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Joan Claybrook, President

May 30, 2002

John Morrall  
Office of Information and Regulatory Affairs (OIRA)  
Office of Management and Budget (OMB)  
NEOB, Room 10235  
725 17<sup>th</sup> Street, N.W.  
Washington, D.C. 20503

**RE: Comments to Draft Report to Congress on the Costs and Benefits of Federal Regulations (67 FR 15014)**

Dear Mr. Morrall:

Public Citizen is a non-profit consumer advocacy organization with about 150,000 members nationwide.<sup>1</sup> We are writing in response to your March 28, 2002 notice in the Federal Register requesting comments to the Draft Report to Congress on the Costs and Benefits of Federal Regulations (hereinafter “Draft Report”).<sup>2</sup>

OMB-OIRA’s Draft Report is prepared annually in response to a Congressional directive requiring OMB-OIRA to provide a yearly “accounting statement and associated report” containing estimates of the “total annual costs and benefits (including quantifiable and non-quantifiable effects) of Federal rules and paperwork, to the extent feasible.”<sup>3</sup>

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<sup>1</sup> For 31 years, Public Citizen has had direct, practical involvement with a wide variety of federal health and safety protections. For example, Public Citizen’s Litigation Group has represented consumer groups, labor unions, worker groups, and public health organizations in standard-setting proceedings and in litigation involving OSHA, EPA, FDA, USDA, NHTSA and other health and safety agencies. Public Citizen’s Health Research Group is the nation’s leading advocate for safe drugs and medical devices and has also worked extensively on ways that federal agencies can improve the healthcare delivery system, and protect worker health and safety. Public Citizen’s Critical Mass Energy and Environment Program is playing a leading role protecting consumers’ rights in the electricity deregulation debate, in testimony on rising gasoline prices and on issues of nuclear safety, and also advocates for strong food safety regulations related to the questionable technology of food irradiation. Public Citizen has also played a critical role in advocating for and participating in the enactment of legislation and the implementation of numerous federal highway and transportation safety standards, and its President, Joan Claybrook, was Administrator of the National Highway Traffic Safety Administration from 1977 to 1981. Public Citizen is also a member of Citizens for Sensible Safeguards (CSS), a broad-based coalition of consumer, environmental, civil rights, labor and health care organizations opposed to proposals and processes that would undermine federal safeguards.

<sup>2</sup> 67 FR 15014.

<sup>3</sup> See 67 FR 15014 (*citing* Sec. 624 of the Treasury and General Government Appropriations Act, 2001).

**Ralph Nader, Founder**

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This year's Draft Report continues the shift in focus that began with last year's report. Due to the major methodological limitations of regulatory accounting, the Draft Report places much less emphasis on providing an accounting of the costs and benefits of federal regulations, which is its statutory purpose. Instead, OMB-OIRA is using this report to seek "public comment" on a range of issues, the most notable being nominations for rules that effectively should be rescinded or changed.

We believe OMB-OIRA has no statutory authority to carry out this function, which largely serves the interests of regulated industry. After all, OMB/OIRA's request is to focus on *deregulatory* efforts and pays scant attention to areas – like workplace safety – where health and safety regulation is urgently needed. In so doing, it is usurping the rightful role of the federal agencies Congress has entrusted with the authority to issue regulations. If members of the "public" or regulated entities wish to propose rescissions or changes in existing regulations or initiate new regulations, they can always submit petitions for rulemaking under 5 USC 553(e) to agencies or lobby Congress to legislatively change policies.

On another more general note, at the same time that OMB-OIRA is moving to impose sweeping "data quality" requirements on federal agencies the Draft Report fails to provide sufficient data regarding its analytical conclusions and default assumptions to allow readers to check for accuracy. Should OMB-OIRA continue to prepare this report as if it were an informal public docket, which we object to, OMB-OIRA should formally respond to public comments and justify its conclusions.

We have several general comments and significant criticisms of the report, which are summarized in the following introduction and discussed in more detail below in Sections I-III.

### *The Overall Tone of the Draft Report Is Clearly Hostile to Protective Regulation*

OMB-OIRA does not strive for any reasonable balance in the Draft Report. In fact, the overall tone of the report is hostile to protective regulation. Its overwhelming emphasis on regulatory costs, its lack of attention to benefits (which outweigh costs by a considerable margin) and to the problems with accurately measuring benefits, its emphasis on soliciting comments on regulations that regulated industry believes should be rescinded or changed, its boasting of the use of the "return" letter, which many view as a tool to gut safeguards on behalf of regulated industry, and numerous other initiatives outlined in the Report all are testament to a major centralization of regulatory power within OMB-OIRA and a concomitant weakening of the power of the federal agencies.

Carefully read, the Draft Report represents an attempt by OIRA to push the envelope of its own limited authority and create numerous mechanisms that will greatly discourage federal agencies from promulgating new regulations and give regulated industries special tools to delay, block or rescind critical safeguards. Because industry has an acute interest in opposing specific regulations, and the public has only, generally speaking, diffuse interests in a particular rule, as OMB-OIRA is well aware the new procedures are likely to be used disproportionately to oppose regulation.

The underlying hostility to protective regulations that animates this report is unfortunate and shortsighted. While it is a well-known truth that corporations will act in their own short-term best interests to maximize profit, it is just as well-known, and just as true, that governmental regulation is necessary to stop the unfettered despoilment of public lands and to protect the public from corporate negligence and cost cutting at the expense of safety. OMB-OIRA needs to stop promoting policies that undercut the government's role of providing a balance to market excesses, and instead, foster policies that assist agencies to carry out *their* statutory mandates to protect the public and protect the environment.

### *The Draft Report Effectively Admits Past Failure with Respect to Regulatory Accounting*

The sole legislative mandate for this annual report is for OMB-OIRA to provide an annual statement about the *total* costs and benefits of Federal regulations and paperwork. Perhaps due to valid criticism from academics and public interest groups, such as Public Citizen, regarding the number of gross uncertainties involved in the dubious exercise of accounting for costs and benefits across hundreds, if not thousands, of government programs and rules, in this Draft Report OMB-OIRA has downplayed such an annual "regulatory accounting" and relegated its fuller statement of costs and benefits to an appendix.<sup>4</sup>

While OMB-OIRA appears to have significant reservations about this requirement, Public Citizen believes that the number of assumptions and differences across agencies renders a government-wide figure for the overall costs and benefits of regulation a ludicrous proposition.

One need only look at the attempts in this and previous annual reports. Several previous annual reports prepared by OMB-OIRA regarding the overall costs and benefits of regulation noted that benefits outweighed regulatory costs by a substantial margin. For example:

- In 1998, OMB-OIRA estimated the net benefits of social regulations to range from \$30 billion to \$3.3 trillion.<sup>5</sup>
- In 1999, OMB-OIRA estimated the net benefits of social regulations to range from \$32 billion to \$1.6 trillion.<sup>6</sup>
- In this year's 2001 Draft Report, OMB-OIRA estimated the net benefits of social regulations to range from \$31 billion to \$1.8 trillion.<sup>7</sup>

This Draft Report de-emphasizes the accuracy of regulatory accounting. Perhaps that is because the benefits of federal regulation (which are generally acknowledged as being woefully underestimated) consistently outweigh the costs (which are typically overestimated by wide margins). Or maybe OMB-OIRA has chosen to downplay these estimates because public interest critiques of the formative studies on which pre-1995 as well as more recent numbers were based.

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<sup>4</sup> See 67 FR 15033.

<sup>5</sup> See Report to Congress on the Costs and Benefits of Federal Regulations, 1998, p. 16; *see also*, Table 3.

<sup>6</sup> See Report to Congress on the Costs and Benefits of Federal Regulations, 1999, p. 12.

<sup>7</sup> See Draft Report, 67 FR 15037, Table 11.

In properly (in our view) backing off from its assignment, OMB-OIRA's solution is to ask for cost-benefit and other related suggestions from the public based upon the notion of increasing overall net benefits.<sup>8</sup> This continuing reliance on cost-benefit analysis is highly inappropriate for several reasons:

- As noted above and discussed below, cost estimates of regulations are often substantially overestimated and estimates of benefits are often substantially underestimated.
- OMB-OIRA's analysis of "net" benefits excludes consideration of re-distributive and wealth effects from regulation, despite the fact that the re-distribution of social wealth in the form of better health or environmental conditions is often the explicit goal of regulatory programs.
- Accounts of costs and benefits do not even *attempt* to describe or include the widely shared values embedded in, and expressed by, social regulation, including such crucial ethical positions as the desire to prevent unnecessary human suffering and death, respect for the environment and wildlife and the desire to preserve natural resources for future generations.

OMB-OIRA's commitment to the expansion of economic evaluation tools contains an intrinsic bias in favor of regulated interests and against public health and safety. We remain deeply concerned that, in defiance of both express and implicit directions from Congress, OMB-OIRA will attempt to overturn years of investment in rules by the public, stakeholders, scientific experts and the agencies, and seek to derail sorely needed new health and safety regulations, thereby turning laws made by Congress into paper promises.

As just one example, OMB-OIRA has blocked a final rule proposed by NHTSA regarding a dashboard monitoring system for tire inflation levels. The rule is now long overdue, but, because of OMB-OIRA's insistence upon an industry-favoring and shoddy "indirect" measuring system, it still has not been issued. Our full objections to OIRA's interference in this critical safety issue are described in Appendix A of these comments.

