park System Organic Act 	10
	<i>Phased Ban</i>	<ul style="list-style-type: none"> • Clean Air Act (ozone depleting materials standard) • Toxic Substances Control Act (polychlorinated biphenyl standard) 	2
Permitted but not required by statute: 6	<i>Multi-factor Balancing</i>	<ul style="list-style-type: none"> • Comprehensive Environmental Response, Compensation, and Liability Act • Federal Insecticide, Fungicide, and Rodenticide Act • Toxic Substances Control Act • National Forest Management Act (multiple use and sustained yield standard) • Federal Land Policy and Management Act (multiple use and sustained yield standard) 	5
	<i>Technology-Based/Cost-Benefit Hybrid</i>	<ul style="list-style-type: none"> • Safe Drinking Water Act³ 	1
Required by statute: 2	<i>Cost-Benefit</i>	<ul style="list-style-type: none"> • Consumer Product Safety Act • Accountable Pipeline Safety and Partnership Act 	2

well as its desire to challenge industry to develop the next generation of more effective pollution control technologies rather than accepting the limits of existing technologies. The cost-blind nature of the NAAQS is tempered by the fact that they are implemented through technology-based standards that do allow for the consideration of costs.

The Endangered Species Act, on the other hand, with only a couple of rarely employed exceptions,⁴ allows no consideration of costs whatsoever in setting standards for the protection of species facing extinction. This reflects Congress' judgment that endangered species implicate such "immeasurable" and "incalculable" values we should "halt and reverse the trend toward species extinction, whatever the cost."⁵ In other words, certain values are simply too important to be balanced against economic costs and therefore stand outside the economic calculus.⁶

C. Phased Bans

In a limited number of instances, Congress has ordered a phased ban of a particular risk-creating substance. In some ways, this standard might be seen as special case of an effects-based standard in which Congress has made a determination that no level of the particular risk to be regulated is safe. A phased ban also reflects Congress' judgment that an immediate ban would impose excessive regulatory costs (*e.g.*, because there is no viable alternative to the banned substance) and that a ban should therefore be phased in to minimize the most disruptive aspects of the regulation.

D. Multi-factor Balancing

Even in those instances in which Congress has instructed agencies to compare costs and benefits, it almost never requires them to perform a full-fledged quantified and monetized cost-benefit analysis. Instead, statutes with a multi-factor balancing standard require an agency to consider a variety of factors, and to weigh them in qualitative terms. Thus, these statutes do not require the agency to attempt to quantify these factors or convert them into monetary units. Moreover, they do not indicate what weight an agency is to give to each factor.⁷ The EPA, for example, is authorized under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) to place conditions on the licensing of pesticides to the extent necessary to avoid "unreasonable adverse effects on the environment."⁸ Congress defined unreasonable adverse effects on the environment as "any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits" of the pesticides' use."⁹

IV. HEALTH, SAFETY, AND ENVIRONMENTAL AGENCIES SHOULD PROMULGATE REGULATIONS USING PRAGMATIC REGULATORY IMPACT ANALYSIS INSTEAD OF TRADITIONAL COST-BENEFIT ANALYSIS FOR CONDUCTING REGULATORY REVIEW

A. Pragmatic Regulatory Impact Analyses Consider the Factors Specified by the Relevant Authorizing Statute Beginning at the Outset of the Rulemaking Process.

As outlined in a recent article, *Beyond Cost-Benefit Analysis: A Pragmatic Reorientation*,¹⁰ by CPR Member Scholars Sidney Shapiro and Christopher Schroeder,

traditional cost-benefit analysis should be replaced with “pragmatic regulatory impact analysis,” (PRIA) an approach that assists agencies in complying with the standards mandated in the various public health, safety, and environmental statutes. The purpose of a pragmatic regulatory impact analysis is to help regulatory agencies work through the difficult science and policy issues that must be resolved in order to promulgate new regulations.

The hallmark of a pragmatic regulatory impact analysis is that it actively seeks out and considers a full range of views on the factors specified by the applicable statute. So, for example, if an environmental statute calls for technology-based standards, the agency would explore the pollution control alternatives that are available throughout the industry, determine the reductions in pollution that those technologies provide, and analyze whether it would be feasible for plants to obtain and install the best of the technologies that are available. The agency would also consider the aspect of public health or the condition of the environmental media or other threatened resource that is threatened by the pollution it is seeking to control, and determine how those conditions would be improved by the installation of the technologies that are available.

