Center for Progressive Regulation

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May 28, 2002

John Morrall
Office of Information and Regulatory Affairs
Office of Management and Budget
NEOB Room 10235
725 17th Street N.W.
Washington, D.C. 20503

Re: Draft 2002 Report to Congress on the Costs and Benefits of Federal Regulations, 67 Fed. Reg. 15014 (March 28, 2002)

Dear Dr. Morrall:

These comments are submitted by the Center for Progressive Regulation (CPR), a newly created organization of academics specializing in the legal, economic, and scientific issues that surround health, safety, and environmental regulation. 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. 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. The Center 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. The Center seeks 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.

The undersigned appreciate the opportunity to present our views on the important issues raised in this year's Draft Report to Congress. However, we must confess at the outset that we

fear our ideas will not be given room to breathe in the current atmosphere at the Office of Information and Regulatory Affairs (OIRA). We sincerely hope that our fears are unfounded

OIRA is developing regulatory policies at a breakneck pace. Those of us who have offered data and analysis that point in a different direction have watched our views vanish into a black hole, apparently without a trace. We are unsure whether OIRA decision-makers simply disagree with our conclusions and therefore ignore the data we offer to support them, or whether they think our data are flawed. In either case, the lack of engagement with our information and ideas undermines the commendable efforts OIRA has made to enhance transparency and its ostensible commitment to consider issues on their merits in a manner insulated from purely political influences.

For example, we found it deeply disturbing to read that OIRA officials met with interested industry representatives almost contemporaneously with placing rules on what is commonly referred to as its "hit list." Our distress was compounded by OIRA's failure to offer any explanation whatsoever for its decisions regarding rules for the hit list. OIRA's emphasis on transparency, with attendant disclosures of the dates of and attendees at private meetings between industry representatives and OIRA officials, and its simultaneous failure to explain the criteria used to select rules for further study, can only breed cynicism and distrust among those not present at such meetings.

To dispel the growing suspicion that the deck is stacked at OIRA, with only those espousing anti-regulatory ideas capable of real influence, we request that you adopt a policy of responding to the points we and others raise when you publish a final decision on any matter following informal notice and comment, beginning with the presentation of the *Final 2002 Report to Congress*. We urge OIRA to recognize that the discipline of responding to divergent information and ideas is a crucial component of more rational and effective regulatory policies, as the agencies and departments subject to Office of Management and Budget (OMB) oversight learn anew each time they issue a decision that displeases regulated entities.

These comments address five matters:

The regulatory hit list set forth in the *Draft 2002 Report*, and OIRA's calls for additional nominees. Candidates for this infamous list were nominated by outside parties who did not even attempt to muster any convincing evidence regarding the candidates' alleged deficiencies. Final decisions to rate rules "high" priority and require additional justification are based on mysterious criteria known only to OIRA itself. Nevertheless, in an effort to illustrate the lost opportunity costs of this myopic focus, we have submitted a "To Do" List of Nominees for regulatory and other administrative action. This list appears as Appendix A to these comments.

OIRA's new aggressiveness in policing the substance and process of agency action. With the resurrection of the "return letter"; the inauguration of the "prompt letter" (including the "deregulatory prompt letter"); new guidelines on data quality; its plan to

revise agencies' methodologies for conducting risk assessment; and its announced intention to second-guess agencies' scientific judgments, the current administration at OMB has adopted a more confrontational posture toward the Executive Branch agencies than any in memory. We believe that OIRA's assertiveness is unwise and, in some respects, is illegal.

The *Draft 2002 Report's* overriding emphasis on cost-benefit analysis as the litmus test for regulatory policy. OIRA's draft report gives preeminent evaluative status to cost-benefit analysis, despite contrary statutory mandates and despite the use in the report of highly misleading, outdated, and blatantly inaccurate estimates of those costs and benefits. We find it ironic that the same senior officials who are gearing up to implement and enforce the data quality guidelines as a *quid pro quo* for affirmative regulatory action would nevertheless rely on such flawed information to bolster exaggerated claims regarding the economic inefficiency of regulation.

The embrace of "quality-adjusted life-years" saved as the metric for evaluating the wisdom of health-related regulation (QALYs). This analytical technique is morally objectionable, empirically ungrounded, and almost certainly illegal. It devalues the lives of the most vulnerable members of society – such as the elderly and the ill.

OIRA's intention to require agencies and departments to demonstrate that they have conducted scientific peer review, without any effort to ensure that such panels are balanced and free of conflicts of interest. The *Draft 2002 Report* emphasizes the use of "sound science" and scientific peer review, but omits any mention of the need to establish peer review panels that are balanced and free of conflicts of interest. Without these crucial safeguards, OIRA will preside over further capture of government science by regulated industries, a development with profoundly negative, long-term implications.

OIRA's Regulatory Hit List

Beginning last year, OIRA has turned its annual report on the costs and benefits of federal regulations into an opportunity for regulated industries to roll back regulations they do not like, in the guise of promoting neutral principles like "sound" science and economic efficiency. (67 Fed. Reg. 15022) The mechanism for the resurrection of this end run around the regulatory process is the compilation of a list of suspect regulations on the basis of nominations submitted by interested members of the "public." In its *Draft 2002 Report*, OMB continues this process, urging commentators to submit additional nominations. (67 Fed. Reg. 15033-34)

As for the status of last year's nominees, the *Draft 2002 Report* explains that OIRA received nominations covering 71 federal regulations; 44 of the 71 were submitted by the Mercatus Center at George Mason University (Mercatus). (67 Fed. Reg. 15022) Mercatus, which is perhaps best described as a conservative think-tank, is funded primarily by industries that are directly regulated by the rules that were targeted, including Enron, International Paper, the American Chemistry Council, and David Koch, the Executive Vice President and member of

the board of Koch Industries, a company with interests in refining, asphalt, natural gas, gas liquids, chemicals, plastics, chemical technology equipment, minerals, fertilizers, ranching, and financial businesses. (For additional information, see http://www.kochind.com.)

In response to these self-interested suggestions, OIRA prioritized the proposals by ranking them from one through three. (67 Fed. Reg. 15022) Twenty-three regulations were ranked one, or "high priority," on the basis of skeletal, summary statements by Mercatus and others who nominated them. (Appendix B to *Draft 2002 Report*, 67 Fed. Reg. 15036-37; see also Mercatus's one-page submissions, available in the OIRA reading room.) OIRA has already put covered agencies and departments through their paces on these priority items, prompting many to take action on the skeletal complaints offered by the nominators. (Appendix B to *Draft 2002 Report*, 67 Fed. Reg. 15036-37) This approach not only distorts an agency's priority-setting process on the basis of the limited information provided to OMB, it takes up agency resources that could otherwise be devoted to the development of other proposals. Thus, the hit list has had a real impact, serving to spread the powerful impression throughout the federal government that OIRA is an escape valve for disgruntled industries that have been unable to achieve their deregulatory ends through other, more transparent means.

OIRA seems understandably self-conscious about this biased process, noting that of the 71 nominations, 43 might be considered "environmental" regulations, a "pattern that is unsurprising since federal environmental regulation is of broad public interest and a source of persistent public controversy." (*Draft 2002 Report*, 67 Fed. Reg. 15022) Yet, OIRA announces proudly, "only 13 of the 33 'environmental' rule nominations were rated 'high priority' for agency reconsideration." (Id.) While we accept the assertion that environmental rules are extremely important to the public, this rationale begs the question whether the agencies responsible for these rules are experiencing unusual problems with the incorporation of sound science and economic efficiency into administrative decision-making or whether the nominators themselves, who are hardly typical members of the public, are nominating candidates on the basis of their own narrow self-interests. We consider it far more likely that the biased nature of the nominations process, which gives institutions like Mercatus an opportunity to "earn their keep" in the eyes of their corporate sponsors, is a far more likely explanation for the disproportionate number of environmental rules on initial lists of nominees.

For more detailed analyses of the problems with the hit list process, please see testimony offered by Professor Lisa Heinzerling on March 12, 2002 before the Subcommittee on Energy Policy, Natural Resources, and Regulatory Affairs of the Committee on Government Reform, U.S. House of Representatives, and testimony delivered by Professor Thomas O. McGarity before the Senate Committee on Governmental Affairs on March 7, 2002.