Moreover, this preoccupation with current regulatory costs may stymie efforts to extend regulation to capture more benefits for society. For example, according to the National Highway Traffic Safety Administration (NHTSA), the cost of motor vehicle crashes in the U.S. in the year 2000 alone was \$230.6 billion, or \$820 for every man, woman and child in the country.<sup>9</sup>

### *The Report Reveals an Unprecedented Power Grab by OMB-OIRA in the Regulatory Process*

A major part of OMB-OIRA's Draft Report does not deal with the report's statutory requirement to prepare an annual estimate of costs and benefits. Instead, it describes the numerous ways that OMB-OIRA is interfering in the regulatory mandates of federal agencies,

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<sup>8</sup> See *id.*

<sup>9</sup> National Highway Traffic Safety Administration, "Economic Impact of Motor Vehicle Crashes, 2000" May 2002 (DOT HS 809 446).

usually without any legislative authority to do so. These range from the use of “return” and “prompt” letters to the creation of a science advisory board to the imposition of time-consuming peer review requirements and one-size-fits-all risk assessment procedures.

The most pernicious aspect of this overreaching by OMB-OIRA is the unauthorized development of what we consider to be a regulatory “hit list.” It began in the 2001 draft report wherein OIRA sought suggestions about specific regulations that should be modified or rescinded. While the public was invited to provide suggestions for this list, it largely served as a vehicle for regulated industry and industry-funded think tanks, such as the energy industry-supported Mercatus Center, to propose regulations to roll back. Consumer, environmental and health groups submitted few, if any, recommendations because their goals are more, not fewer, safeguards.

OMB-OIRA came under a great deal of criticism for this effort because it appeared to declare “open season” on rules mandated by Congress. While OMB-OIRA has tried to make the process look more benign in the 2002 Draft Report, it still represents a free-for-all allowing industry to take pot shots at regulations that already have undergone labor-intensive research, public notice-and-comment periods and multiple agency revisions. Public Citizen views this as an illegitimate exercise and as an end-run around the public regulatory process in which we avidly participate.

Below we address particular sections of the Draft Report, including OMB-OIRA’s claims of a new transparency, and the request for recommendations that will result in a new “hit list” of rules to revise and rescind. We also address OMB-OIRA’s use of the Report as a bully pulpit for promotion of pro-trade deregulatory principles and other examples of OIRA’s over-reaching since John Graham’s confirmation as Administrator. The comments next describe why regulatory accounting is incompatible with promoting public health and safety, critique the serious deficiencies of cost-benefit analysis and highlight numerous problems that undermine its effectiveness as a tool for evaluating regulatory decisions. We provide several appendices on particular aspects of the issues discussed in the comments to elaborate further on our concerns and objections.

## **I. OMB-OIRA Regulatory Over-Reach and New Assertions of Power**

In the Draft Report, OMB-OIRA boasts of its many new initiatives regarding regulatory oversight.<sup>10</sup> We take a far dimmer view of these activities. OMB-OIRA’s focus and activities, as described in the Draft Report, include at least the following components that are objectionable and/or of concern:

- The numerous meetings with and overrepresentation of regulated industry in discussions with OMB-OIRA about pending issues combined with limited disclosure of the attendees at and substance of those meetings;
- The continued creation of a statutorily unauthorized hit list of regulations that should be rescinded or changed;

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<sup>10</sup> See 67 FR 15014.

- The creation of additional hit lists for which OMB-OIRA requests nomination of: regulations, guidance documents and paperwork requirements that especially impact small businesses “without an adequate benefit justification,” “problematic” agency guidance documents that should be reformed; and instances of “insufficient” consultation by federal agencies with State, local and tribal governments, including a focus on paperwork requirements and agency guidance documents;
- The resurgence of the “return letter” as a tool to delay, eviscerate, or block regulations targeted by industry;
- The creation of the “prompt letter,” which exceeds OMB-OIRA’s statutory role and could shift agency priorities away from other pressing needs;
- The unwarranted and unauthorized expansion of requirements that agency data be “peer reviewed,” thereby illegitimately creating an OMB-OIRA super-mandate out of terms used in a single statute (the Safe Drinking Water Act);
- The limiting of the public’s right to receive timely, significant public health and environmental information through the creation of procedural hurdles in the form of the agency’s new “data quality” guidelines; and,
- The use of OIRA as a bully pulpit for the promotion of free trade principles as they may pertain to international regulatory issues.

#### *OIRA’s “New and Improved” Transparency Initiatives*

While OIRA has made some welcome improvements in openness and transparency, as noted in Chapter I, section B of the Draft Report, we are concerned about the office’s recent practice of holding more meetings with regulated interests.<sup>11</sup> In general, we believe OIRA’s meetings with outside parties counteract the notice and comment process of federal agency rulemaking and reflect the agency’s preoccupation with favoring the demands of industry over ignoring the interests of citizens.

In the Draft Report, OMB-OIRA states that it met with “more than 100” outside groups between July 2001 and December 2001.<sup>12</sup> Of these, 82 groups representing regulated industries can be easily identified in the docketed meetings held by OIRA regarding pending issues. Only 13 citizen interest groups were represented at these same meetings.<sup>13</sup> Undocumented meetings on issues not pending before OIRA likely reflect an even larger slant toward the concerns of industry, since these meetings need not be disclosed. The only rationale for such meetings is OMB-OIRA interference in the role delegated by Congress to the substantive agencies. If regulated interests have concerns, they should be meeting with the agencies with the substantive expertise. OIRA has neither the expertise nor the depth of information to address such particular issues.

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<sup>11</sup> See 67 FR 15018.

<sup>12</sup> 67 FR 15018.

<sup>13</sup> From meeting records listed online at <http://www.whitehouse.gov/omb/oira/meetings.html>. These figures exclude those in attendance at the April 25, 2002 meeting regarding Retention and Reporting of Information for F, J, and M Non-immigrants; Student and Exchange Visitor Information System (SEVIS) because these attendees were entirely from the academic community.

For example, OIRA's April 17, 2002 meeting regarding the Transportation Recall Enhancement, Accountability, and Documentation (TREAD) Act was attended by three representatives of OIRA, two representatives of the Rubber Manufacturers Association (RMA), and former Congressman and prominent Republican Vin Weber, an attorney from the firm of Clarke and Weinstock, whose client is not listed. NHTSA, which drafted the rule, was not in attendance. A February 21, 2002, meeting regarding tire pressure monitoring systems was attended by three representatives of the RMA, Mr. Weber, and four representatives of OMB or OIRA. Again, NHTSA was not in attendance. An earlier meeting on the same topic was attended by seven representatives of the auto industry or individual auto manufacturers, four representatives of OIRA, and two representatives of NHTSA.

The lack of information listed in the meeting records is troubling because it appears that industry is anonymously influencing the regulatory process. By listing several attorneys who attended the meetings only by their firms and not revealing whose interests they represented (such as Mr. Weber above), OIRA obscures from the public the regulatory lobbying that is being performed by these attorneys. In some cases, the client *is* listed in the record, showing that OIRA can and does collect this information. OIRA should collect client names for each attorney present and publish the information in the meeting record along with the name of the attorney's firm.

In addition, the skeletal information provided regarding the substance of even docketed meetings means that the interested public is still largely left in the dark. In contrast, regulatory agencies, such as NHTSA, post a summary of the topics discussed at meetings related to a pending regulatory matter.

Though OMB-OIRA's modest improvements in transparency and promptness are long overdue, the agency is more than compensating for these improvements with ambitious new programs designed to bring ever more agency actions under OMB-OIRA's watchful eye.

#### *OMB-OIRA as an Unauthorized Clearinghouse for Industry Complaints Regarding Regulation*

OMB-OIRA has no statutory authority to supplant agency expertise or to determine the substance of final rules. Rather, its function under the Executive Order is to play a specific and discrete oversight role in reviewing the paperwork collections related to regulatory activities. Moreover, the statutory mandate for this annual report *to Congress* regarding the overall status, including the costs and benefits, of federal regulation, and making *recommendations to Congress for reform of the regulatory accounting process* is quite limited. Nowhere is authorization provided, either implicit or explicit, for OIRA to report *to agencies* regarding suggestions for the rescission or alteration of extant *regulatory programs*, a process OIRA proposed last year and has greatly expanded in this Draft Report.

In the Draft Report, OIRA requests "public nominations of regulatory reforms to specific existing regulations that, if adopted, would increase overall net benefits to the public, considering both qualitative and quantitative factors."<sup>14</sup> In addition, OMB-OIRA proposes the creation of several other target lists as well: 1) "Identification of specific regulations, guidance documents, and paperwork requirements that impose especially large burdens on small businesses and other

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small entities without an adequate benefit justification;” 2) “Reviews of problematic agency ‘guidance’ documents of national or international significance that should be reformed through notice and comment rulemaking, peer review, interagency reviews, or rescission;” 3) “Comments on any cases where consultation under the Unfunded Mandates Reform Act between federal agencies and State, local and tribal governments were not sufficient or timely enough to have a meaningful impact on the rulemaking process;” and 4) “Suggestions of analytical issues needing refinement or development to improve OMB’s analytic guidance document.” We view each of these invitations as providing special mechanisms for potential interference by OMB-OIRA and regulated industry in agency rulemaking.