Under an effects-based standard, the EPA would consider everything that scientists and other technical experts can tell them about the release of pollutants, their “fate and transport” through ambient air, the exposure levels experienced by the population as a whole and, especially, by vulnerable populations (*e.g.*, the elderly or young children), and the health effects likely to result from those exposures. The EPA would weigh the inevitable uncertainties that plague such estimates. It would explore the best methods available for reducing pollution to levels that will eliminate harmful exposures. It would then consider any other methods that might be available to accomplish these results.

Pragmatic regulatory impact analyses are nothing more—and certainly nothing less—than a methodical exploration of these factors and considerations in a carefully designed and well-conducted rulemaking process. In practice, tentative PRIAs should be published early in the regulatory decision-making process. In effect, they would serve as the discussion draft of the Notice of Proposed Rulemaking (NPR). The purpose of this document would be to outline the issues that must be resolved in promulgating a new regulation and to describe the relevant factors that must be considered in resolving these issues. Through this document, a regulatory agency could even seek to invite input from relevant stakeholders on how to resolve the necessary issues for reaching a regulatory decision. The agency would be able to take this input into account as it moves towards a tentative regulatory decision, which it would announce in the Notice of Proposed Rulemaking. Notably, the individual regulatory agencies would conduct and make decisions to finalize their own pragmatic regulatory impact analyses rather than submitting individual rules to an office like OIRA for centralized review.

As a discussion draft for a Notice of Proposed Rulemaking, a pragmatic regulatory impact analysis would therefore not only assist decision-makers in formulating the NPR; it would provide the public with the background to the NPR in a form that would be accessible and understandable. By establishing this relationship between the underlying statute and the NPR, a pragmatic regulatory impact analysis would make the rulemaking process transparent and accessible to the public. Moreover, if agencies invited public comment on this document, the regulatory impact analysis process would take on a further participatory element. Because the

regulatory impact analysis itself would seek to assist the public in understanding the issues at stake and the advantages and disadvantages of policy options, this process should produce better public input and be of more assistance to the agency.

B. Pragmatic Regulatory Impact Analysis Is a Substantial Improvement over Traditional Cost-Benefit Analysis

As suggested above, the use of a PRIA would offer a number of advantages over cost-benefit analysis. Specifically, PRIAs help agencies to promulgate regulations that are consistent with the provisions of the statutes passed by Congress; it is better at informing the public about how agencies have resolved the key issues necessary for promulgating new regulations; and by inviting consideration of a broader array of factors relevant to regulatory decision-making, it offers the promise of reaching better regulatory decisions.

1. Respects Democracy

First and foremost, the goal of a PRIA is to implement Congress' commitment to a precautionary approach to protecting people and the environment. Cost-benefit analysis, by comparison, supports an entirely different and inconsistent goal—maximization of economic efficiency. PRIAs offer an approach for analyzing the issues that Congress requires an agency to resolve in order to regulate, rather than deflecting the agency into the dubious exercise of measuring economic efficiency, which is almost always irrelevant to the statutory mission of the agency. The pragmatic alternative is therefore preferable because it serves democracy by working to implement the laws as Congress intended.

2. Informs the Public

Most of the elements of cost-benefit analysis are subject to manipulation, whether by interested parties with sufficient resources to do so or by agencies pursuing their own agendas. This manipulation can be done in ways that are far from transparent to the untrained outsider. Even when citizen groups, environmental organizations, or others have the resources to hire the experts necessary to expose questionable data, models, or assumptions, successfully challenging them is extremely difficult. In addition, cost-benefit analyses are typically released to the public only after the NPR has been published. Even assuming that the general public could understand these complex and lengthy documents, the timing of their release ensures that the public has no opportunity to participate in the process of identifying the potential impacts of a proposed regulatory action and determining how those potential impacts ought to contribute to regulatory decision-making.

A pragmatic regulatory impact analysis, by comparison, lays on the table the issues that an agency confronts and forces out into the open the value judgments that often hide behind numerical estimates of cost-benefit analysis. Unable simply to rely upon a cost-benefit computation for analysis, an agency will have to engage these issues by discussing them. This in turn will inform members of the public and arm them, if necessary, to challenge the agency's analysis. The PRIA methodology has this impact because the agency head will eventually have to articulate why the agency reached the judgment it reached in light of the counter-claims and

arguments that were raised in the PRIA. This will enable outsiders to evaluate and critique the judgment according to the same criteria that the agency head utilized in reaching it, thereby producing a debate that focuses on the appropriate questions and concerns.