Given our strong misgivings about the nature of the hit list and OIRA's use of it as a tool to pressure agencies to provide regulatory relief to favored industries, we approach the prospect of participating in the nominations process with a mixture of ambivalence and dread. On one hand, if we do not participate, we will never know whether OIRA is sincere about its often-repeated assertion that it harbors no antipathy for regulation and is willing to judge proposals

purely on their policy merits. On the other hand, we view the process thus far with such dismay that we are extremely reluctant to contribute, even tangentially, to its credibility. Our predicament is akin to the dilemma public interest groups confronted when they were asked to submit comments on the work of the Energy Task Force chaired by Vice President Cheney. Based on documents produced in litigation under the Freedom of Information Act, it is clear that this request came too late to influence the work of the Task Force, although the Administration has attempted to invoke this ephemeral opportunity as evidence that the Task Force considered all views.

On balance, we have decided to submit our own list of administrative actions – some pending and some never taken – as Appendix A to these comments, in response to OIRA's request for public comments on reforms that would extend or expand existing regulatory programs. (*Draft 2002 Report*, Executive Summary) Together, the actions on our list would take a large step toward addressing some of the most stubbornly persistent, and some of the newly emerging, threats to health, safety, and the environment. In submitting this list, we are interested in motivating affirmative actions that are long overdue. We also think our list illustrates the enormous price paid by the public when OIRA diverts agency resources at the bidding of regulated entities.

OIRA's Appropriate Role

In its *2001 Report to Congress*, OIRA announced the return of the "return letter," asserting that it will issue such letters when (1) an agency proposal suffers from inadequate analysis; (2) the "regulatory standards adopted are not justified by the analyses;" (3) the rule is not consistent with the principles announced in E.O. 12866 or with "the President's policies and priorities;" or (4) the rule is "not compatible with other Executive Orders or statutes." (*2001 Report* at 39-40) This assertion of authority over agency decision-making is problematic for four reasons.

First, many statutes establish principles for standard-setting that are themselves inconsistent with Executive Order 12866. For example, the Clean Air Act's National Ambient Air Quality Standards are to be set without regard to economic costs. (*Whitman v. American Trucking Assn*., 531 U.S. 457 (2001)) Despite its ostensible recognition of this legal mandate, OIRA's actual behavior gives reason to fear that the return letter may be used as a vehicle for undermining statutory requirements OIRA does not like.

One prominent case study of this serious problem is OIRA's announced intention to review the New Source Review program and pending enforcement efforts in response to a Mercatus Center nomination. OIRA has assigned them "high priority" status despite the conclusion of the Department of Justice, following a thorough study of the matter, that "EPA may reasonably conclude that the enforcement actions are consistent with the Clean Air Act and its regulations." (U. S. Department of Justice, Office of Legal Policy, "New Source Review: An Analysis of the Consistency of Enforcement Actions with the Clean Air Act and Implementing Regulations," at iv (Jan. 2002))

A second basic problem with OIRA's policy on return letters is that agencies are bound to follow the instructions of Congress even where these instructions may collide with the President's current "policies and priorities." OIRA may not interfere with agency action that is consistent with the statute under which the agency operates simply on the ground that the President does not like those policies.

A third, closely related problem is that OMB has no legal power to announce authoritative constructions of statutes. That prerogative rests with regulatory agencies. In reviewing agency decisions and deciding whether to issue a return letter, OIRA may not tell an agency charged with implementing a particular statute how to construe that statute. OIRA has never clarified whether it intends to return regulatory proposals to agencies on the basis of disputes over statutory interpretation and has never acknowledged its obligation to respect agencies' interpretations of the statutes they are charged with administering.

Over-Dependence on Cost-Benefit Analysis

A fourth and, in many ways, the largest problem with OIRA's aggressive use of return letters is its traditional emphasis on conventional economic analysis and the predominantly economic training and experience of its staff. These biases lead OIRA to disapprove of agency decisions simply because that decision departs from a tenet of mainstream, conventional microeconomic analysis as interpreted by OIRA's staff. Yet, inconsistency with the narrow economic perspective reflected in OIRA's version of cost-benefit analysis does not demonstrate that an agency's actions are unjustified. Rather, it would only prove that the agency's analysis rests on different intellectual frameworks – frameworks that are often based on explicit statutory mandates. Indeed, it appears that OIRA is insisting upon quantification and monetization of regulatory benefits even where the relevant agency has concluded that such analyses are either impossible or unnecessary. This insistence on waiting for "the numbers" will, at the least, inappropriately delay agency action, and it may even stop many good rules in their tracks.

In order to compare the pros and cons of any particular regulatory standard, cost-benefit analysis seeks to translate all relevant considerations into monetary terms. In the case of life-saving programs, a great deal is lost in the translation. For example, cost-benefit analysis implicitly equates the risk of death with death itself, when in fact they are quite different and should be accounted for separately in considering the benefits of regulatory actions. Cost-benefit analysis also ignores: (1) the fact that citizens are concerned about risks to their families and others as well as themselves; (2) the fact that market decisions are often very different from political decisions; (3) methodological and other problems with the labor studies on which the monetary value of risk reduction is based; and (4) the incomparability of many different types of risks to human life. The same kinds of problems arise in attempting to define in monetary terms the benefits of protecting human health and the environment.

In addition, the costs and (particularly) the benefits of regulation often will be realized in the future. In such cases, in OIRA's analysis, they are also "discounted," i.e., treated as

equivalent to smaller amounts of money today. The use of discounting systematically and improperly downgrades the importance of environmental regulation. While discounting makes sense in comparing alternative *financial* investments, it cannot reasonably be used to make a choice between preventing harms to present generations and preventing similar harms to future generations. Nor can discounting reasonably be used even to make a choice between harms to the current generation; choosing between preventing an automobile fatality and a cancer death does not turn on prevailing rates of return on financial investments. Finally, discounting tends to trivialize long-term environmental risks, minimizing the very real threat our society faces from potential catastrophes and irreversible environmental harms, such as those posed by global warming and nuclear waste.

Cost-benefit analysis further ignores the question of *who* suffers as a result of environmental problems and, therefore, threatens to reinforce existing patterns of economic and social inequality. Cost-benefit analysis treats questions about equity as, at best, side issues, contradicting the widely shared view that equity should count in public policy. In fact, poor countries, communities, and individuals are likely to express less "willingness to pay" to avoid environmental harms, simply because they have fewer resources. Therefore, cost-benefit analysis would justify imposing greater environmental burdens on them than on their wealthier counterparts. With this kind of analysis, the poor get poorer.

It is worth noting in this regard that one of the decisions on OIRA's high priority hit list is EPA guidance on the use of economic incentive programs, which in its original form eschewed the development of "hot spots" of pollution in poor and minority neighborhoods. "Eliminate or modify the equity principle," Mercatus advised OIRA bluntly, presumably so that such economic incentive programs could be implemented without restraint. In placing this guidance on its list of priorities, OIRA implicitly endorsed this blatant appeal to ignore discrimination that compromises public health on the basis of race, national origin, and class.

Finally, cost-benefit analysis fails to produce the greater objectivity and transparency promised by its proponents. Cost-benefit analysis rests on a series of assumptions and value judgments that cannot remotely be described as objective. Moreover, the highly complex, resource-intensive, and expert-driven nature of this method makes it extremely difficult for the public to understand and participate in the process. Thus, in practice, cost-benefit analysis is anything but transparent.

Beyond these inherent flaws, cost-benefit analysis suffers from serious defects in practical implementation. Many benefits of public health and environmental protection have not been quantified and cannot easily be quantified given the limits on time and resources; thus, in practice, cost-benefit analysis is often akin to shooting in the dark. Even when the data gaps are supposedly acknowledged, public discussion tends to focus on the misleading numeric values produced by cost-benefit analysis while relevant but non-monetized factors are simply ignored. Finally, the cost side of cost-benefit analysis is frequently exaggerated, because analysts routinely fail to account for the economies that can be achieved through innovative efforts to meet new regulatory standards.

For further information and analysis on these points, please see a monograph on cost-benefit analysis, written by Professors Frank Ackerman and Lisa Heinzerling and entitled *Pricing the Priceless: Cost-Benefit Analysis of Environmental Protection* (Georgetown Environmental Law and Policy Institute 2002), which describes in detail the ways in which cost-benefit analysis is inherently biased and unreliable as a method for evaluating health, safety, and environmental regulation. As we discuss in the next section, OIRA compounds the inherent flaws of cost-benefit analysis through its inexplicable reliance on biased, outdated, and incorrect data.

OIRA's Data Quality Mistakes

OIRA's disturbing negligence in the use of data undermines OIRA's credibility as it seeks to implement the Data Quality Act, demanding from a position of ostensible superiority that the agencies under its supervision stop misusing flawed data to support regulatory actions. Until OIRA gets its own house in order, its credibility in this endeavor will remain extraordinarily shallow.