In opening up a “public comment” process OMB-OIRA has put the public interest community into a double bind. On the one hand, should we fail to submit suggestions, OMB-OIRA could suggest that we have missed the openings given to us. However, we strongly believe that the proper avenue for such suggestions resides with the particular agencies charged with accomplishing a relevant congressional mission. Therefore, we believe that if we do participate in this dubious exercise, it could be used to lend a patina of propriety to OMB-OIRA’s activities, which are wholly unjustified under the law.

We therefore submit, under protest and with qualifications, *Stuck in Neutral*, at Appendix B, a report by Advocates for Highway and Auto Safety that details many sorely needed changes in transportation safety.

How these public comments that result in what we call “hit lists” are likely to be used by OIRA is well demonstrated by recent experience arising out of OMB-OIRA’s previous report. Last year, OMB-OIRA solicited suggestions from the public on “specific regulations that could be rescinded or changed that would increase net benefits to the public by either reducing costs and/or increasing benefits.”<sup>15</sup> The 2001 final report listed 71 regulations, 23 of which OIRA identified as “high priority,” meaning that OIRA is “inclined to agree with the suggestion” and a “prompt” letter “may be sent to the responsible agency for deliberation and response.”<sup>16</sup>

The rules placed on OMB-OIRA’s high priority list included many highly controversial and significant ones, including a handful of major environmental protections that have been at the center of political firestorms over the past year, such as the New Source Review regulations under the Clean Air Act, the arsenic in drinking water standard, and the roadless lands conservation area rules. The reasons provided by submitters regarding why rules should be re-examined were extremely sparse.<sup>17</sup> Furthermore, there appears to be no attempt by OIRA to compare the basis of the nominations to the rulemaking record, or to describe the reason for OIRA’s designation of some of them as “high priority.” In contrast to the sparse record underlying the nominations, the targeted rules were promulgated by agencies following a rigorous public notice and comment period, during which agencies were required to thoroughly explain the basis for the rules and respond to commenters opposing the rules.

As we make clear in Appendix C, in several cases we investigated, the assertion by

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<sup>15</sup> OMB Draft Report to Congress on the Costs and Benefits of Federal Regulation, May 2, 2001.

<sup>16</sup> OMB 2001 Report on the Cost of Regulation.

<sup>17</sup> The format OMB-OIRA suggests for nominations requires only a bare description of the problem and a proposed solution.

submitters that the targeted rules are cost-ineffective is not supported by the record or the facts. Yet, outrageously, OMB-OIRA has not hesitated to send a message, through its publication of this list, that it considers aspects of these rules ripe for revision. Allowing random commentators to take pot shots at federal regulation in this wholly extra-legal process is a waste of federal money and constitutes an innovative power grab by OMB-OIRA.

Moreover, nowhere does OIRA explain the basis for its authority to target regulations for rescission or change, nor does OIRA set forth any of its own analysis of last year's 23 targeted regulations. Indeed, it appears that OIRA was somewhat confused during the process as one of the 23 targeted regulations for rescission – labeling of trans-fatty acids in food products – was previously the subject of one of OIRA's prompt letters last fall urging the agency to take action on that exact regulation.<sup>18</sup> And in a speech Administrator Graham gave to the National Economists Club, he described the decision by the Administration to issue a new standard for arsenic in drinking water as well founded in science and therefore deserving of OMB-OIRA's deference,<sup>19</sup> yet that rule was on the "high priority" list of rules for rescission published by OIRA in December 2001, a month after the arsenic standard was issued. The Draft Report indicates that EPA has decided not to modify the arsenic rule and that OMB-OIRA has since dropped this item from its priority list.<sup>20</sup>

#### *Industry-Funded Groups Use OMB-OIRA's "Hit List" to Put Rules on the Chopping Block*

The record regarding responses to OIRA's initial efforts to target regulations for rescission or change demonstrates industry's advantage in the process. Well over one-half of the "high priority" regulations, 14 of the 23, came from a single submitter, the Mercatus Center of George Mason University.<sup>21</sup> The Mercatus Center is funded primarily by industry and has a strong bias against health, safety and environmental regulations.<sup>22</sup> Koch Industries, Inc., the

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<sup>18</sup> September 18, 2001 Prompt letter to the Department of Health and Human Services Secretary Thompson regarding Labeling of Trans Fatty Acids.

<sup>19</sup> Graham stated that OMB is deferring to rules supported by "independent" peer review and implied that the decision on arsenic would receive deference on those grounds: "[EPA] Administrator Whitman's recent decision on arsenic in drinking water was supported by just that type of review." See Remarks of John Graham to National Economists Club, Mar. 7, 2002, <http://www.whitehouse.gov/omb/legislative/testimony/graham030702.html>.

<sup>20</sup> See 67 FR 15037.

<sup>21</sup> Mercatus nominated the following regulations that were identified by OIRA as high priority: (1) Forest Service Planning Rules (USDA); (2) Roadless Area Conservation Regulations (USDA); (3) Central Air Conditioner and Heat Pump Energy Conservation Standards (DOE); (4) Standards for Privacy of Individually Identifiable Health Information (HHS); (5) Food Labeling: Trans Fatty Acids in Nutrition Labeling, Nutrient Content and Health Claims (FDA); (6) Amendments to National Park Service's Snowmobile Regulations (DOI); (7) Regulations Governing Hardrock Mining Operations (DOI); (8) Proposal Governing "Helpers" on Davis-Bacon Act Projects (DOL); (9) Hours of Service of Drivers; Drivers Rest and Sleep for Safe Operation (DOT); (10) Proposed Changes to the Total Maximum Daily Load Program (EPA); (11) Economic Incentive Program Guidance (EPA); (12) New Source Review (EPA); (13) Concentrated Animal Feeding Operations (CAFOs) Effluent Guidelines (EPA); and (14) Arsenic in Drinking Water (EPA).

<sup>22</sup> [The list of persons affiliated with the Mercatus Center reads like a who's who of regulated industry. Formerly, OIRA Administrator Graham served on the Mercatus Center's Board of Advisors, alongside C. Boyden Gray, a well-known corporate lobbyist, and Kip Viscusi, a law professor who has authored numerous pieces supporting regulatory rollback. Wendy Gramm, the Director of the Mercatus Center, serves on the board of directors of Enron Corporation, and her connections to the Enron scandal and the energy industry are well documented in a recent Public Citizen report](#), that may be downloaded at [http://www.citizen.org/documents/Blind\\_Faith.PDF](http://www.citizen.org/documents/Blind_Faith.PDF).

nation's largest privately held energy corporation, has significant influence over the Mercatus Center both administratively and financially.<sup>23</sup> CEO Charles Koch and executive VP Richard Fink both serve on Mercatus' six-person board of directors.<sup>24</sup>

Although the Mercatus Center does not disclose its donor list, it has been widely publicized that it received \$50,000 from Enron and another \$10,000 from Enron's former CEO Kenneth Lay<sup>25</sup> as well as donations by conservative foundations like Koch family foundations.<sup>26</sup> George Mason's Web site states that the Koch foundations gave "\$3 million in 1997, which helped launch the Mercatus Center."<sup>27</sup> Cumulatively, GMU reports that over the past four years, there have been \$13 million in donations by Koch, including a \$10 million, multi-year grant in 1998 to the George Mason University Foundation. David Roe, the CFO of GMU Foundation, told Public Citizen that the money is donated annually in \$2 million allotments. These funds are then given to the Mercatus Center for a program of studies conducted by Mercatus and GMU but "the Mercatus faculty are the ones that administer it."<sup>28</sup>

In addition to Mercatus, the American Petroleum Institute and American Chemical Council also each submitted a regulation targeted by OIRA for review or rescission given high priority by OIRA.<sup>29</sup> Both organizations donated unrestricted funds to Administrator Graham's Harvard Center for Risk Analysis in undisclosed amounts. (The American Chemistry Council is listed as a donor by its former name, the Chemical Manufacturers Association.)

### *Resurrection of the Return Letter*

In the Draft Report, OIRA describes itself as the "gatekeeper for new rulemakings" with its resurrection of the "return letter."<sup>30</sup> A return letter accompanies OIRA's rejection of an agency's rulemaking proposal, an event that can occur at the final stages of the rulemaking following a full notice and comment process. From July 2001 to December, OIRA issued 17 return letters regarding significant rulemakings. Under the Clinton Administration, no return letters were issued in the last three years and just 25 were issued over Clinton's entire eight-year term. Even outside of the context of OIRA's other moves to consolidate power within OMB-OIRA, such as the list of 71 rules for rescission or change contained in the 2001 Report, OIRA's activism in returning rules constitutes a major escalation of OMB-OIRA's interference in agency rulemaking.

In an interview with *Congressional Quarterly*, Administrator Graham stated that agencies are now operating under a thinly veiled threat of return letters if they fail to consult with OIRA at

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<sup>23</sup> [www.kochmembrane.com/ABOUT.HTM](http://www.kochmembrane.com/ABOUT.HTM)

<sup>24</sup> [http://www.kochind.com/newsroom/bio\\_detail.asp?ID=1](http://www.kochind.com/newsroom/bio_detail.asp?ID=1); *see also*, <http://irr.gmu.edu/factbooks/0001/bov.html>

<sup>25</sup> Washington City Paper, "Bull Market: Enron Collapsed. The Earth Is Warming Up. And GMU's Mercatus Center Says the Solution Lies in Two Public Policy Heroes: Supply and Demand", Garance Franke-Ruta, March 8-14, 2002 [hereinafter Franke-Ruta].