3. Improves Decision-Making

Proponents of cost-benefit analysis argue that pros and cons of a proposal can only be meaningfully and rationally weighted by quantifying them and converting them to a single monetary metric. But the fact that a pragmatic regulatory impact analysis does not attempt to compare and weigh precisely the pros and cons of a decision according to a single metric, such as monetary value, is an advantage, not a disadvantage. The pragmatic approach allows consideration of the pros and cons of a decision from multiple points of view and acknowledges that one's assessment of pros and cons can change as a result of the process of thought and reflection upon different perspectives.

In addition, the pragmatic approach is as capable of ranking priorities among competing projects as it is capable of determining how to proceed with any single project. Indeed, priority-setting in a democracy cannot and should not be reduced to any technical exercise, whether cost-benefit analysis or any other. Setting priorities goes to the heart of the enterprise of governing, frequently implicating a contest among competing values. This is why a pragmatic regulatory impact analysis can produce better priority-setting by agencies than cost-benefit analysis can. When compared to cost-benefit analysis, a pragmatic regulatory impact analysis articulates a wider range of perspectives, analyzes choices using a broader range of disciplines, and discusses the values that are at stake in particular choices. As such, a pragmatic regulatory impact analysis is able to recognize the public concerns and values that are at stake in regulatory decision-making better than cost-benefit analysis.

V. OIRA SHOULD FOCUS ON HELPING HEALTH, SAFETY, AND ENVIRONMENTAL AGENCIES ACHIEVE THEIR STATUTORY MISSIONS IN A TIMELY AND EFFECTIVE MANNER

As described above, 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. For the past several years, OIRA has played a prominent role in contributing to this state of affairs by serving as a hurdle to much-needed regulatory action. To rescue this failed system, it will be necessary to bring about a fundamental reorientation in OIRA's role. Rather than viewing its job as ferreting out allegedly excessive regulation, OIRA's role should be redesigned so that it is centered on ensuring that agencies are able to fulfill their regulatory missions in a vigorous, timely, effective, and wise manner. Rescuing regulatory 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 make up the new role of a reinvented OIRA. In addition, OIRA is also well-positioned to undertake broad research on topics that can help improve the information that agencies use in their pragmatic regulatory impact analyses.

A. OIRA Should Help Insure That Health, Safety, and Environmental Agencies Have the Resources They Need to Achieve Their Statutory Missions.

OIRA should undertake an analysis of how much it would cost to increase agency budgets to the point that their statutory missions could be fulfilled. One of the reasons that regulatory agencies cannot fulfill their statutory missions is that financial resources and available personnel have been reduced or maintained at constant levels in recent years. This has been occurring as the problems these agencies have faced have become more complex, thus forcing these agencies to effectively do more with less. To make matters worse, these agencies have faced an ever greater number of analytical requirements, which draw upon agencies' already stretched resources and distract them from focusing on their regulatory missions.

Even if these unnecessary analytical requirements were to be eliminated, agencies would still not have the necessary resources and personnel to achieve their regulatory missions. OIRA, as a bureau within the White House Office of Management Budget, is in an ideal position to help remedy this problem. OIRA can serve as an advocate for these agencies, helping them to explain to the president and Congress the agencies' budgetary needs and priorities. Through this supportive role, OIRA can work with regulatory agencies to ensure that they have sufficient resources and personnel to carry out their regulatory missions.

In particular, OIRA should work with agencies to help them develop analyses that lay out for Congress all of the money an agency would need to fully perform its mandated duties. These analyses would include the funds necessary to make current programs function effectively, to implement newly mandated programs, and to keep up with changing circumstances. An analysis for the Consumer Product Safety Commission, for example, would include the funding necessary to increase the number of inspectors at the borders in order to ensure the safety of the vast proportion of our consumer goods that are now imported from overseas.

B. OIRA Should Help Health, Safety, and Environmental Agencies Develop Strong, Proactive Agendas

Adequate resources and personnel alone will not ensure that regulatory agencies achieve their missions. Agencies also need to be able to leverage those resources and personnel effectively. To do this, agencies will need to develop strong regulatory agendas. In particular, each agency will need a regulatory agenda that both properly establishes the agency's regulatory actions and allows the agency to anticipate and respond to new emerging issues. Once OIRA takes a supportive role in helping agencies to develop their budgetary needs and priorities, it will be well-positioned to help them to develop their regulatory agendas as well. In this process, however, economic efficiency must be treated as only one of many important considerations.