For example, in its *Draft 2002 Report*, OIRA includes two separate estimates of the aggregate costs and benefits of federal regulations. The first set, contained in Tables 5 and 6, and covering regulations issued between April 1, 1999 through September 30, 2001 (Table 5) and April 1, 1995 through September 30, 2001 (Table 6), is ostensibly based on "agency analyses subject to public notice and comments and OMB review under E.O. 12866. (67 Fed. Reg. 15024)

Table 5 shows that EPA regulations issued in 1999 and 2001 had aggregate costs of $16,104 to 19,264 billion and aggregate benefits of $23,738 to 43,491 billion. Table 6, covering regulations issued between 1995-2001, shows EPA regulations with aggregate costs of $41,523-42,326 billion and aggregate benefits of $29,140 to 66,092 billion. Thus, OMB appears to claim that the costs of environmental regulations between 1995 and 2001 may well have exceeded benefits by as much as $13 billion.

Even the most cursory glance at the calculations underlying these Tables shows OIRA's analysis to be deeply, indeed disturbingly, flawed. Consider the description of the roadless area conservation policy, announced by President Clinton's Department of Agriculture and forsaken by the Bush Administration. OIRA describes this rule as providing just $219,000 per year in benefits; these benefits come from a savings in road maintenance costs. (*Draft 2002 Report*, Table 7) Yet the policy, according to OIRA, would also produce $184 million in annual costs. (*Draft 2002 Report*, Table 14) These are the cost and benefit figures used to reflect the cost-benefit profile of this policy in Table 5. They are ludicrous figures to use for this policy.

In issuing the roadless area conservation decision, the Forest Service discussed numerous and multifarious benefits that would flow from protecting almost 60 million acres – approximately one-third of the land area of the national forests – from road building and timber

harvesting. High quality soil; healthy watersheds; flood protection; safe drinking water; clean air; healthy and diverse fish and wildlife populations; recreational opportunities such as hiking, camping, picnicking, wildlife viewing, hunting, fishing, cross-country skiing, and canoeing; reference landscapes for scientific research; natural, beautiful landscapes; traditional cultural properties, sacred sites; and other locally identified unique characteristics – all of these were cited by the Forest Service as benefits of conserving the national forests' remaining roadless areas. None of these benefits appears in OIRA's calculations of the benefits of this policy; indeed, in almost a parody of the cost-benefit method, OIRA mentions only the savings in road-building costs in describing the quantitative benefits of preserving almost 60 million acres of the national forests.

To be sure, many of the important values protected by the roadless area policy are impossible to quantify and monetize. Nevertheless, even the most glancing familiarity with the changing economy of the Western states most affected by this policy suggests a large economic benefit to the policy in addition to the non-economic values protected by it. Tourism is the fastest-growing industry in many of the states most affected by the conservation of roadless areas. Indeed, tourism is already one of the top three industries in all of the states most affected by this policy. Tourism is not popular in these states because of timber cuts and strip mines; it is popular because of the abundant natural resources and beautiful scenery these states offer to visitors. In addition, many of the timber sales that would be prevented by this conservation decision were, according to the Forest Service, "likely to cost more to prepare and sell than they realize in revenues received." OIRA, with its eagle eye for government inefficiencies, should love the forest conservation rule. Yet, bizarrely, OIRA describes this policy in a way that makes it look outlandishly expensive.

OIRA's ridiculously lopsided presentation of the roadless area policy is just one example of OIRA's penchant for trivializing – indeed, dismissing entirely – the kinds of unquantified values that lie at the heart of this country's health, safety, and environmental laws.

The second set of aggregate cost and benefit estimates, set forth in Appendix C to the *Draft 2002 Report*, is, according to OIRA, "based on studies of varying quality." (Id.) These estimates are, essentially, the same numbers that appeared in the *Final 2002 Report* updated to reflect 2001 dollars. Probably because OIRA received harsh criticism of the methodology it used to arrive at these numbers, it relegated them to an appendix. This formatting solution to profound substantive problems is ineffective.

Table 11 in Appendix C states that the "net benefits" of "social regulation" in the "environmental" arena are $[minus] 83 to 1,663 billion. (67 Fed. Reg. 15037) Appendix D of the *Draft 2002 Report*, entitled "Explanation of Calculations for Costs and Benefits Tables," explains at some length the possible reasons for these inexplicably disparate estimates. (67 Fed. Reg. 15041) As OIRA itself admits, its aggregate estimates of the costs and benefits of environmental regulation are based on obsolete, inaccurate, and conflicting data. In particular, lower-bound estimates of benefits -- at least in Appendix C -- are drawn from a 1991 study, which in turn relied on analyses published in 1978 and 1979 for key categories of benefits.

Thus, OIRA's estimates inevitably overlook the benefits of regulations adopted in the last 20 years, as well as the substantial advances in the measurement and analysis of regulatory benefits that have occurred in those years.

For example, Table 11 unreasonably credits the possibility that, as of 2001, environmental regulation had somehow produced a net loss of benefits amounting to as much as $83 billion that are hardly outweighed by net costs between $120-203 billion. (67 Fed. Reg. 15037) In presenting this striking and implausible finding, OIRA relies heavily on a 1991 study by Robert Hahn and John Hird. (See Robert W. Hahn and John A. Hird, *The Costs and Benefits of Regulation: Review and Synthesis*, 8 Yale J. on Reg. 233 (1990) [hereinafter *Hahn and Hird*].) Although *Hahn and Hird* is not mentioned in the *2002 Draft Report*, previous OMB reports provide citations for the estimates found in this year's report. The *Hahn and Hird* study is too outdated to be of present utility: most of the data on which the study was based are two decades old.

For air pollution, the lower-bound benefits incorporated in Table 11 are from a *single year, more than twenty years ago* – 1978. (See Paul R. Portney, Air Pollution Policy, in *Public Policies for Environmental Protection*, at 57 Table 3-5 (Paul R. Portney ed., 1990) [hereinafter *Portney*].) Thus, they do not reflect the enormous amount of information that has been developed in the last two decades concerning the adverse effects of air pollution on human health and the environment. They do not reflect the scientific literature finding an association between exposure to particulate matter and mortality – the very literature on which EPA has relied, in a retrospective study on the costs and benefits of the Clean Air Act, in finding enormous benefits in air pollution control. They also do not reflect findings over the last two decades on the adverse human and ecological effects of acid rain, ozone, and lead.

The data regarding water pollution control benefits are also obsolete. The basic data come from a study performed by Myrick Freeman in 1979. (See Myrick Freeman III, Water Pollution Policy, in *Public Policies for Environmental Protection*, at 147 n. 28 (Paul R. Portney ed., 1990).)

In addition, there is good reason to believe that the lower-bound estimate of benefits provided in *Hahn and Hird*, and implicitly incorporated in Table 1 of the *Draft 2002 Report*, dramatically understates the benefits of environmental regulation. Yet that lower-bound estimate is the only estimate that makes it possible for OIRA to speculate that environmental regulation might have produced negative net benefits as of 1999. *Hahn and Hird's* underlying data on the benefits of air pollution control reflect a value of a statistical life of $1 million, a value that is exceedingly low by current standards. (*Portney* at 56) This value had a significant effect on the results: three-quarters of the benefits reported in the study on which *Hahn and Hird* relied were human health benefits. (*Hahn and Hird* at 273) Moreover, OIRA's lower-bound estimate of the benefits of environmental regulation (again, incorporated implicitly in Table 11 of this year's report) reflects one researcher's own lower-bound estimate of the benefits of air pollution control. (*Portney* at 55) This estimate generally reflected studies finding "*little or no pollution damage to health, vegetation, and the like*." (Id.)

In other words, OIRA's lower-bound estimate of benefits embodies an assumption that air pollution causes little or no damage to humans and the environment. In estimating the benefits of air pollution control, the researcher in question also considered only actual improvements in air quality between 1970 and 1978, and thus he did not account for benefits from preventing the degradation of air quality (nor, of course, for changes since 1978). As for the benefits of water pollution control, OIRA again chooses to rely (implicitly, again, in Table 11) on this same researcher's outdated lower-bound estimate.