<sup>26</sup> See [www.mediatransparency.org](http://www.mediatransparency.org).

<sup>27</sup> <http://www.gmu.edu/development/pubs/benefact/fall01/pages/teamrecruit.html>

<sup>28</sup> Interview, David Roe, CFO George Mason Foundation Inc., 3: 45 p.m., May 31, 2002.

<sup>29</sup> The American Chemical Council nominated the Mixture and Derived From Rule (EPA) and the American Petroleum Institute nominated the Notice of Substantial Risk (EPA).

<sup>30</sup> 67 FR 15018.

the formative stages of rulemaking: “What we’ve been working on . . . is to create an incentive for agencies to come to us when they know they have something that in the final analysis is going to be something we’re going to be looking at carefully. And I think that agencies that wait until the last minute and then come to us – well, in a sense, they’re rolling the dice.”<sup>31</sup>

Of the 17 return letters issued, OIRA has approved only 5 of the targeted rules, meaning that OMB-OIRA action has delayed issuance of the remaining 13 rules.<sup>32</sup> Of course, as OIRA Administrator Graham told *Congressional Quarterly*, the threat of a return letter may be most critical in assuring that OIRA is able to exert power at the early stages of every rulemaking, with leverage over formative decisions that are largely out of sight to the public or to Congress.<sup>33</sup>

Return letters are being used to delay, alter and block rules. As described in the letter contained in Appendix A of these comments, after meeting with the Alliance of Automobile Manufacturers, OMB-OIRA used highly dubious analysis to force a change in a rule on dashboard tire pressure monitoring systems developed after full notice and comment by NHTSA. NHTSA’s experts had concluded that a requirement for a direct measuring system would be most beneficial to consumers. The industry protested to OMB, arguing that indirect measuring systems should be allowed. However, NHTSA’s research had confirmed that indirect measuring systems are highly unreliable and plagued by other serious problems. Despite the agency’s expertise, OMB-OIRA over-ruled its decision and forced NHTSA to adopt a two-part plan for implementation of the systems, which was announced as a final rule May 30, 2002.

#### *Introduction of the Prompt Letter*

As a complement to the return letter, in the Draft Report OIRA touts the introduction of the “prompt letter.”<sup>34</sup> OIRA states that it is “taking a proactive role in suggesting regulatory priorities for agency consideration” and that it “devised the ‘prompt’ letter as a modest device to bring a regulatory matter to the attention of agencies.”<sup>35</sup> OIRA does not explain however, where it derives the statutory authority to suggest regulatory priorities or shape regulatory agendas. Indeed, that responsibility rests with agencies alone. Only agencies have the scientific expertise to properly evaluate and rank competing regulatory issues.

As a side note, OIRA itself is not clear about regulatory priorities, as illustrated by its conflicting attitude towards labeling trans fatty-acids. As noted in the Draft Report, on September 18, 2001, OIRA sent a prompt letter to the Food and Drug Administration requesting “that a consumer labeling rule involving the trans fatty-acid content of foods be finalized in order to reduce an established risk factor for coronary artery disease.”<sup>36</sup> Not mentioned in the Draft Report however, is the fact that OIRA adopted and identified as “high priority” the Mercatus Center’s nomination of the FDA’s proposed trans fatty-acid rule for “reform or rescission” in its 2001 Report. This example suggests that there is some confusion about priority setting within

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<sup>31</sup> See Rebecca Adams, “Regulating the Rule-Makers: John Graham at OIRA,” *Congressional Quarterly*, Feb. 23, 2002, at 521.

<sup>32</sup> 67 FR 15018.

<sup>33</sup> See *id.*

<sup>34</sup> 67 FR 15020.

<sup>35</sup> *Id.*

<sup>36</sup> *Id.*

OMB-OIRA, and underscores the importance of deferring to agencies' expertise in their relevant subject areas.

### *Unwarranted Emphasis on Peer Review Guidelines Established by a Single Statute*

The Draft Report reviews the requirements of a September 20, 2001 memorandum from the OIRA Administrator to the President's Management Council [hereinafter "OIRA Memorandum"], one component of OIRA's "new and improved" regulatory approach under the Bush Administration.<sup>37</sup> In the Memorandum, OIRA pressures agencies to subject technical supporting documentation to independent, external peer review by promising "a measure of deference to agency analysis that has been developed in conjunction with such peer review procedures."<sup>38</sup>

The Memorandum makes four "recommendations" for agency peer review procedures: "(a) peer reviewers be selected primarily on the basis of necessary technical expertise, (b) peer reviewers be expected to disclose *to agencies* prior technical/policy positions they may have taken on the issue at hand, (c) peer reviewers be expected to disclose *to agencies* their sources of personal and institutional funding (private or public sector), and (d) peer reviews be conducted in an open and rigorous manner."<sup>39</sup> (Emphasis added.)

There are a number of problems with peer review that are not addressed by the Memorandum. First, the "recommendations" do not promote unbiased review because information about the peer reviewers is *only* disclosed to the agencies. Peer reviewers are only expected to disclose information regarding their prior technical/policy positions and their sources of personal and institutional funding *to agencies*, not to the public.<sup>40</sup> As a result, the recommendations are not conducive to public accountability. Additionally, there is no requirement that peer reviewers be free of any conflict of interest. Given the history of intense industry interest and participation in agency peer review, the need for such requirements is acute. We would suggest that OMB-OIRA adopt the practice of affirming the absence of conflicts of interest in peer reviewers.

Furthermore, there is no statutory basis for establishing peer review as a guarantor of quality. In 1999, the Senate considered and rejected S. 746, the Regulatory Improvement Act of 1999, which required peer review of agency risk assessments supporting major rules and agency cost benefit analyses of rules costing more than \$500 million. Several problems were identified with the peer review requirement, including the fact that it invited parties with a direct stake in the outcome of the rulemaking process to participate in the peer review process. It is well known that the stakeholders that can usually afford to sponsor peer review panel members are from regulated industry.

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<sup>37</sup> 67 FR 15019.

<sup>38</sup> *Id.*

<sup>39</sup> *Id.*

<sup>40</sup> The General Accounting Office concluded just last summer that EPA's Science Advisory Board panels, a model suggested by peer review proponents, were plagued by undisclosed conflicts of interest and that the public was consequently left uninformed about the nature of the panelists backgrounds in a manner that thwarted the intent and importance of conflicts laws and rules. *See* General Accounting Office, *EPA's Science Advisory Board Panels: Improved Polices and Procedures Needed to Ensure Independence and Balance*, GAO-01-536, June 2001.

Thus, the peer review requirement of S. 746 greatly limited participation by public interest groups, labor unions, environmental groups, and civil rights organizations. Further problems associated with the peer review requirement of S. 746 included the diversion of valuable agency time and money from other important priorities. The peer review requirement contained in the OIRA Memorandum is even more problematic than that contained in the proposed Regulatory Improvement Act because it covers more types of agency information. It also does not guarantee quality where there are no conflict-of-interest prohibitions.

In spite of the shortcomings of the peer review recommendations contained in the OIRA Memorandum, they have been extended into at least two new arenas. First, OIRA incorporated them in its final data quality guidelines to agencies. As a result, agencies are “encouraged” to subject scientific, financial and statistical information disseminated to the public to formal, external peer review in order to meet quality standards. OIRA also explained in the Draft Report that the formation and composition of its proposed science advisory panels will “comply with the guidance on competent and credible peer review mechanisms espoused” in OIRA’s Memorandum.<sup>41</sup> OMB-OIRA’s peer review “recommendations” should not be further exported until and unless they are revised to require public disclosure of information relating to peer reviewers and provide better oversight of potential conflicts of interest.

*OIRA’s Data Quality Guidelines Exceed the Authority Provided Under the Data Quality Act*

The Draft Report discusses OMB-OIRA’s information quality guidelines promulgated by OMB-OIRA this winter, pursuant to the Data Quality Act passed by Congress in December 2000.<sup>42</sup> OMB states in the Draft Report that the Act “reflects a concern by Congress that some agencies are distributing information to the public that is of questionable quality, objectivity, usefulness and security.”<sup>43</sup> It is unclear however, how OMB-OIRA arrived at this conclusion since the Act was passed without benefit of a single legislative hearing and without any floor debate.

Indeed, contrary to OMB-OIRA’s assertion, the lack of legislative history suggests that the Act was prompted by interests other than data quality. This perception is underscored by OMB-OIRA’s emphasis in the Draft Report on the corrective mechanisms of the Act, rather than its quality standards. Indeed, the first substantive provision of OMB-OIRA’s quality guidelines mentioned in the Draft Report is the ability of “members of the public to challenge agencies when poor quality information is disseminated.”<sup>44</sup>

Although OMB claims that “independent agencies” are also subject to the data quality guidelines, that is incorrect as a matter of law.<sup>45</sup> The agencies subject to the Section 515 are

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<sup>41</sup> 67 FR 15023.

<sup>42</sup> 67 FR 15021.

<sup>43</sup> *Id.*

<sup>44</sup> 67 FR 15014. *See also*, 67 FR 15021, “The OMB guidelines provide affected parties concerned about poor quality information with the opportunity to seek administrative corrections to agency information, with assurances that their complaints will be addressed in a timely manner.”

<sup>45</sup> *See* 67 FR 15021.

identical to those subject to the Paperwork Reduction Act,<sup>46</sup> a category that does not include the independent regulatory agencies.