As a corollary to this agenda-setting function, OIRA's role should also reflect a greater emphasis on interagency coordination and dispute resolution. Once OIRA is working closely with each agency on its regulatory agenda, it will be in an ideal position to carry out this function. It can work with agencies to ensure that their regulatory actions do not conflict or overlap, and thus result in a senseless waste of limited government resources. When conflicts

between agencies do arise, OIRA should work to help the agencies reach a mutually agreeable resolution.

C. OIRA Should Ensure That Health, Safety, and Environmental Agencies Receive Enhanced Legal Authority to Take Decisive Legal Action

In addition to helping individual agencies develop their budgetary requests and regulatory agendas, OIRA can also work with regulatory agencies to identify those areas where the agency needs enhanced legal authority in order to address new and emerging issues that are relevant to their statutory missions. For many health, safety, and environmental agencies, the statutes under which they operate have not been reviewed or refreshed in two decades. In the interim, shortcomings in those statutes have been revealed and new public health, safety, and environmental issues that were not initially addressed by the original statutes have emerged. OIRA can help regulatory agencies to identify what updates and expansions of statutory authority are needed and can act as advocate on behalf of the agencies, helping them to present critical information to Congress and the President so that they can make informed policy choices.

D. OIRA Should Explore Broad Research Topics That Will Assist Health, Safety, and Environmental Agencies to Conduct Pragmatic Regulatory Impact Analyses in a More Effective Manner

As described above, the use of pragmatic regulatory impact analyses will advance as new and better ideas are introduced to improve regulatory decision-making. OIRA can play an important role in helping to develop new information vital to improved regulatory decision-making. For example, OIRA is uniquely positioned to research topics of broad importance to regulatory decision-making, such as exploring the seemingly chronic over-estimation of regulatory costs by regulated industries. Regulatory agencies can use the results of this research to inform and improve their regulatory decision-making.

VI. CONGRESS REJECTED COST-BENEFIT ANALYSIS FOR GOOD REASON; IT PRODUCES IRRATIONAL AND UNRELIABLE RESULTS

Congress has good reason to be skeptical of cost-benefit analysis. Put simply, when applied to environmental health and safety regulation, cost-benefit analysis rests on the untenable assumption that complex ecological and human health processes can be quantified and expressed in dollar terms. In practice, scientific understandings are rarely fine-grained enough to predict impacts in quantifiable terms. Even where they are, data are inevitably vastly incomplete. And even for those quantifiable data that do exist, the process of converting such data into dollar terms raises intractable practical and theoretical difficulties that make most monetized estimates of impacts endlessly contestable. As a result, cost-benefit analysis fails miserably at its appointed task. Rather than providing a common sense tool for insuring reasonable regulation, cost-benefit analysis produces Alice-in-Wonderland results that most of the time are so incomplete and unreliable, they provide endless opportunity for interest groups to manipulate and contest the results.¹¹

The EPA's cost-benefit analysis of its rule regulating cooling water intake structures at existing power plants provides an illustrative example. Power plants withdraw millions of gallons of water a day for cooling purposes. In the process, billions of aquatic organisms are killed, either by being trapped against the components of the cooling water intake structure or by being sucked up into the cooling water system itself. In order to quantify the environmental benefits of a rule that would require power plants to take steps to reduce these adverse impacts, the EPA had to attempt to first quantify and then monetize the number of organisms harmed by this process that would be saved by the rule.

As is typical of such attempts to estimate the environmental benefits of regulation, the data the EPA had to work with were vastly incomplete. First, from the outset, the EPA left out whole categories of aquatic organisms for which it simply had no data. These included a number of species that the EPA acknowledged might play crucial roles in the food chain and other aspects of the aquatic ecosystem—phytoplankton and zooplankton; endangered sea turtles; and even certain commercially valuable species, such as shrimp, lobsters, crabs, and mussels. But even of the fish species it did include in its analysis, the EPA counted only the less than two percent that would be caught by commercial or recreational fisherman if they escape the cooling water intake structures. The EPA candidly admitted that its estimate “does not account for the benefits from the remaining 98.2% of the . . . aquatic organisms estimated to be protected nationally under today's rule.”¹²