Turning to the cost side of the ledger, OIRA continues to rely on *Hahn and Hird*, although no longer tilting so strongly toward their lower-bound estimates. *Hahn and Hird's* cost estimates are also problematic. *Hahn and Hird* obtained these estimates from a 1990 study by Michael Hazilla and Raymond Kopp. (See *Hahn and Hird* at 272, citing Michael Hazilla & Raymond J. Kopp, *Social Cost of Environmental Quality Regulations: A General Equilibrium Analysis*, 98 J. Polit. Econ. 853 (1990).) OIRA implicitly relies upon the *higher* of Hazilla and Kopp's pairs of estimates for both 1981 and 1985, although these estimates relied on different methodologies. In Table 11, OIRA also implicitly relies upon an EPA cost estimate of $54 billion. (This estimate is presented in Table 1 of the 2000 Report, one of the three sources for Table 2 in this year's report.) This estimate is obtained from EPA's 1990 report, *Environmental Investments: The Cost of a Clean Environment* [hereinafter *Cost of Clean*], and EPA's *Section 812 Retrospective* on the costs and benefits of the Clean Air Act. OIRA failed to ensure that the *costs* of water pollution control programs were excluded from Table 2 unless their *benefits* were also reflected therein. *Hahn and Hird's* data on the benefits of water pollution control, for example, do not include the benefits of control of toxic water pollutants, whereas the costs of this program are provided in *Cost of Clean*.

In short, for all of these reasons, OIRA is wrong to continue to rely on the *Hahn and Hird* study in preparing this report. As OIRA so often reminds federal agencies and departments, improving data quality is a central goal of this Administration. In accordance with those principles, it is crucial for OIRA to incorporate the wealth of newer information and analyses that have become available since that study was published. By lumping Hahn and Hird's flawed study with better and more recent analyses, OIRA continues to refuse to give credence to EPA's massive, peer-reviewed retrospective cost-benefit analysis of the Clean Air Act. The impression that OIRA simply cannot abide analysis that shows large benefits from environmental regulation is hard to avoid.

Benefits Defined as Quality-Adjusted Life-Years Saved: QALYS

Although the *Draft 2002 Report* is not the vehicle for OMB's apparent decision to expand its use of "quality-adjusted life-years" (QALYs) as a major consideration in analyses of regulatory benefits, there does not appear to be any other forum in which to register objections to this decision. Thus we take this opportunity to oppose OIRA's increased use of QALYs on legal, ethical, and practical grounds.

Most fundamentally, using QALYs to evaluate – or, in effect, to ration – regulatory protections conflicts with our society's legal and ethical norms of equality. An emphasis on life-years implies that a regulatory measure that saves the lives of the elderly is not as good as one saving the lives of the middle-aged and a measure saving the lives of the middle-aged is not as good as one saving the lives of the young. Likewise, an emphasis on the quality of life can easily degenerate into a way of introducing discrimination based on health status and disability into the regulatory equation. Indeed, the Department of Health and Human Services found just that in its evaluation of Oregon's QALY-based health care rationing proposals several years ago. Similarly, statutes such as the Clean Air Act do not allow EPA to ration environmental protections on the basis of age or health status; indeed, the Clean Air Act affirmatively requires EPA to protect vulnerable subpopulations in setting air quality standards. Our society's constitutional and statutory norms weigh strongly against offering less protection to people based simply on age, life expectancy, health status, or disability. Legally and ethically speaking, therefore, a QALY-based regulatory regime inappropriately devalues the lives of the elderly, the sick, and the disabled.

In addition, QALY-based analyses give less weight to fatalities and more weight to minor health conditions than do other valuation schemes. Certainly, it is important to consider whether regulation prevents nonfatal illnesses and other adverse conditions, as well as preventing deaths. But there is good reason to believe that QALYs skew analysis against life-saving measures in a way that is difficult to defend. (See, generally, Erik Nord, *Cost-Value Analysis in Health Care: Making Sense out of QALYs* (1999).)

In one recent study, for example, researchers found that a QALY-based analysis would have put traffic noise on the top of a list of five problems, while a willingness-to-pay analysis would have picked air pollution and its resulting fatalities as a more important problem. (See Hofstetter and Hammitt, *Human Health Metrics for Environmental Decision Support Tools: Lessons from Health Economics and Decision Analysis,* EPA/600/R-01/104 (September 2001).) As this study shows, QALYs can have the effect of elevating quite small insults or injuries, accumulated in a large population, over much more serious harms affecting a relatively small group of people. The use of QALYs can – as happened when Oregon experimented with QALYs in prioritizing health-care expenditures – make us think we should spend money to fix crooked teeth but not to fix potentially fatal ectopic pregnancies. This kind of analytical tool will not, we believe, lead to a more rational or more just regulatory system.

Finally, we are at a loss to understand how OIRA's new preoccupation with QALYs fits into its larger emphasis on cost-benefit analysis and the monetization of health-related regulatory benefits. There is limited empirical evidence on the question whether old people and sick people are willing to pay less to avoid risks than young people and well people are. However, the evidence that does exist suggests that the former are just as anxious – and just as willing to pay – to avoid risks as the latter are. (See statement of economist Alan Krupnick's views, available at http://www.rff.org/news/newsarticles/keyeconomisturges.htm.) Given this evidence, it is unclear why OIRA is proposing heightened emphasis on QALYs at the same time as it is highlighting the importance of cost-benefit analysis and consumer willingness to pay.

"Sound Science"

The *Draft 2002 Report* encourages scientific peer reviewers to disclose potential conflicts of interest and sources of bias, but never demands that these disclosures be made public. (67 Fed. Reg. 15019) It instructs agencies to select peer reviewers on the basis of their "expertise," without providing that peer review panels be balanced and free of members who have clear conflicts of interest. (Id.) Finally, OMB has urged agencies to seek peer review for regulatory impact analyses and "supporting technical documents," and the *Draft 2002 Report* announces that OIRA will soon assemble its own staff of scientists, presumably to supervise compliance with these instructions. (67 Fed. Reg. 15022)

Expanded peer review is a worthwhile goal, at least in theory. However, we are concerned that OMB's recommendations omit crucial safeguards that could compound severe problems with this process in practice, exacerbating industry capture and non-disclosure traits that presently dominate peer review at agencies like EPA. We are concerned that by insisting on peer review of relatively minor decisions, OMB will congeal the regulatory process at the same time that it sanctions peer review of major decisions that is overwhelmingly biased in industry's favor. These issues are explained in further detail in the article entitled *Bad Science*, written by Dr. Linda Greer and Professor Rena Steinzor and published in the *Environmental Forum*, January/February 2002.

These two unacceptable outcomes could occur because, in our experience, regulated industries are by far the most common source of "third party data" considered by regulatory agencies. Indeed, to cite just one example, companies and their trade associations have mounted a concerted campaign to persuade EPA scientists to downgrade its toxicological assessments of such dangerous substances as vinyl chloride and dioxin, often without providing either the underlying data or the supposedly proprietary models used to justify those conclusions. Whether or not EPA staff succumbs to such pressure, high-profile decisions are then subject to peer review by panels overwhelmingly dominated by industry scientists, which typically rubber stamp the outcome industry advocates wanted all along.

A crucial purpose of peer review is to ensure that research is conducted in an intellectually honest and scientifically appropriate manner and that the results claimed by the researchers are supportable by the data they generate. To permit others to make these judgments, scientists must stand ready to disclose their underlying data, even if the results of a study were not what they – or the sponsors of their studies – had hoped or anticipated. Of course, reasonable accommodations should be made to safeguard patient confidentiality. Trade secrecy and the potential use of information by competitors, however, are not appropriate reasons for nondisclosure of health and safety data. (See Federal Insecticide, Fungicide, and Rodenticide Act Section 10(b), 7 U.S.C. § 136h(b).)

Scientists participating in peer review panels should disclose to the public – and not just to government officials -- all sources of potential conflicts of interest and bias, including

financial benefits, specific grants, and other forms of institutional support. Scientists are expected to have opinions. If scientists with a financial stake in the outcome of a scientific inquiry participate, the objectivity of the review is immediately suspect. Candidates with a conflict of interest should not serve on a panel except under the most unusual circumstances: i.e., they are the only ones who have essential expertise on the subject being reviewed.

Further, OIRA must place the use of so-called "sound" science in the appropriate context of laws that instruct agencies to act on the basis of the "precautionary principle" rather than waiting the underlying science on any given decision is absolutely certain. Knowledgeable scientists would be among the first to acknowledge that the risks posed by pollution or workplace exposure cannot be perfectly understood and that uncertainty is inevitable in scientific research. To take a simple example, an epidemiologist typically will have a set of data about the adverse health effects of a chemical (e.g., the number of exposed people who die), but will not be able to precisely quantify the risk the chemical poses in the general population, or even in a worker population. To quantify risk, the researcher must estimate the amounts of the chemical to which human subjects are exposed. These estimates in turn rely on assumptions about individual behavior (e.g., the amount of time spent outdoors or at the workplace). Such estimates can be made using more or less conservative assumptions, but the simple fact is that they are educated assumptions, not scientific facts.