OMB-OIRA's data quality guidelines contain numerous extra statutory provisions and other requirements that may allow the Act to be exploited by regulated industry to limit information disseminated to the public by federal agencies and to inhibit agencies' rulemaking activities. First, the administrative review mechanism, which can be used retroactively to challenge information that has been disseminated for years by an agency, dramatically complicates the information review process contemplated by the Data Quality Act and is wholly unsupported by statutory language. With this provision OMB-OIRA has announced open season on information disseminated by agencies regardless of the date on which it was first disseminated, potentially forcing agencies to explain or defend information that is outdated, or more troubling, information for which the supporting materials are lost or otherwise no longer available. This is a serious diversion of limited agency resources away from future and ongoing research, information gathering and rulemaking activities.

OMB-OIRA provides no explanation for the retroactive effect of the review mechanism. Indeed, the issue is not even mentioned in the preamble to OMB-OIRA's final guidelines. Supporters of the provision assert that unless the review mechanism applied retroactively, agencies would rush to disseminate information prior to the October 1, 2002 effective date to avoid complying with the data quality guidelines. Such a scenario seems unlikely and, even assuming it were a legitimate concern, could be addressed in a more limited way.

Second, the Data Quality Act passed by Congress allowed one bite at the apple by requiring agencies to establish an administrative mechanism "allowing affected persons to seek and obtain correction of information maintained and disseminated" by agencies that does not comply with OMB-OIRA or agency data quality standards.<sup>47</sup> However, OMB-OIRA greatly expanded upon this mandate by creating a reconsideration process out of thin air. OMB-OIRA's guidelines state: "If the person who requested the correction does not agree with the agency's decision (including the corrective action, if any) the person may file for reconsideration within the agency. The agency shall establish an administrative appeal process to review the agency's initial decision."<sup>48</sup> Thus, OMB-OIRA enlarges the grounds upon which a party can challenge agency action.

OMB-OIRA provides no explanation for its expansion of the review provision. In the preamble to the final guideline, OMB-OIRA states only that it agreed with several comments suggesting the creation of an administrative appeals process.<sup>49</sup> According to well-published threats, industry hopes to use the reconsideration process to try to open the door to judicial review of agency dissemination of information. During a data quality workshop sponsored by the National Academy of Sciences, several agency representatives expressed grave concern that the guidelines would expose them to increased risk of litigation. Fred Anderson, a partner at the law firm Cadwalader, Wickersham & Taft, validated these concerns during his presentation at the

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<sup>46</sup> See P.L. 106-554.

<sup>47</sup> PL-106-554.

<sup>48</sup> Section III(3)(ii).

<sup>49</sup> See 67 FR 8458.

workshop when he stated “that the courts can and will engage in judicial review of decisions under the statute.”<sup>50</sup> Mr. Anderson’s position was echoed by several industry representatives present at the NAS workshop who made no effort to disguise their eagerness to take advantage of this provision to stall and inhibit agency rulemaking.<sup>51</sup>

Third, as mentioned previously, OMB-OIRA has taken every opportunity to extend the peer review “recommendations” contained in its September 20, 2001 Memorandum, and not surprisingly, they appear in OMB-OIRA’s final data quality guidelines. OMB-OIRA’s guidelines advise agencies that scientific, financial and statistical information subjected to formal, external peer review, are presumed, but not certain, to meet the “objectivity” standard. Pursuant to OMB-OIRA’s guidelines, agency sponsored peer review “shall meet the general criteria for competent and credible peer review recommended by OMB-OIRA to the President’s Management Council (9/20/01).”<sup>52</sup> The substitution of OMB-OIRA’s broad-brush application of peer review for agency discretion in utilizing peer review only when it is likely to improve or enhance information quality, evinces OMB-OIRA’s low regard for agencies’ expertise and autonomy.

Fourth, one of the most troubling aspects of OMB-OIRA’s data quality guidelines is the application of the Safe Drinking Water Act’s (SDWA) quality standards for information disseminated by agencies related to the analysis of risks to human health, safety and the environment.<sup>53</sup> Specifically, the guidelines require agencies to “adopt or adapt” the SDWA quality standards, though the standards may be temporarily waived in “urgent situations.”<sup>54</sup> This is not the first time OMB-OIRA has sought to extend the application of the Safe Drinking Water Act. Just as it did with respect to peer review requirements, the OIRA Memorandum “recommended” that agencies “consider adopting or adapting these basic congressional standards for judging the quality of scientific information about risk it uses and disseminates.”

OMB-OIRA justifies its importation of the SDWA standards by falsely claiming in the preamble to the final guidelines that Congress “adopted a basic standard of quality for the use of science in agency decision making” when it enacted the SDWA standards.<sup>55</sup> Nowhere in the SDWA does Congress state or imply such a thing. In contrast, the SDWA clearly states that the quality standards apply “in carrying out this section,” a portion of the statute OMB-OIRA

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<sup>50</sup> See Transcript of NAS-sponsored Workshop “Ensuring the Quality of Data Disseminated by the Federal Government” March 21, 2002, pp.114-117.

<sup>51</sup> See Transcript of NAS-sponsored Workshop “Ensuring the Quality of Data Disseminated by the Federal Government” March 21, 2002, pp. 91-92, exchange between presenter, Alan Morrison, and a representative of the American Chemical Council regarding the likelihood of judicial review. Also, the Center for Regulatory Effectiveness, founded by Jim Tozzi, triumphantly declares on its web site that “Executive Branch Officials Opine that Agency Denials of Data Quality Act Petitions are Judicially Reviewable.” See <http://www.thecre.com/index.html>. Finally, on the CRE web site is a comment letter to EPA, wherein CRE requests “that the United States Global Change Research Program and the Office of Science and Technology withdraw the First National Assessment on Global Climate Change because it violates the objectivity, utility and reproducibility requirements of the Data Quality Act and OMB’s guidelines implementing the Act.” See [http://www.thecre.com/quality/20020211\\_climate-letter.html#start](http://www.thecre.com/quality/20020211_climate-letter.html#start).

<sup>52</sup> See OMB’s final data quality guidelines Section V(3)(b)(i), available online at <http://www.whitehouse.gov/omb/fedreg/reproducible.html>

<sup>53</sup> See OMB’s final data quality guidelines Section V(3)(b)(ii)(C).

<sup>54</sup> OMB’s final data quality guidelines Section V(3)(b)(ii)(C).

<sup>55</sup> 67 FR 8457.

conveniently chose to ignore.<sup>56</sup>

EPA's recent record for safeguarding our drinking water hardly recommends exporting the SDWA quality standards to other programs or agencies. Since the SDWA scientific data quality standards went into effect in 1996, EPA's drinking water program has been crippled by delays, in part due to the extraordinary new scientific hurdles. EPA has not adopted a single safeguard for a new contaminant from its "contaminant candidate list" in the nearly six years since the 1996 law passed. The agency's only new or revised standards issued during that period were a handful that were issued in response to explicit Congressional deadlines (and even those generally were issued after the statutory deadlines had passed, in one case only after a deadline lawsuit). Maximum contaminant levels mandated by Congress under the SDWA limiting the level of radon and emerging contaminants in drinking water are long overdue. Furthermore, in 2000, the D.C. circuit court struck down EPA's maximum contaminant level goal for chloroform, in large part because it found that the quality standards of the SDWA were not met. While the SDWA quality standards are not solely to blame for this abysmal state of affairs at EPA, it is reason to be concerned that other agencies may be similarly hamstrung by the standards.

OMB-OIRA fails to provide any explanation as to why the SDWA quality standards are appropriate for agency action pursuant to other statutes. In addition, there is a grave danger that the standard's insistence on using only the "best available" data will render any study that is older than a few years irrelevant, yet such studies are often needed to provide the basis for rulemaking on chemicals and other health hazards where information is scarce. As a result, it seems reasonable to assume that agencies will choose to "adapt" the SDWA quality standards so as to tailor them to the extent possible to the types of information disseminated.

### *OIRA's Intrusion into the Realm of Science*

In the Draft Report, OIRA announces that it intends to expand and diversify its professional staff by bringing in four new staff members with expertise in science and engineering.<sup>57</sup> OIRA asserts that these new staff members will enable it to "ask penetrating technical questions about agency proposals" and will "complement OIRA's historical staffing strengths in economics, policy analysis, statistics and law."<sup>58</sup> Additionally, in the Draft Report, OIRA indicates that it is in the process of forming a scientific advisory panel that "will suggest initiatives to OIRA, evaluate OIRA's ongoing activities, comment on national and international policy developments of interest to OIRA, and act as a resource and recruitment mechanism for OIRA staff."<sup>59</sup>

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<sup>56</sup> OMB cites the Safe Drinking Water Act at 42 U.S.C. 300g-1(b)(3)(A) & (B) to support its contention that Congress "adopted" government wide quality standards for the use of science in agency decision making. A plain reading of the text of the statute clearly shows OMB's mistaken understanding of Congress' intent. Section 300g-1(b)(3)(A) states in relevant part, "Use of science in decision making. *In carrying out this section*, and, to the degree that an Agency action is based on science, the [EPA] Administrator shall use. . . ." Similarly, Section 300g-1(b)(3)(B) states in relevant part, "Public information. *In carrying out this section*, the [EPA] Administrator shall ensure that the presentation of information on public health effects is comprehensive, informative, and understandable."