Once it had arrived at this grossly incomplete quantification of the number of fish benefited by the rule, the EPA faced the difficult task of trying to attach a dollar figure to the saved fish. With respect to the tiny percentage of those fish that would be commercially caught, the EPA simply used the market price. With respect to the even smaller number of recreationally caught fish, it used a controversial model that inferred anglers' willingness-to-pay for recreational fishing based on their travel costs for visiting particular fishing sites and then used a mathematical model to estimate how that willingness-to-pay would likely increase in response to increased catch levels. Even putting aside the difficulties with this model, the EPA acknowledged that monetizing only the commercial and recreational value of these fish accounted for only a small slice of their overall ecological value. Initially, in the cost-benefit analysis accompanying its proposed rule, the EPA used several methods to attempt to monetize at least some of these ecological values. These methods proved controversial, however, and after receiving considerable criticism in the comments to the proposed rule, the EPA finally threw up its hands and simply attached no dollar value to these ecological values at all. Thus, by the time it issued the final rule, the EPA's benefits estimate—grossly incomplete by its own admission to begin with—had shrunk by nearly tenfold, from \$735 million in the proposed rule to just \$83 million in the final rule.¹³

In reporting the costs and benefits of the final rule, the EPA flatly acknowledged that its benefits estimate was grossly incomplete, making a meaningful comparison with costs impossible: “EPA notes that these analyses are based on a comparison of a partial measure of benefits with a complete measure of costs; therefore, the results must be interpreted with caution.”¹⁴ Nonetheless, it appears that OIRA pressured EPA into changing its proposed rule on the basis of this highly flawed, incomplete, and irrational cost-benefit analysis. Although records of the communications between the EPA and OIRA during the review process are not public, the

rule emerged from the OIRA review process without the more stringent requirement that certain plants use the far more environmentally friendly closed cycle cooling process. The only reason the EPA cited for the change was the results of its cost-benefit analysis: the dollar benefits of the rule did not outweigh the dollar costs.¹⁵

This is just one example of the irrational results that routinely result when cost-benefit analysis is applied to environmental, health and safety regulation. We could have cited many others. One study looked at 25 cost-benefit analyses of agency rules reviewed by OMB in a one-year period and found that in 19 of the 25 cases, the agencies were unable to monetize *any* of the rules' benefits. In the remaining cases, significant benefits were omitted.¹⁶ The National Highway Traffic Safety Administration's CBA of its new rule setting fuel efficiency standards for light trucks in 2006 omitted the climate change impacts of the rule entirely.¹⁷ And the EPA's cost-benefit analysis of its Mobile Source Air Toxics Rule literally left out all of the benefits at which the rule was aimed—*i.e.*, those associated with reductions in air toxics.¹⁸

Nor have we even touched on the litany of theoretical conundrums that plague efforts to apply cost-benefit analysis to environmental health and safety regulation. Cost-benefit analysis attempts to assign value to things based on people's willingness-to-pay, but this is a notoriously problematic measure of value. A person's willingness to pay, for example, is tied in part to her wealth. This leads to ethically questionable practices like valuing the lives of people in the U.S. 30 times higher than the lives of people in India.¹⁹ The practice of discounting the benefits of regulation that will accrue in the future also creates unending controversy. After decades of debate, there has been no agreement on what discount rate is appropriate for valuing future benefits, particularly those that accrue to future generations. Some argue that no discount rate at all should be used. OMB suggests a rate of seven percent. Yet final benefits estimates can vary enormously—by orders of magnitude—depending on the discount rate used.

In the end, the intractable practical and theoretical difficulties that plague any attempt to apply cost-benefit analysis to environmental health and safety regulation inevitably produce irrational and unreliable results. This indeterminacy only undercuts the justifications for its use—namely, that by providing a rational standard for decisionmaking, cost-benefit analysis increases transparency and reduces the undue influence of interest groups. In fact, its indeterminacy invites manipulation that leads to litigation and, accordingly, to increased transaction costs for the promulgation of new regulations. The end result is that the agencies have less time and fewer resources to develop new regulations to protect people and the environment or to improve old regulations.