Because of the gaps inherent in scientific knowledge, as well as concerns about the social and economic impact of regulation, applicable law rarely directs agencies to regulate exclusively on the basis of scientific considerations. Instead, Congress and the Executive Branch have assumed for 30 years that social considerations, as well as science, must inform the regulatory process. For example, the Clean Air Act instructs EPA to protect public health with an "adequate margin of safety." Many other environmental laws require the Agency to explore the possibility of less damaging alternative products or practices and to consider the cost of pollution controls before mandating them. Commanding agencies to wait until science is certain about every possible salient fact would mean decades of delay, flouting provisions of many laws and regulations that set deadlines for action in response to the risks of toxic exposure.

We would be pleased to meet with you in person or by conference call if you wish to pursue any of the recommendations made in these comments. Please call Professor Heinzerling (202) 662-9115 or Professor Steinzor (410) 706-0564 to schedule such an appointment.

Sincerely,

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Center for Progressive Regulation

"To-Do" List of Nominees

Pending Administrative Actions

National Ambient Air Quality Standard for Fine Particulate Matter

Regulating Agency: EPA

Citation: 61 Fed. Reg. 65638

Authority: Clean Air Act, 42 U.S.C. §§7408-09

Description of Problem: In 1997, EPA set a new National Ambient Air Quality Standard (NAAQS) for fine particulate matter. After five years of litigation, the federal appeals court for the District of Columbia Circuit has upheld this standard against the last remaining legal challenges to it.

Proposed Solution: EPA should immediately proceed to implement the new NAAQS for fine particulate matter. Specifically, given the large delays that have already attended implementation of these standards, EPA should require the governor of each state to designate areas as non-attainment, attainment, or unclassifiable, pursuant to section 107(d)(1)(A) of the Clean Air Act, within 120 days of the Court of Appeals' ruling, as permitted by CAA section 107(d)(1)(A). (The court's ruling was issued on March 26, 2002.)

Estimate of Regulatory Impacts: In issuing a new NAAQS for particulate matter in 1997, EPA estimated that the standard would save approximately 15,000 lives per year. Since that time, the evidence of particulate matter's harmful effects on human health has grown stronger. Even according to EPA's earlier, more conservative estimate of the health risks posed by particulate matter, approximately 75,000 Americans have died due to exposure to particulate matter pollution in the five years since the new standard was first promulgated. This estimate does not include the thousands of cases of nonfatal health effects caused by particulate matter in the five-year period since the new NAAQS was promulgated. EPA should begin implementing this standard without further delay.

National Ambient Air Quality Standard for Ozone

Regulating Agency: EPA

Citation: 61 Fed. Reg. 65716

Authority: Clean Air Act, 42 U.S.C. §§7408-09

Description of Problem: In 1997, EPA set a new National Ambient Air Quality Standard (NAAQS) for ozone. After five years of litigation, the federal appeals court in Washington has upheld this standard against the last remaining legal challenges to it. Two matters remain before EPA as a result of previous legal challenges to the ozone NAAQS. First, EPA has not finalized its response to the D.C. Circuit's ruling that EPA must consider the potentially beneficial health effects of ozone in setting a NAAQS for this air pollutant. Second, EPA has not issued a decision responding to the U.S. Supreme Court's directive that EPA rework its plan for implementing the new ozone standard.

Proposed Solution: EPA should issue final decisions on (1) the ozone standard itself, in light of the D.C. Circuit's ruling ordering the agency to consider the potentially beneficial effects of ozone in setting this standard; and (2) the implementation of the ozone standard, in light of the U.S. Supreme Court's directive that it devise a new implementation plan for ozone. EPA issued a proposed ruling on the first matter on January 19, 2001 – well over a year ago. EPA should finalize this decision now. In addition, it has been over a year since the Supreme Court instructed EPA to devise a new plan for implementing the ozone standard. EPA should develop this plan forthwith. Finally, EPA should require the governor of each State to designate areas as non-attainment, attainment, or unclassifiable, pursuant to section 107(d)(1)(A) of the Clean Air Act, within 120 days of issuing a final ozone standard in response to the court remand.

Estimate of Regulatory Impacts: In issuing a new NAAQS for ozone, EPA predicted that its rule would prevent and mitigate many respiratory illnesses. In particular, EPA concluded that the new rule would help children with asthma, by helping them to avoid such ozone-related measures as taking medication, visiting the doctor, and being admitted to the hospital. Under the Supreme Court's 2001 ruling in *Whitman v. American Trucking Associations*, the scientific evidence of such health effects – and not, for example, evidence of economic effects – must be the basis for EPA's decisions on the NAAQS.

Ergonomics Program

Regulating Agency: OSHA

Citation: 65 Fed. Reg. 68262

Authority: Occupational Safety and Health Act**,** 29 U.S.C. §655(b)

Description of the Problem: OSHA has replaced the ergonomic injury standard promulgated under the previous administration with voluntary guidelines.

Proposed Solution: This decision should be reversed. The literature indicates that voluntary guidelines are not an adequate substitute for regulatory standards. *See* Sidney A. Shapiro & Randy S. Rabinowitz, *Punishment versus Cooperation in Regulatory Enforcement: A Case Study of OSHA*, 49 Admin. L. Rev. 713 (1997).

Estimate of Regulatory Impacts: OSHA's extensive evidence indicates that ergonomic risk factors – such as repetitive motion, force, awkward posture, and vibration – are present in all types of general industry workplaces, including small, medium, and large workplaces. According to OSGA's most conservative estimate, 24 to 813 per 1000 general industry employees will suffer a musculoskeletal disorder (MSD) over the life-time that they work, depending on the particular industry in which the worker is employed. (This estimate is undoubtedly too low because it is clear that the injury data used by OSHA understate the number of injuries.) Another indication of the magnitude of these injuries is that employers annually pay out, in direct workers' compensation costs, between $15-$18 billion, or about 1 dollar of every 3 workers' compensation dollars, for MSD-related claims. OSHA estimated that its regulation would result in at least a $9.1 billion benefit and a $3.9 billion cost in its first 10 years (using a discount rate of 7 percent).

Radon Standard for Drinking Water

Regulating Agency: EPA

Citation: 64 Fed. Reg. 59246

Authority: Safe Drinking Water Act, 42 U.S.C. §300g-1(b)(13)

Description of Problem: The Safe Drinking Water Act mandates EPA to take action on radon in drinking water. EPA's effort to comply with this statutory mandate is more than a year overdue, in large measure because it was sent back to OMB for further review pursuant to the Card memo. The rulemaking record is exhaustive and the public health benefits clear.

Proposed Solution: EPA should issue the final radon in drinking water rule, and OMB should not block its issuance.

Estimate of Regulatory Impacts: Radon exposure from drinking water accounts for 1-2 percent of the amount of radon that enters homes. Radon is extraordinarily carcinogenic. EPA estimates the average costs to water consumers of implementing a strict radon standard are low (less than $20/household per year for over 90% of affected households if a national standard of 300 pCi/L were established). See 64 Fed.Reg. 59328 (1999).

Standards for Emerging Contaminants, Including Perchlorate, in Drinking Water

Regulating Agency: EPA

Citation: 63 Fed.Reg.10274

Authority: Safe Drinking Water Act, 42 U.S.C. §300g-1(b)(1)

Description of Problem: The Safe Drinking Water Act mandates that EPA must review unregulated contaminants and propose standards for contaminants if there is a "meaningful opportunity for health risk reduction" because the contaminants occur in tap water at levels that may have adverse health effects. The first decision on whether to issue new standards under this mandate was required by August 2001. In 1998, EPA published its final "Drinking Water Contaminant Candidate List" setting forth chemicals for which standards would be written, including 50 chemical and 10 microbiological contaminants/contaminant groups.

Proposed Solution: EPA should issue new standards for many contaminants that are not currently regulated, but that pose significant health risks, and OMB should not block their issuance. For example, perchlorate, a component of rocket fuel that appeared on the proposed list, contaminates tap water in millions of homes at levels above those that EPA's draft risk assessment says are safe.

Estimate of Regulatory Impacts: The treatment technologies available to control many of these contaminants are already available and their costs have been assessed for removing other contaminants.

Groundwater Disinfection Rule

Regulating Agency: EPA

Citation: 65 Fed. Reg. 30193

Authority: Safe Drinking Water Act, 42 U.S.C. §300g-1(b)(8)

Description of Problem: The rule addresses public health risks associated with the consumption of waterborne pathogens from fecal contamination for a substantial number of people served by groundwater systems. It is due to be issued next year.