<sup>57</sup> 67 FR 15022.

<sup>58</sup> *Id.*

<sup>59</sup> *Id.*

Public Citizen strongly objects to OIRA's expansion into science with the hiring of scientists and engineers and the formation of a science advisory panel. Such initiatives go far beyond the scope of OIRA's intended purpose. Federal agencies are the home of government's scientific expertise, not OIRA.

Furthermore, with respect to OIRA's proposed science advisory panels, OIRA left much unsaid about the composition of the panel, the scope of the panel's mission and the autonomy with which the panel will operate. Nor has OIRA sufficiently addressed concerns stemming from panel members' potential conflicts of interest or described adequate peer review standards. As discussed previously, OMB-OIRA imported the peer review "recommendations" contained in the OIRA Memorandum. These peer review "recommendations" are seriously deficient in that they do not allow for public accountability, since information about panel members is disclosed only to agencies. Moreover, because they are only "recommendations," there is no assurance that even these minimal standards will be adequately enforced. Additional problems with OIRA's proposed science advisory panel are set forth in comments submitted separately by the Center for Science in the Public Interest, Integrity in Science, and Public Citizen.

#### *Promoting Pro-Market International Regulatory Principles*

Public Citizen notes Chapter III of the Draft Report with curiosity, wherein OIRA included information on regulatory developments in other parts of the world.<sup>60</sup> The Draft Report states that the information was "drawn from reports from the Organisation for Economic Co-operation (OECD), Asian Pacific Economic Cooperation (APEC) and the European Commission (EC) and supplemented by insights drawn from OIRA discussions with OECD, APEC, and EC officials."<sup>61</sup> As OIRA does not indicate what it intended to do with the information presented, we hope that it was included simply to provide an overview of regulatory developments outside of the United States.

Regulatory cooperation between nations is best left to the agencies with expertise in specific regulatory issues. OIRA should not have any role in these discussions. However, if OIRA does plan to become involved in the development of regulations or regulatory procedures overseas, OIRA should clearly and publicly describe the extent and purpose of its involvement. Furthermore, OIRA must allow for public notice and comment on any recommendations OIRA might make to international organizations regarding regulatory management, quality or policy.

We are also cognizant that the OIRA Administrator has, at least once before in his September memorandum to agencies regarding Executive Order 12866, undertaken a significant new regulatory initiative by initially making statements that appear hortatory. For example, the observations in that memo regarding the expansion of the Safe Drinking Water Act and peer review standards have now re-appeared as a part of the "Data Quality" Guidelines. We caution OMB-OIRA against once again becoming involved in policy making regarding issues more appropriately left to Congress or other federal agencies.

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<sup>60</sup> See 67 FR 15029.

<sup>61</sup> *Id.* at 15029-30.

## II. Serious and Unresolved Problems Plague OMB-OIRA's Attempts At Regulatory Accounting

Regulatory accounting – the exercise of aggregating and monetizing the total costs and benefits of disparate public protections and then subtracting one from the other in an attempt to calculate the net benefits of all federal health, environmental and safety protections suffers from many fatal flaws. In fact, in the Draft Report, OMB admits as much because it is beset with "bureaucratic disincentives, resource constraints" and befuddling complexity.<sup>62</sup> It would be fair to say that OMB-OIRA's past and present attempts at this over-ambitious exercise have been a significant waste of time and resources and should be abandoned.

Of what possible use is it to the public or policy makers to know, for example, that OMB-OIRA estimates the total annual net benefits of environmental regulation as anywhere between negative \$83 billion and \$1.663 trillion dollars.<sup>63</sup> Any economist or financial analyst who attempted to use such an indeterminate figure as the basis for decision making would surely be laughed out of the corporate boardroom. OMB-OIRA's range of estimates is so large, and, due to persistent uncertainties and inadequate and often biased data, must remain so large, as to render it ludicrous as a priority-setting mechanism.

The fundamental problem with regulatory accounting stems from OMB-OIRA's inability to obtain reliable information. Agencies lack the resources to calculate costs and industry estimates are grossly over inflated. At the same time, benefits are undervalued due to a lack of information and the inadequacy of available information. In addition, agency cost estimates have, for the most part, only been updated to account for inflation; however, in many cases, it is likely that "costs" of complying with a regulation have been partially or wholly absorbed by the regulated industry and are therefore now small or even non-existent. Without accurate information, the methodologies underlying OMB-OIRA's regulatory accounting process are meaningless.

For example, OMB-OIRA's estimates of net benefits are likely significantly understated due to limited agency reporting. Of the 34 regulations listed in Table 7 of the draft report, the regulating agency did not estimate benefits in 13 cases. Agencies also failed to estimate costs, though they did this in only 7 cases, and in 3 of these they failed to estimate benefits as well. The net benefits figure is therefore somewhat incomplete. A complete accounting of regulatory benefits would likely substantially increase this figure. Despite undercounting, estimated net benefits are consistently very positive.

The lack of information in OMB-OIRA's report shields its overall cost and benefit estimates from full criticism. For example, Table 11, in Appendix C, calculates "net benefits" from four categories of regulation. OMB-OIRA cites Table 6 in Chapter II and Table 4 from the 2000 Report as sources for this table, yet these tables do not provide a complete explanation of OMB-OIRA's process in quantifying costs and benefits, particularly when the issuing agency has not done so itself. Both source tables are summaries of work that OMB-OIRA did prior to issuing the Report, and citing them as the sources for OMB-OIRA's ultimate estimates of costs

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<sup>62</sup> 67 FR 15033.

<sup>63</sup> See 67 FR 15037.

and benefits obscures the process OMB-OIRA uses in converting non-monetized or non-annualized estimates into annual present dollar figures. OMB-OIRA should show how it arrived at each of the monetized figures in the report so the process of conversion and summation is more transparent to the reader.

Moreover, OMB-OIRA gets the math wrong. OMB-OIRA's overall benefits estimate from major rules from April 1, 1995 to September 30, 2001<sup>64</sup> is incorrect based on the information provided in the table. Total benefits, as presented, actually range from \$48,652 million (in 2001 dollars) to \$94,195 million, not \$67,602 million, as stated.

In general, OMB-OIRA provides little-or-no analytical explanation for its particular choices in monetizing numbers or applying a single agency's approach (i.e., the Department of Transportation's approach to valuing injuries)<sup>65</sup> to other agency programs. OMB-OIRA's summary accounting format is not accompanied by any truly meaningful explanation that would enable a reader to check its accuracy or to draw different conclusions. Surely this kind of approach could not be characterized as "sound science," despite OMB-OIRA's claimed commitment to the concept.

Regulatory accounting is clearly a waste of time and resources. But the more pernicious agenda of proponents of regulatory accounting is to use it as a basis for making decisions about federal health, safety and environmental protections. Ultimately, its use could choke the public's investment in these priorities and be used to overturn Congressional mandates based upon a false "scarcity." Aggregating costs and benefits is the first step towards a "regulatory budget," in which federal agencies would have to compete with each other in order to impose a tightly-controlled amount of costs upon the private sector. If costs to the private sector exceeded the cap established in the budget, some agency rules may be brought up for elimination and no new rules could be issued, no matter how pressing the need. Furthermore, a "budgetary" year would establish opportunities for arbitrary game playing regarding the issue date of regulations, given their cost consequences.

In the typical discussions of these so-called "off-budget costs" for regulated interests, the issue of countervailing benefits regularly fails to enter the discussion. It does not appear to matter, for example, that in every year that OMB-OIRA has attempted the hocus-pocus of regulatory accounting, the benefits of health, safety and environmental regulation have vastly outweighed the costs by billions of dollars. Rarely do we hear from anyone in Congress that regulation, overall, in fact is a bargain. And it is very likely to be far more of a bargain than even these estimates allow. Because of the default assumptions used in cost-benefit analysis as it is currently practiced, the process systematically overstates the costs of regulation and understates its benefits in myriad ways, which are discussed below in some detail.

In sum, the use of regulatory accounting is deeply suspect for the following reasons:

- It implies that the overall numbers are reliable, which they are not.

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<sup>64</sup> See 67 FR 15024.

<sup>65</sup> See 67 FR 15041

- It is biased toward cutting regulations opposed by industry because government agencies do not have the funds to fully evaluate claimed industry costs or to gather information on the full range of benefits.
- The conclusions are highly manipulable because they are based on a raft of assumptions, a change in any one of which could affect the outcome.
- By relying on discounting of benefits, it subverts the importance of longer-term goals and protections.
- It ignores tangential but critical benefits of regulation that help industry by limiting the risk of developing new products (for example, in environmental and product standards), forces industries to update and upgrade manufacturing processes (in the area of textiles) and making them more competitive with imports, or to improve products to help ride out market disruptions (*i.e.*, fuel economy in cars).
- It fails to document the public value attached both here and abroad by businesses as well as the public to advances in the quality of life and standard of living that are fostered by regulation.
- It is impossible to present meaningful conclusions in an accounting format because of the many values that are not quantifiable.
- The underlying purpose — to set a regulatory budget — would impose false limits on safeguards across the entire federal regulatory system, undermining public health and safety. This purpose makes little sense given the excess of benefits over costs documented today and the lack of evidence that protective regulation has inflicted irreparable harm on any industry or sector of society.
- It is a significant waste of public resources, particularly for those agencies charged with protecting the public health, which are already starving for funds.
- As a practice, it is profoundly out-of-step the necessary protective role of government as a check upon market excesses.