VII. RATHER THAN AIDING REGULATORY DECISION-MAKING, THE USE OF COST-BENEFIT ANALYSIS HAS IN FACT HARMED THE REGULATORY SYSTEM BY DILUTING OR DELAYING MUCH-NEEDED REGULATION

As detailed above, the vast majority of federal health, safety, and environmental statutes Congress prohibited agencies from basing their regulatory decisions on cost-benefit analysis. And it did so for good reason. Cost-benefit analysis in this context produces irrational results. Accordingly, the cost-benefit analysis mandated by EO 12,866 in most instances creates

pointless bureaucratic make-work that serves only to needlessly delay and dilute regulatory initiatives. Indeed, that was the original goal of the cost-benefit mandate.

The widespread use of formal cost-benefit analysis by federal agencies began in 1981, when President Reagan signed Executive Order 12,291, requiring formal cost-benefit analysis to be prepared for all major federal regulations. The executive order was seen at the time as a highly partisan effort to slow regulatory activity, and it “proved extremely controversial.”²⁰ Indeed, it explicitly stated that its purpose was “to reduce the burdens of existing and future regulations.” Executive Order 12,291 gave authority to oversee agency compliance with the new cost-benefit analysis mandate to the newly created Office of Information and Regulatory Affairs (OIRA).

It was widely assumed that OIRA review of regulations under the executive order’s cost-benefit analysis mandate would have the effect of delaying and weakening rather than spurring regulation, and that, indeed, has been the effect, even during subsequent administrations. For example, as mentioned above, a study of 25 rules that the U.S. Government Accountability Office found had been significantly affected by OIRA between June 2001 and July 2002 concluded that in 24 of the 25 instances, OIRA’s recommendations would have reduced regulatory protections.²¹ This evidence suggests that the original—politically motivated—regulatory relief objective for White House review continues to play a significant role in the review process.

Even where the use of cost-benefit analysis is not able to produce reductions in regulatory stringency, the mere process of subjecting individual regulation to comprehensive centralized regulatory review has the effect of delaying regulations. Because of OIRA’s small staff (at last count, around 30-35 professional staff) and its large workload (OIRA reviewed around 600 regulations in fiscal year 2006-2007), the review process can last several months, and in some cases, well over a year.

One example of how cost-benefit analysis has been used to hobble much-needed regulation involves the EPA’s 2002 proposed regulation to restrict emissions of nitrogen oxide from large ships.²² Nitrogen oxide is a precursor to particulate matter pollution, which results in tens of thousands of deaths in the United States every year. It also contributes to ground level ozone, which triggers countless asthma attacks and other lung-function incidents a year—many requiring emergency room visits. In its proposed rule, the EPA offered OIRA two different levels of stringency for controlling nitrogen oxide emissions from large ships. The first imposed a standard essentially identical to what was already required under international law. The second level of stringency mandated a 30-percent cut from the international requirement.

When OIRA ran the rule through its cost-benefit process, it estimated that the economic benefits of deaths and emergency room visits avoided from the more stringent rule at zero dollars. Zero dollars for lives saved, and not a penny for emergency visits avoided. Apparently the EPA reached this conclusion because it lacked adequate data to quantify accurately the number of premature deaths and health emergencies that would be averted by the more stringent standard. OIRA and the EPA had no reason to doubt there were such savings, and there was no shortage of data to prove it. But in the absence of a firm estimate, OIRA assigned zero value.

Under OIRA's warped approach, rules that produce no benefits are treated exactly the same as rules for which the benefits defy quantification. That meant the tighter standard for nitrogen-oxide literally had nothing going for it, and was therefore rejected. The EPA ended up adopting a rule based on the far less stringent standard, and the air that Americans breathe today has that much more nitrogen-oxide in it as a result.²³

VIII. THE INSTITUTION OF CENTRALIZED REVIEW OF INDIVIDUAL REGULATIONS BY OIRA SHOULD BE TERMINATED

The institution of centralized regulatory review by the Office of Information and Regulatory Affairs (OIRA) has also contributed to the current inability of regulatory agencies to fulfill their regulatory missions. The institution of centralized review in effect allows the personnel of OIRA to substitute their judgment about the substantive content of regulations for that of the agencies trying to promulgate the regulations. This phenomenon is inconsistent with the specific provisions of the public health, safety, and environmental statutes. Moreover, OIRA lacks the institutional capacity to carry out this function.

The practical effect of centralized review is that it gives OIRA substantial power to influence the substantive content of the regulations. Thus, under the current system of regulatory review established by Executive Order 12,866, OIRA has the authority to review all major rules (*i.e.*, rules with some specified large impact on the economy or the federal budget) to determine whether the rules are economically efficient—that is, whether the rule has passed a strict cost-benefit test. Until OIRA has approved the agency's cost-benefit study for a particular rule, that agency is prohibited from finalizing the rule. Through this centralized review process, OIRA retains substantial authority to reject or change agency rules that fail to achieve its conception of economic efficiency.