Proposed Solution: The rule should be issued on time.

Estimate of Regulatory Impacts: EPA has found that average cost for 90 percent of U.S. households served by public ground water systems is expected to be less than $5.00 per year. See 65 Fed. Reg. 30248 (2000)

Report on Waterborne Diseases & Campaign to Educate Health Care Providers About Drinking Water Problems

Regulating Agency: EPA

Citation: N/A

Authority: Safe Drinking Water Act, 42 U.S.C. §300j-18(d)

Description of Problem: The Safe Drinking Water Act requires EPA and the Centers for Disease Control and Prevention (CDC) to complete a series of five joint studies of waterborne disease in major U.S. cities, and to develop a national waterborne disease occurrence estimate. The statute set a 1998 deadline, and the national estimate and report were due no later than August 2001, but EPA and CDC have yet to indicate when these actions will be finished. EPA and CDC also were required to implement a national campaign to educate health care providers regarding waterborne disease and drinking water-related health problems, and have not done so.

Proposed Solution: EPA and CDC should complete the studies and report, and implement an aggressive waterborne disease education effort as soon as possible.

Estimate of Regulatory Impacts: Congress authorized $3 million/year for these and related efforts, which it deemed to have significant potential public health benefits.

Total Maximum Daily Loads under the Clean Water Act

Regulating Agency: EPA

Citation: 65 Fed. Reg. 43585 (establishing framework for setting Total Maximum Daily Loads (TMDLs); 66 Fed. Reg. 53043 (deferring effective date of TMDL rule for 18 months)

Authority: Clean Water Act, 33 U.S.C. §1313(d)

Description of Problem: The Clean Water Act requires states to set water-quality-based standards that are intended to serve as back-ups to the technology-based standards also required by the Act. Water quality standards are operationalized through the use of TMDLs, which set a level of allowable pollution for waters impaired by water pollution. In the three decades of the Act's existence, water quality standards have yet to serve a meaningful role in protecting the nation's waters. This is changing, as EPA has been involved in extensive litigation concerning the states' failure to implement the TMDL program. EPA's guidance on setting TMDLs is an important part of moving this process forward to the point where TMDLs can be used in the way they were intended: as a means of reducing pollution in waters that remain too polluted for their designated uses.

Proposed Solution: EPA should adopt and implement the TMDL framework that it has put on hold.

Estimate of Regulatory Impacts: Thirty years after the Clean Water Act was passed, approximately half of the nation's surface waters remain too polluted for swimming and fishing, even though achieving "fishable, swimmable" waters was one of the Act's primary purposes. A large portion of these polluted waters remain impaired due to the effects of "nonpoint sources" – i.e., runoff. TMDLs are the Clean Water Act's mechanism both for achieving the long-delayed water quality goals of the Act and for finally beginning to bring nonpoint sources within the Act's regulatory structure.

Concentrated Animal Feeding Operations

Regulating Agency: EPA

Citation: 66 Fed. Reg. 3134

Authority: Clean Water Act, 33 U.S.C. §§1311, 1314, 1316, 1317, 1318, 1342, 1361

Description of Problem: The existing technology standards and permitting rule for concentrated animal feeding operations (CAFOs) was developed in the 1970's, when livestock and poultry were produced on a much smaller scale. These regulations are outdated and woefully inadequate to control water pollution from an industry that continues to concentrate into fewer large-scale operations. The nutrients in animal manure are causing eutrophication and toxic algal blooms that harm recreational waters, kill fish, and alter the species composition of our coastal fisheries, and threaten human health by contaminating groundwater used for drinking water supplies with nitrate, causing blue baby syndrome and spontaneous abortions.

Proposed Solution: EPA should issue strong rules requiring farmers to obtain individual discharge permits for their CAFOs. Final regulations should eliminate the 25-year, 24-hour permitting exemption, bring dry poultry operations under the NPDES program, and make it clear that the land application area is considered part of a CAFO.

Estimate of Regulatory Impacts: Forcing such operations to obtain permits that require them to control the devastating pollution they cause will compel CAFO owners and operators to internalize the enormous costs of water pollution that are now transferred to the fishing, tourism, and health care industries.

Roadless Area Conservation

Regulating Agency: Forest Service

Citation: 66 Fed. Reg. 3244

Authority: National Forest Management Act, 16 U.S.C. §§1600 et seq.

Description of Problem: In 2001, the Forest Service issued a rule protecting 58.5 million acres of the national forests, owned and managed by the federal government, from road construction, road reconstruction, and timber harvesting. After receiving a record 1.6 million comments on its proposed rule, and after conducting approximately 600 public meetings on the rule, involving some 25,000 people, the Forest Service issued this final rule protecting roadless areas. The roadless area conservation "rule" was a decision by the federal government regarding the uses of its own land; it was a decision to dedicate our commonly held forest's remaining roadless areas to some uses – recreation, wilderness experiences, watershed improvements, and the like – rather than to other uses, such as logging, which require roads. The "rule" is thus not a regulation in the traditional sense; it preserves existing entitlements to use the public resources, often at deeply subsidized rates, but changes the mix of uses of public land that will be available in the future. The Bush Administration has refused to defend this forward-looking, government-prerogative-protecting, landmark rule in court.

Proposed Solution: The Forest Service should (1) defend the 2001 rule against the legal challenges that have been filed against it; and (2) implement the rule as issued in 2001.

Estimate of Regulatory Impacts: In issuing the roadless area conservation decision, the Forest Service discussed numerous and multifarious benefits that would flow from protecting almost 60 million acres – approximately one-third of the land area of the national forests – from road building and timber harvesting. High quality soil; healthy watersheds; flood protection; safe drinking water; clean air; healthy and diverse fish and wildlife populations; recreational opportunities; reference landscapes for scientific research; natural, beautiful landscapes; traditional cultural properties, sacred sites; and other locally identified unique characteristics – all of these were cited by the Forest Service as benefits of conserving the national forests' remaining roadless areas. Many of these important values are impossible to quantify and monetize. But even the most glancing familiarity with the changing economy of the Western states most affected by this decision suggests a large economic benefit to the decision in addition to the noneconomic values protected by it. Tourism is the fastest-growing industry in many of the states most affected by the conservation of roadless areas. Indeed, tourism is already one of the top three industries in all of the states most affected by this policy. Tourism is not popular in these states because of timber cuts and strip mines; it is popular because of the abundant natural resources and beautiful scenery these states offer to visitors. In addition, many of the timber sales that would be prevented by this conservation decision were, according to the Forest Service, "likely to cost more to prepare and sell than they realize in revenues received."

Surface Management of Mining Claims

Regulating Agency: BLM

Citation: 66 Fed. Reg. 54863

Authority: Federal Land Policy and Management Act, 43 U.S.C. §§ 1732(b), 1733, 1740; General Mining Law, 30 U.S.C. § 22

Description of Problem: In 2000, the Clinton Administration amended the BLM's surface management rules prohibiting activities that result in unnecessary and undue degradation of the public lands. The stated purpose of the amendments was to make it clear that operators must not cause substantial irreparable harm to surface resources that cannot effectively be mitigated, even if customary and prudent practices would lead to that result. In 2001, the BLM repealed the 2000 amendments, thereby restoring the pre-2000 regulations, which the BLM had previously characterized as too subjective and vague. The BLM explained that it should not have adopted this "truly significant provision" without affording better opportunity to comment. The 2001 amendments also repealed performance standards installed by the 2000 amendments. At the same time as it adopted the 2001 amendments, the BLM solicited further comment on its most recent changes.

Proposed Solution: Restore the 2000 definition of "unnecessary and undue degradation" and the 2000 performance standards repealed in 2001 to ensure that the integrity of surface resources on the public lands is protected against damage caused by mining activities, regardless of whether customary and prudent practices would have caused that damage.

Estimate of Regulatory Impact: The BLM estimated that the costs of the 2000 regulations would have ranged between $106 million and $649 million. The proposed solution would generate benefits in the form of increased protection of natural resources found on public lands on which mining operations occur, including the avoidance of both land and water pollution on those public lands. Like the roadless area policy, the former BLM rule was not a "regulation" in the traditional sense; it was an attempt by the federal government to impose on users of public lands – here, miners who extract the minerals from public lands *for free* – some of the true costs of doing business. This is another efficiency-promoting rule OIRA should support enthusiastically.