Finally, in the Draft Report OIRA indicates that it plans a review of differences in methods among the agencies for calculating costs and benefits. However, such differences are often the result of widely varying levels of data, certainty about outcomes and important distinctions in the wording and intent of statutory mandates. OIRA should allow agencies to produce their own estimates, as they do now, and act as a repository for these estimates. Given the immense gaps in the available data and the persistent and glaring uncertainties, this limited role for OIRA may help to minimize the potential for damage to regulatory programs from misleading and inaccurate conclusions.

This approach would also far more consistent with the legislative history of this provision. Floor statements in the Senate regarding this statute, and identical language in the previous year's appropriations bill, demonstrate that the legislators who backed these measures did not intend for OIRA to spend tax dollars generating new data. During the debate on the initial measure, Section 628 of the Treasury and General Government Appropriations Act for 2000 (P.L. 196-58), a colloquy between Sen. Ted Stevens (R-AK) and Sen. Carl Levin (D-MI) focused on this topic. Sen. Levin stated that:

The amendment does not, and this is why I am able to support it, does not require OMB to conduct new studies or analyses or develop new data or information. That would be a time-consuming and expensive use of taxpayer money. Better that the OMB staff use its time and money to help make sure new regulations follow the dictates of common sense and be cost-effective regulations. No, this amendment simply directs OMB to put together the already available information that it has on existing Federal regulatory programs and use that to estimate the total annual costs and benefits of each.

When the current statute creating an ongoing annual reporting requirement, Section 624 of the Treasury and General Government Appropriations Act for 2001 (P.L. 106-554), was passed, Sen. Fred Thompson (R-TN) sounded a similar note, saying that "OMB is not mandated to devote vast resources to create such models. Instead, OMB may use available reports, studies, and other relevant information to assess the direct and indirect impacts of Federal rules."

### **III. OMB-OIRA Should Either Fix or Abandon Cost-Benefit Analysis As a Tool Due to Its Many Uncertainties and Ethical Flaws**

In the 2002 Draft Report, OMB-OIRA requests that commenters "nominate . . . analytic issues for consideration" in the regulatory accounting process.<sup>66</sup> A major analytical issue that is badly in need of refinement or delimitation is OMB-OIRA's over reliance on cost-benefit analysis.

As explored below, cost-benefit analysis is in fact rife with numerous flaws that seriously undermine its value as a tool for evaluating regulatory efficiency. It systematically short-changes public health and environmental goals and can easily be manipulated on behalf of industries opposed to regulation. Overall, as in regulatory accounting at the more general level, analyzing an entire federal regulatory program along cost-benefit lines requires so many assumptions and extrapolations that the report's conclusions are most appropriately characterized as myth. At the level of abstraction required to include all health, safety and environmental government programs in the analysis, the exercise is literally meaningless.

The Administration's myopic reliance on cost-benefit analysis, as expressed in current OIRA practices and guidelines to the agencies,<sup>67</sup> does not reflect the high level of controversy surrounding its use. As two academics have noted:

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<sup>66</sup> See 67 FR 15021.

<sup>67</sup> OMB's Guidelines to Standardize Measures of Costs and Benefits and the Format of Accounting

The reputation of cost-benefit analysis (CBA) among American academics has never been as poor as it is today, while its popularity among agencies in the United States government has never been greater. Many law professors, economists, and philosophers believe that CBA does not produce morally relevant information and should not be used in project evaluation. A few commentators argue that the information produced by CBA has some, but limited, relevance. Defenders of CBA form an increasingly beleaguered minority, consisting mostly of applied economists who feel compelled to respond to attacks on the methodological underpinnings of their work. Modern textbooks on CBA are plentiful, and some of them are optimistic about the usefulness of their procedure, but most of them frankly acknowledge its serious flaws and the inadequacy of the standard methods for correcting these flaws.<sup>68</sup>

OMB-OIRA virtually admits as much in its de-emphasis of the regulatory accounting exercise that is the original purpose of the Draft Report. OIRA must look beyond this “beleaguered minority” of cost-benefit analysis adherents and corporate supporters, and make a real effort to address the legitimate and persistent concerns of those who doubt the value of cost-benefit for regulatory decisions.

In considering its analytical shortcomings, OMB-OIRA should use this Report to address and subject to peer review several crucial methodological assumptions in its cost-benefit calculations that regularly result in the significant underestimation of the public benefits of federal health, safety and environmental regulation. As components of OMB’s Guidelines to Standardize Measures of Costs and Benefits and the Format of Accounting Statements to the agencies,<sup>69</sup> the factors discussed below result in a significant bias against protective regulations.

#### *Cost Estimates Are Badly Inflated*

The value of any cost-benefit analysis is limited by the available scientific or other factual data. This has euphemistically been called “garbage in, garbage out.” OMB-OIRA needs to acknowledge that there are serious factual deficiencies that plague and confuse such analysis. For example, cost calculations are often based upon numbers submitted by industry, yet studies have repeatedly shown that industries’ numbers are badly inflated, because companies often find highly cost-effective means of complying with regulations once implemented. Some regulations may even stimulate productivity through the development of more sustainable technologies and the net social benefits of a regulation may also allow the creation of more jobs within the overall economy.

According to a pre-publication draft of an exhaustive study prepared by Ruth Ruttenberg and Associates, Inc., and submitted separately to this docket, entitled *Why Do Regulatory Agencies Overestimate the Compliance Costs of Their Regulations*, agencies regularly, and

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Statements, March 22, 2000.

<sup>68</sup> Matthew D. Adler & Erica A. Posner, “Rethinking Cost-Benefit Analysis,” *Yale Law Journal*, November 1999.

<sup>69</sup> OMB’s Guidelines to Standardize Measures of Costs and Benefits and the Format of Accounting Statements, March 22, 2000.

admittedly, overestimate regulatory costs, thus weighting the scales of cost-benefit analysis against regulation.<sup>70</sup> The following examples are excerpted from the study:

- An industry-financed economic impact study estimated that the cost of compliance with the OSHA Vinyl Chloride Standard would be \$65 billion to \$90 billion. The Congressional Research Service found the cost to users was \$300 million and the cost to producers only \$25 million to \$35 million.
- A utility industry study predicted that the cost of implementing an acid rain SO<sub>2</sub> program would be \$4.1 billion to \$7.4 billion per year. Recent estimates by EPA and the General Accounting Office (GAO) put the cost at approximately \$2 billion, and estimates from independent economists and researchers range as low as \$1 billion.
- A pre-regulatory estimate by an OSHA consultant found the cost of asbestos abatement in workplaces would be \$150 million. The actual cost of compliance was later estimated at \$75 million by a leading OSHA consultant, John Mendeloff.
- OSHA estimated that industry's workplace compliance costs for limiting exposure to formaldehyde would be \$11.4 million per year. Actual costs were \$6.0 million per year, according to the Congressional Office of Technology Assessment (OTA).

The Ruttenberg study notes that agencies generally acknowledge that there is this tendency to overestimate costs, attributing the problem, in part, to the desire to avoid potential legal challenges by industry and to a political reticence to incur costs at the present time that yield benefits in the future. In evaluating numerous examples of agency cost estimates, Ruttenberg finds that cost exaggerations are the result of three inherent flaws in agency practice: (1) the use of poor and inaccurate information; (2) the use of conservative assumptions throughout the information gathering process; and (3) employment of static, rather than dynamic, market analysis.

First, cost information is normally provided to agencies by regulated industry, which has financial incentives to skew the cost-benefit analysis against the proposed regulation. Additionally, informational surveys on cost are often limited to a small number of companies, meaning that the results may not be representative of industry as a whole. This problem is compounded by the fact that industry data sources are often confidential, making it difficult or impossible to verify their factual validity. Moreover, there are very limited sources, other than regulated industries, from which agencies can obtain cost information.

The second major flaw is the agencies' tendency to base estimates on conservative and/or inappropriate assumptions. Numerous problems present themselves in attempting to determine cost, the resolution of which invariably reflects the decision-maker's bias. For example, it may be difficult to distinguish regulatory compliance costs from other capital expenditures by the

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<sup>70</sup> Ruth Ruttenberg, Ph.D, is an economist with 28 years of experience on the economics of regulation. She has been a senior economist at OSHA, a consultant to OSHA, EPA and the Congressional Office of Technology Assessment, and regularly testifies before the U.S. Congress and federal regulatory agencies and advisory bodies.

company, or to avoid double counting regulatory costs when more than one regulation is involved. Problems also arise in measuring incremental cost differences between what would have been spent prior to regulation and what must be spent after regulation.

Finally, agencies apply only static market analysis, failing to consider new and innovative ways that industry can, and often does, comply with new regulations. Yet there is substantial evidence that new processes and improved products are the result of new regulation and subsequent new profits to the company. Also, costs often fail to consider the offsetting economic gains caused, for example, by the license and sale of pollution abatement equipment or the avoidance of problems arising later in the marketplace. Similarly, cost savings resulting from safer substitutes and the elimination of hazards are often omitted from regulatory cost estimates.

All of these omissions and distortions impoverish the usefulness of cost-benefit analysis and result in cost figures that are significantly inflated.