The influence that centralized regulatory review gives OIRA over the substance of regulations, however, is inconsistent with the provisions of public health, safety, and environmental statutes, which expressly delegate the function of determining the substantive content of implementing regulations to regulatory agencies. In passing these statutes, Congress had good reason to delegate rulemaking functions to executive agencies. With large staffs of scientists, policy analysts, attorneys, economists, and other professionals, executive agencies are able to leverage a unique and multidisciplinary expertise in resolving the complex substantive issues that are at the core of regulatory decision-making.

In contrast, OIRA has a surprisingly small staff at its disposal. In 2003, the last year for which reliable statistics were available, OIRA had only 30 to 35 professionals conducting its regulatory reviews. This small staff has to review hundreds of regulations in any given year. For example, in fiscal year 2006-2007, OIRA reviewed approximately 600 regulations. This large number of regulatory reviews does not even represent the full scope of work performed by OIRA's professional staff, which also includes approving thousands of paperwork requests as well as other tasks. This large workload suggests that OIRA's professional staff is not able to undertake a thorough review of each individual rule. To the extent that OIRA does attempt to

conduct a thorough review of a particular rule, this process inevitably entails severe delays of perhaps a year or longer. Needless to say, these delays greatly inhibit the ability of regulatory agencies to take necessary regulatory action to protect the public health, safety, and the environment. Moreover, because OIRA's professional staff is composed almost entirely of economists, it is not able to offer the same broad, multidisciplinary expertise to regulatory decision-making that the regulatory agencies can.

Congress also chose to delegate rulemaking authority to the executive agencies with the knowledge that a number of existing procedures and institutions ensure that such agencies can be held accountable for the substantive decisions they make. For example, through the oversight process, the democratically elected Congress is able to keep tabs on each agency's regulatory actions, and to encourage agencies to act in accordance with the provisions of the statutes it has enacted. In addition, either through the Administrative Procedures Act or through the provisions of some public health, safety, and environmental statutes, individuals and organizations have the ability to challenge the substance of an agency's regulatory decision-making as well. Through these accountability measures, regulatory agencies have a very strong incentive to abide closely to the provisions of the statutes they are implementing when they promulgate new regulations.

In contrast, there is no effective means for holding OIRA politically accountable. No committee or subcommittee in the democratically elected Congress has direct oversight authority over OIRA. In addition, no statutory provisions, including those in the Administrative Procedures Act, authorize individuals and organizations to challenge the substance of any decisions that OIRA makes. And because OIRA operates so far below the radar of the general public and the media, presidential elections can hardly be viewed as an effective check on OIRA's exercise of its regulatory review authority.

IX. CONCLUSION

The two proposed reforms described above—(1) eliminating OIRA's centralized regulatory review function and reorienting OIRA's role so that it is centered on helping agencies to fulfill their regulatory missions and (2) replacing cost-benefit analysis with pragmatic regulatory impact analysis—would help to fix the broken regulatory system. If adopted, these two proposals will help the regulatory system get back to the business of doing what it was created to do: protecting people and the environment.

Thank you for considering these comments.

Sincerely,

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¹ 2 *A Legislative History of the Water Pollution Control Act Amendments of 1972*, Ser. No. 93-1, at 1423 (1973); S. Rep. No. 92-414, at 7 (1971).

² *Weyerhaeuser v. Costle*, 590 F.2d 1011, 1042 (D.C.Cir. 1978).

³ Under the Safe Drinking Water Act Amendments of 1996, EPA is authorized but not required to deviate from the technology-based standards on the basis of cost-benefit analysis.

⁴ *See* 16 U.S.C. § 1539 (2000).

⁵ *Tennessee Valley Authority v. Hill*, 437 U.S. 153, 184 (1978).

⁶ CASS R. SUNSTEIN, RISK AND REASON 213-14 (2002) (suggesting that ESA may be "rooted in a theory of rights, one that rebuts the presumption in favor of cost-benefit balancing"). *See also* Amy Sinden, *In Defense of Absolutes: Combating the Politics of Power in Environmental Law*, 90 IOWA L. REV. 1405 (2005).