Tire Safety

Regulating Agency: DOT

Citation: 66 Fed. Reg. 38982

Authority: Transportation Recall Enhancement, Accountability, and Documentation (TREAD) Act (2000), Public Law 106-414, §13

Description of the Problem: The National High Safety Transportation Administration (NHTSA) has proposed requiring automobile manufacturers to install Tire Pressure Monitoring Systems (TPMSs) in each tire that would activate a warning light on vehicle dashboards when tire pressure has dropped significantly. OMB has written NHTSA indicating that it should require the use of indirect TPMSs, which do not have tire pressure sensors and which rely on the presence of an anti-lock braking system (ABS) to detect and compare differences in the rotational speed of a vehicle's wheels.

Proposed Solution: OMB should support the use of direct monitoring systems that prevent 30 more deaths and over 4,000 fewer injuries per year a cost of approximately $30.00 more per vehicle than the less protective alternative that OMB favors.

Estimate of Regulatory Impacts: NHTSA estimates that the direct monitoring systems would prevent 10,635 injuries and 79 deaths at an average cost of $66.33 per vehicle.
However, if the average per vehicle fuel and tread life savings ($32.22 and $11.03, respectively) over the lifetime of the vehicle are factored in, the average net cost of direct systems drops to $23.08 per vehicle. The net cost per equivalent life saved is $1.9 million for direct monitoring systems.

NHTSA estimates that indirect monitoring systems would prevent 6,585 injuries and 49 deaths at an average cost of $30.54 per vehicle. When the average per vehicle fuel and tread wear savings ($16.40 and $5.51, respectively) over the lifetime of the vehicle are factored in, the average net cost drops to $8.63 per vehicle.

Air Conditioner Efficiency Standards

Regulating Agency: DOE

Citation: 66 Fed. Reg. 38822 (withdrawing previous regulation and proposing substitute); 66 Fed. Reg. 7170 (promulgating final regulation)

Authority: Energy Policy and Conservation Act, 42 U.S.C. §§6291 et. seq.

Description of the Problem: On January 22, 2001, DOE promulgated a regulation that raises the energy efficiency of new central air conditioners to a SEER of 13 for new central air conditioners with a corresponding HSPF of 7.7 for heat pumps. On July 25, 2001, DOE withdrew its final rule to comply with President Bush's Regulatory Review, indicating that it would weaken these energy efficiency requirements.

Proposed Solution: DOE should reverse its decision.

Estimate of Regulatory Impacts: The higher energy requirements are feasible because there are central air conditioners and heat pumps in the market at all of the efficiency levels prescribed in the regulation. DOE found that approximately 61 percent of all consumers purchasing a new typical air conditioner would either save money or would be negligibly impacted as a result of the regulation, and that, in the case of a new typical heat pump, 94 percent of all consumers either would save money or would be negligibly impacted. At the same time, the regulation would have saved approximately 4.2 quads of energy over 25 years (2006 through 2030), which is the equivalent to all the energy consumed by nearly 26 million American households in a single year, producing a net benefit to the nation's consumers of $1 billion over the same period.

New Initiatives

Chemical Plant Safety Standards

Regulating Agency: EPA

Citation: N/A

Authority: Clean Air Act, 42 U.S.C. §7412(r).

Description of Problem: Efforts to reduce hazards at toxic chemical manufacturing and storage facilities have lagged dangerously, both within the government and among affected facility owners and operators. Despite analyses of the serious hazards posed by potential terrorist attacks on such facilities, including a U.S. Army analysis showing that the destruction of facilities storing acutely toxic chemicals is second only to biological warfare events in any list of highest priority concerns, EPA has yet to take effective action to require that the most threatening targets be eliminated or, if elimination is impossible, that available site security be strengthened.

Proposed Solution: In the wake of September 11, 2001, EPA should propose regulations requiring the adoption of "inherently safer technologies" that would eliminate or sharply reduce the vulnerability of facilities storing, producing, or using toxic chemicals in any significant amount.

Estimate of Regulatory Impacts: Depending on the size of a facility, conducting vulnerability assessments could cost a few thousand to several hundred thousand dollars. Compared to the economic and human impacts of a terrorist attack, however, these amounts are equivalent to a reasonable insurance premium against catastrophic damage.

Greenhouse Gases

Regulating Agency: EPA

Citation: N/A

Authority: Clean Air Act, 42 U.S.C. § 7521

Description of Problem: The emission of greenhouse gases (especially carbon dioxide) from automobiles and other mobile sources is a major source of overall greenhouse gas emissions in the United States. EPA has promulgated standards for new motor vehicles and motor vehicle engines under the Clean Air Act, but the existing standards do not regulate carbon dioxide emissions.

Proposed Solution: EPA should amend the emission standards for new motor vehicles to contain emissions limitations on carbon dioxide reflecting the greatest degree of emission limitation achievable through the application of technology which the Administrator determines will be available for the model year to which such standards apply.

Estimate of Regulatory Impacts: New motor vehicle manufacturers will incur additional costs in complying with new emission standards designed to reduce greenhouse gases. However, the reduction in greenhouse gases resulting from the promulgation of the standards should help ameliorate the enormous costs to human health, the environment, and the economy imposed by global warming. For further analysis of the benefits of regulating greenhouse gases emitted by mobile sources, see International Center for Technology Assessment, Petition for Rulemaking and Collateral Relief Seeking the Regulation of Greenhouse Gas Emissions from New Motor Vehicles Under Section 202 of the Clean Air Act (1999) (available at www.icta.org).

CAFE Standards

Regulating Agency: NHTSA

Citation: 49 CFR Pt. 538

Authority: Energy Policy and Conservation Act of 1975, 49 U.S.C. §§32901 et seq.

Description of Problem: Under the Energy Policy and Conservation Act of 1975, NHTSA is directed to promulgate and update corporate average fuel economy standards for automobiles and light duty trucks. The existing standards are now obsolete in light of the availability of more fuel-efficient cars, including hybrid-electric and electric vehicles.

Proposed Solution: The National Highway Traffic Safety Administration should raise CAFE standards to 40 mpg.

Estimate of Regulatory Impacts: A move toward more efficient motor vehicles will be economically beneficial for the automobile manufacturing industry and for consumers in general. It will reduce our reliance on foreign oil at a time when this reliance is especially problematic. There may be a slightly negative economic impact for the petroleum industry.

Protections for Farm Children from Pesticide Exposures

Regulating Agency: EPA

Citation: Petition for a Directive That the Agency Designate Farm Children as a Major Identifiable Subgroup and Population at Special Risk to Be Protected under the Food Quality Protection Act, filed by a coalition of groups including the United Farm Workers of America, Farmworkers Justice Fund, American Public Health Association, and the Natural Resources Defense Council , et al.(October 22, 1998).

Authority: Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §346a, as amended by the Food Quality Protection Act of 1996

Description of Problem: Hundreds of thousands of children live on farms, play or attend schools on or near agricultural lands, and have family members who routinely handle pesticides. The nation's 2.5 million workers have approximately one million children who spend considerable time on farms, often out in fields where pesticides are applied, because their parents cannot afford other child care. These vulnerable children are routinely exposed to dangerous levels of the 950 million pounds of extremely toxic pesticides that are applied to agricultural land annually, suffering acute and chronic health effects.

Proposed Solution: EPA should identify children living on and near farms as a "major identifiable subgroup" for all Food Quality Protection Act determinations and designate these children as a "population at special risk" who must be protected in order to fulfill the FQPA requirement that pesticide tolerances provide a "reasonable certainty that no harm will result to infants and children from aggregate exposure to pesticide chemical residue."

Estimate of Regulatory Impacts: Even the narrowly economic benefits of this action will far outweigh costs if total health benefits of reducing health care costs, reduced health risks to farm children, and associated benefits to their parents and neighbors (e.g., reduced health effects and fewer lost work days) are considered appropriately.

HACCP Regulations

Regulating Agency: USDA/FSIS

Citation: Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) Systems, 60 Fed. Reg. 6774, 6774 (codified at 9 C.F.R. pts. 308, 310, 320, 325, 326, 327 and 381).

Authority: Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §603(a)

Description of Problem: The pathogen reduction standards with Salmonella as the reference pathogen were critical to the implementation of the Hazard Analysis and Critical Control Point (HACCP) regulations. The court in *Supreme Beef Processors v. USDA,* 275 F.3d 432 (5th Cir. 2001), held that USDA lacked authority to enforce the pathogen reduction standards. Although USDA may still enforce other aspects of the HACCP regulation (e.g., the requirement to prepare and adequate HACCP plan), it may not test for Salmonella as a surrogate for pathogens in general to determine compliance with the rule's sanitation requirements.