⁷ SIDNEY A. SHAPIRO & ROBERT L. GLICKSMAN, RISK REGULATION AT RISK: RESTORING A PRAGMATIC APPROACH 39 (2003).

⁸ 7 U.S.C. § 136a(d)(1)(C) (2000).

⁹ 7 U.S.C. § 136(bb) (2000).

¹⁰ Sidney A. Shapiro & Christopher H. Schroeder, *Beyond Cost-Benefit Analysis: A Pragmatic Reorientation*, 32 HARV. ENV. L. REV. 433 (2008).

¹¹ For a collection of critiques of cost-benefit analysis from a wide variety of accomplished academics, many of whom are CPR scholars, see THOMAS O. MCGARITY, SIDNEY A. SHAPIRO, & DAVID BOLLIER, SOPHISTICATED SABOTAGE: THE INTELLECTUAL GAMES USED TO SUBVERT RESPONSIBLE REGULATION (2004).

¹² National Pollutant Discharge Elimination System—Final Regulations to Establish Requirements for Cooling Water Intake Structures at Phase II Existing Facilities, 69 Fed. Reg. 41,576, 41,660-61 (July 9, 2004) (to be codified at 40 C.F.R. pts. 9, 122, 123, 124, and 125).

¹³ Compare EPA, *Economic and Benefits Analysis (EBA) for the Proposed Section 316(b) Phase II Existing Facilities Rule*, EPA-821-R-02-001 (February 2002), at D1-4 with National Pollutant Discharge Elimination System—Final Regulations to Establish Requirements for Cooling Water Intake Structures at Phase II Existing Facilities, 69 Fed. Reg. 41,576, 41,666 (July 9, 2004) (to be codified at 40 C.F.R. pts. 9, 122, 123, 124, and 125).

¹⁴ National Pollutant Discharge Elimination System—Final Regulations to Establish Requirements for Cooling Water Intake Structures at Phase II Existing Facilities, 69 Fed. Reg. 41,576, 41,666 (July 9, 2004) (to be codified at 40 C.F.R. pts. 9, 122, 123, 124, and 125).

¹⁵ National Pollutant Discharge Elimination System—Proposed Regulations to Establish Requirements for Cooling Water Intake Structures at Phase II Existing Facilities, 67 Fed. Reg. 17,122, 17158 (April 9, 2002) (to be codified at 40 C.F.R. pts. 9, 122, 123, 124, and 125).

¹⁶ David M. Driesen, *Is Cost-Benefit Analysis Neutral?* 77 U. COLO. L. REV. 335, 376, 397 (2006).

¹⁷ See U.S. Department of Transportation, National Highway Traffic Safety Administration, Final Regulatory Impact Analysis, Corporate Average Fuel Economy and CAFÉ Reform for MY 2008-2011 Light Trucks VIII-64 to VIII-65 (March 2006), available at

http://www.nhtsa.dot.gov/staticfiles/DOT/NHTSA/Rulemaking/Rules/Associated%20Files/2006_FRIAPublic.pdf.

¹⁸ Control of Hazardous Air Pollutants From Mobile Sources, 71 Fed. Reg. 15804, 15907-10 (Mar. 29, 2006).

¹⁹ See David W. Pearce, W.R. Cline, A.N. Achanta, Samuel Fankhauser, R.K. Pachauri, Richard S.J. Tol, & P. Vellinga, *The Social Costs of Climate Change: Greenhouse Damage and the Benefits of Control*, in CLIMATE CHANGE 1995: ECONOMIC AND SOCIAL DIMENSIONS OF CLIMATE CHANGE 179, 197 (J.P. Bruce, H. Lee, & E.F. Haites eds. , 1995).

²⁰ CASS R. SUNSTEIN, RISK AND REASON 20 (2002).

²¹ See David M. Driesen, *Is Cost-Benefit Analysis Neutral?*, 77 U. COLO. L. REV. 335, 365, 380 (2006).

²² See Control of Emissions of Air Pollution from New Marine Compression-Ignition Engines At or Above 30 Liters/Cylinder, 67 Fed. Reg. 37,548, 37,597-98 (proposed May 29, 2002) (to be codified at 40 C.F.R. pt. 94).

²³ See Control of Emissions From New Marine Compression-Ignition Engines At or Above 30 Liters Per Cylinder, 68 Fed. Reg. 9746, 9755 (Feb. 28, 2003) (to be codified at 40 C.F.R. pts. 9, 94).