Proposed Solution: USDA should support legislation to clarify its authority to test for Salmonella and other pathogens and to shut down plants that consistently fail to meet minimum pathogen standards. Pending the enactment of clarifying legislation, USDA should devote additional resources to conducting intensive inspections of plants and reassessing all HACCP programs. Whether or not new legislation is enacted, USDA should promulgate regulations requiring suppliers of meat to intermediate "grinding" plants to certify that their products are relatively free from pathogens. USDA should also promulgate regulations providing for prominent public dissemination of the names and addresses of all plants that repeatedly fail Salmonella tests.

Estimate of Regulatory Impacts: The regulations would have minimal economic impact on meat producers. They will prevent hundreds of illnesses and many deaths from meat-borne pathogens per year.

Labeling Genetically Modified Foods

Regulating Agency: FDA

Citation: Draft Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering, 66 Fed. Reg. 4830 (2001).

Authority: Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§321(n), 343(a)(1), 343(i)

Description of Problem: Many people are allergic to certain foods, and genetic modification may lead to foods that cause allergenic reactions in unsuspecting consumers. FDA has promulgated draft guidelines for labeling genetically modified foods that discourage companies from informing consumers that food sold in commerce is or is not genetically modified.

Proposed Solution: FDA should promulgate binding regulations requiring manufacturers and importers to label all genetically modified foods as such. Sufficient uncertainties surround the health "consequences" of genetically modified plants to support a conclusion that the fact that a food derives from GM plants is material in light of those consequences. For markets to function properly, consumers must be well-informed. By depriving consumers of information about the status of food available for purchase, companies who market genetically modified foods are distorting markets for food. Government action is required to reduce this distortion.

Estimate of Regulatory Impacts: Food manufacturers will encounter some modest costs in placing appropriate labels on products containing genetically modified foods. The food processing industry will encounter some transitional costs in segregating genetically modified plants and plant products from those that are not genetically modified. Consumers will benefit greatly from knowing whether or not the food they may purchase is or is not genetically modified.

Hormones in the Food Supply

Regulating Agency: FDA

Citation: N/A

Authority: Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §343(i)(2)

Description of the Problem: The Food and Drug Administration (FDA) does not currently require that meat taken from cattle given bovine growth hormone, estrogens, or other hormones be labeled to that effect.

Proposed Solution: FDA should promulgate regulations requiring that meat taken from cattle given bovine growth hormone, estrogens, or other hormones be labeled to that effect.

Estimate of Regulatory Impacts: Competitive markets require that consumers have full and complete information about the products that they purchase. The cost to manufacturers of providing the labels should be relatively small as compared to the benefit of enabling consumers to determine for themselves whether to purchase meat products processed from cattle given bovine growth hormone, estrogens, or other hormones.

Antibiotics in the Food Supply

Regulating Agency: FDA

Citation: N/A

Authority: Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §351

Description of the Problem: The Food and Drug Administration (FDA) does not currently regulate the use of antibiotics in cattle, chickens, pigs, and hogs in order to prevent any further erosion of the effectiveness of such drugs in humans

Proposed Solution: FDA should promulgate regulations regulating the use of antibiotics in cattle, chickens, pigs, and hogs that would prevent any further erosion of the effectiveness of such drugs in humans

Estimate of Regulatory Impacts: Antibiotics in animal feed contributes to antibiotic resistance that will eventually result in ineffective antibiotics in humans. The World Health Organization, the CDC, the American Public Health Association, the Association of State and Territorial Health Officials, the Natural Resources Defense Council, the American Medical Women's Association, among other health organizations, support a ban on the sub-therapeutic use of antibiotics. The costs of antibiotic resistance are considerable. The National Foundation for Infectious Diseases estimates an annual cost of antibiotic resistance to be "as high as four billion dollars annually." USDA, *Anti-microbial Resistance Issues in Animal Agriculture* at 1 (Dec. 1999). The benefits from a ban are likely to exceed the cost. The National Research Council's Committee on Drug Use in Food Animals estimated that the total cost of banning sub-therapeutic use of antibiotics in agriculture would be between $1.2 billion to $2.5 billion per year, with the average annual per capita cost to consumers of such a ban would be in the range of $4.84 to $9.72 per year. This estimate does not take into account the likely adoption of suitable alternatives. Nat'l Research Council, Board on Agriculture, *The Use of Drugs in Food Animals, Benefits and Risks* (1999).

Strengthened Environmental Liability Reporting

Regulating Agency: SEC

Citation: Regulation S-K, 17 CFR 229.10-229.702

Authority: Securities Exchange Act of 1934, 15 U.S.C. §78

Description of Problem: The SEC narrowly construes and grudgingly enforces its authority to require proxy disclosures "in the public interest or for the protection of investors." 15 U.S.C. 78n. For example, the SEC has asserted that it may require disclosure of the environmental liabilities and characteristics of firms only where they are "economically material." There are two large problems with the SEC's refusal to assert a larger role in requiring environmental disclosures. First, many environmental characteristics of firms – such as emissions reported for the Toxic Release Inventory and penalties paid as a result of violations of environmental laws – have been demonstrated to have a relationship to the economic performance of firms; that is, better environmental performance is correlated with better economic performance. Thus, even under the SEC's economic materiality test, many environmental matters would be material to financial investors. Second, many investors today are concerned with social performance as well as economic performance. These investors would be aided by enhanced environmental disclosures from firms.

Proposed Solution: The Securities and Exchange Commission should expand its investor disclosure rules to require release of information regarding environmental performance, such as the status of the company's permits, whether it has been the subject of an environmental enforcement action, and the emissions it reports to the Toxic Release Inventory.

Estimate of Regulatory Impacts: The Bush Administration in general, and OIRA in particular, have expressed an interest in using information as an alternative to more conventional regulation, while at the same time acknowledging the critical role good information plays in the proper functioning of markets. Strengthening environmental disclosure requirements under the securities laws would serve both of these goals at the same time, and well.

Low-cost Timber Sales and Grazing Fees

Regulating Agencies: United States Department of Agriculture: Forest Service; Department of the Interior: Bureau of Land Management

Citation: 43 C.F.R. 4130.8-1 (grazing fees); 36 C.F.R. Part 223 (timber sales)

Authority: Taylor Grazing Act, 43 U.S.C. §315b (grazing fees); 16 U.S.C. §472a(a) (timber sales)

Description of Problem: Low cost timber sales conducted by the Forest Service amount to government subsidies for a few industries which operate in direct competition with other corporations. Similarly, grazing fees for cattle on federal lands are depressed to the point that they amount to a subsidy for ranchers.

Proposed Solution: The Forest Service and BLM should reform these programs by raising the rates charged to ranches and timber companies to at least the level of market rates.

Estimate of Regulatory Impacts: Raising grazing and timber fees charged for private use of public resources is consistent with the Administration's emphasis on government approaches that harness the market in the service of environmental protection. As OIRA recognizes in Appendix B of the Draft Report, "[e]conomic theory predicts that regulation that restricts competitive prices … produces no social benefits" except in circumstances not present in the grazing and timber setting. OIRA should press the Forest Service and BLM to ensure that their regulation of grazing and timber on the public lands produces competitive prices.

Withdrawal of State Delegations

Regulating Agency: EPA

Citation: N/A

Authority: Clean Air Act, 42 U.S.C. §7410; Clean Water Act, 33 U.S.C. §1342; Safe Drinking Water Act, 42 U.S.C. §300g-2; and the Resource Conservation and Recovery Act, 42 U.S.C. §§6926, 6946, and 6991c

Description of Problem: The major environmental laws allow EPA to delegate the authority to implement federal regulatory programs to the states. Despite clear evidence that programs in many states have fallen far below the federal floor, EPA has withdrawn a state's authority on only one occasion, and even in that case, EPA almost immediately signed a contract with that state to pay its employees to continue operating the program. Examples of poor performance include failure to issue or renew permits under the Clean Air and Clean Water Acts for major facilities emitting millions of tons of toxic pollution in a timely fashion. Not only does such negligence damage the environment and public health, it creates an atmosphere of lawlessness that places companies operating in a more responsible manner at a competitive disadvantage.

Proposed Solution: EPA should subject all state programs to rigorous oversight and stand ready to assume responsibility for permitting and enforcement when a state's performance is poor.

Estimate of Regulatory Impacts: More aggressive oversight of poorly performing states will not produce any further costs than were anticipated when the relevant statutes were enacted and regulations promulgated. These actions will enable us to achieve the benefits promised by Congress and EPA.