#### *Benefits Are Devalued Because Information Is Inadequate, Unavailable or Incalculable*

Government agencies rarely have the funding to accomplish their mandates *and* to follow up by gathering and refining benefit data for regulatory programs. A full appreciation of regulatory benefits is made more difficult by the lack of funding for other research that would be necessary to study the effects of regulation, or even to understand the health and environmental effects of activities. As just one example, because there are not accurate epidemiological exposure data for diseases other than cancer, benefits such as a reduction in gastrointestinal or reproductive ailments are usually left out of the calculation altogether.

Benefits may also be understated, because, whether in terms of lives saved, injuries and diseases avoided, property damage avoided, or more subtle quality of life issues, they can possess a self-effacing quality. As societal expectations are upgraded, it may become more difficult to notice the considerable success of these society-altering improvements. Over time, for example, we learn to take clean air and water for granted; or we assume that government programs will protect us from workplace hazards and will help us to survive automobile crashes that would have killed us twenty years ago.

In addition, due to a near-exclusive focus on the number of human lives that are saved by a regulation, and the difficulty of deriving a definitive value for so-called *non-tangible* benefits, such as a clear and unpolluted view of the Grand Canyon, the practice of cost-benefit analysis also often fails to take these factors into account. Yet the focus of much protective environmental legislation is precisely to protect and preserve the value of a healthy ecosystem, or to minimize the effect of human activities upon animal life and habitat. To the extent that OIRA demands quantification of a benefit before it can be included in the analysis,<sup>71</sup> the real benefits of much regulation are greatly understated.

In addition, translating the value of life into dollar amounts, as a basis for societal decision-making, is morally reprehensible and represents an unwarranted incursion by economists into profound questions of social, cultural and ethical value. Calculating the impacts

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<sup>71</sup> See 67 FR 15041-42.

of a rule in preventing human suffering and death in monetary terms is a practice that is utterly out of touch with public notions of the value of life, and this deep discontinuity that divides cost-benefit practice from the way most people conceive of the value of life should matter to democratic decision-makers. Thus, OMB-OIRA puts the cart before the horse: Regulatory decisions must be a matter of human judgment, relying on shared notions of moral values, to be supplemented where appropriate data and other quantitative calculations.

### *Discounting Undervalues Future Benefits*

OMB-OIRA indicates in the Draft Report that it intends to apply a seven-percent discount rate to future costs and benefits in its guidelines for agency regulatory impact analyses, and that it intends to work with the agencies to impose a uniform system for calculating benefits and costs, which will doubtless include the recommendation of a standardized discount rate.<sup>72</sup> Public Citizen flatly objects to these proposals.

This practice devalues future generations and the environment by inappropriately discounting the value of the future benefits of regulation. This occurs when the value of goods received in the future are reduced to an estimate of their present value. OIRA's use of a seven-percent discount rate significantly undervalues all benefits expected to accrue in the future, and thus seriously distorts its evaluation of the benefits of public protection.

The practice of discounting is perhaps most easily explained by reference to the present and future value of money. In financial terms, it is correct that receiving \$1,000 today is worth more than receiving \$1,000 in ten years because the \$1,000 received today can be invested, and thus would be expected to be worth more ten years from now. This fact requires an adjustment in the estimate of that sum's value in the present, which is why discounting is appropriate for financial transactions.

However, it is not true that *non-monetary* benefits, such as health, safety, and environmental benefits, are worth less tomorrow than if they were immediate. Discounting the value of future health, safety and environmental benefits, which cannot be invested, at the same rate used to discount money is illogical because such benefits do not become less valuable over time, the way that money does.

In some cases, particularly with respect to environmental regulations, benefits actually become more valuable. For instance, it would certainly be less costly to implement programs to reduce global warming in the present than to pay for its very costly consequences decades from now.

Discounting also means that saving a single life this year will be considered more valuable to society than saving ten lives thirty-five years from now. This simply does not reflect our actual preferences as a nation that cares about future generations. The practice also makes regulations with long-range benefits appear to be far less beneficial than they actually are. By

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<sup>72</sup> 67 FR 15021; [67 FR 15042](#).

discounting health, safety and environmental benefits received in the future, we underestimate their true value to society. Such a system will therefore produce policy decisions that are fundamentally out of step with environmentally sound regulation and with Congress= expressed desire, in legislative mandates to the federal regulatory agencies, to preserve the earth for our children and future generations.

Discounting can have an enormous effect upon whether a rule appears sensible or ridiculous. For example, because there is typically a 30- to 40-year lag time between exposure to a harmful substance such as asbestos and a persons resulting death from cancer, Adiscounting@a life saved 40 years from now is calculated to a mere fraction of that persons present value. Moreover, the higher the discount rate that is used, the greater the bias against protecting future generations and the environment.

Although experts disagree over whether health, safety, and environmental outcomes may properly be discounted, among academic economists who do support discounting such benefits, the consensus is to use the so-called Asocial rate of time preference,@estimated to be a real rate of approximately three percent.<sup>73</sup> However, the agencies are currently urged by an OMB-OIRA circular to discount all goods at a rate of seven percent, which represents the Aopportunity cost of capital,@or the rate that money could likely earn if invested. That means that each dollar of benefits that become evident in thirty years B including lives saved by regulations B are considered to be worth 87 percent less than they would be worth today.

An example of how the choice of discount rate can affect cost-benefit results is a 1996 Housing and Urban Development (HUD) regulation of lead-based paint.<sup>74</sup> This regulation was estimated by the agency to have net benefits of \$1,080 million when a three- percent discount rate was used, even though it showed net benefits of only \$39 million at a seven- percent rate. As agencies are pressured by OIRA to identify the most Acost-effective@regulatory option, or the option with greatest Anet benefits,@the discount rate that is used could determine which regulatory option survives – hardly a “sound science” methodology.

In responding to comments on the 1998 Draft Report to Congress on the Costs and Benefits of Federal Regulation that the practice of discounting averted deaths and other health, safety, and environmental benefits had resulted in an erroneously low valuation of these benefits, the 1998 Final Report offered only the following conclusory response: “Discounting is a generally agreed practice in the economics profession and required by the Best Practices document and an OMB circular.”<sup>75</sup> In 2000, OMB-OIRA responded to complaints regarding its discount rate similarly:

The report reflects the fact that the economics profession has reached a general consensus that discounting procedures are necessary to make meaningful comparisons of benefits and costs that occur in different time periods. *The Guideline to Standardize Measures of Costs and Benefits and the Format of Accounting Statements* (reproduced in the

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<sup>73</sup> Richard O. Zerbe, *Benefit-Cost Analysis in Theory and Practice* 281, 287 (1994).

<sup>74</sup> Comment: *Judicial Review of Discount Rates Used in Regulatory Cost Benefit Analysis*, 65 U. Chi L. Rev. 1333, 1337 (1998) (citing 61 FR 29170 (1996)).

<sup>75</sup> OMB Report to Congress on the Costs and Benefits of Federal Regulations, 1998, at 96.

Appendix) reflect this fact. The discount rate of 7 percent is specified in *The Guideline to Standardize Measures of Costs and Benefits and the Format of Accounting Statements*, the “Best Practices” document, and the OMB Circular A-94 as the appropriate discount rate to approximate the opportunity cost of capital for incremental private investment.<sup>76</sup>

This argument is unconvincing, since OMB-OIRA is free to change the discount rate specified in its own circular. Moreover, discounting is *not* a “generally agreed practice” among economists, and, to the extent that there is a consensus among those who do practice it, it does not support the seven-percent rate.

Many economists have persuasively argued that human lives and other intangible goods should not be discounted at all.<sup>77</sup> After all, “harms to future generations deserve no less protection than harms to the current generation.”<sup>78</sup> The 2000 Final Report assumes that benefits only accrue at the time the injury would have occurred, not at the time the harm is avoided. These assumptions also appear to have been embraced by the current Draft Report, although any amount of methodological discussion is not included in the document. But, as Lisa Heinzerling points out, that is not at all obvious. She noted that discounting these benefits embraces “a bizarre metaphysics which holds that an illness is not prevented, nor a death averted, at the moment when it is avoided, but at the moment when the physical hardships otherwise would have become patent.”<sup>79</sup> For these reasons, the dubious practice of discounting human lives and other goods, such as health and environmental goods, that have intangible components should be abandoned.

Other analytical issues, such as the OMB-OIRA’s use of willingness-to-pay as the valuation basis, are also in need of reconsideration by OIRA and are addressed in Appendix D.

## Conclusion

As we have emphasized, Public Citizen does not believe that this statutorily mandated regulatory accounting exercise provides useful information to the public or policy makers. Reliance on the methodological assumptions discussed in these comments systematically and significantly undervalues the benefits of public health, safety and environmental regulation. At the same time, costs are inflated, making such efforts misleading and undercutting the public purpose of health, safety and environmental protection standards.

In addition, Public Citizen objects to OIRA’s overreaching. Recently inaugurated initiatives and practices, such as the return letter, the prompt letter, emphasis on peer review, the formation of a science advisory panel, and the creation of a regulatory “hit list,” not only infringe on agencies’ statutory mandates, they inhibit agencies from developing and pursuing their own

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<sup>76</sup> 2000 Final Report at 11.

<sup>77</sup> Lisa Heinzerling, *Environmental Law and the Present Future*, 87 GEORGETOWN L. J. 2025 (1999); Thomas McGarity, *A Cost Benefit State*, 50 ADMIN. LAW REV. 7, 71-72 (1998) (citing Douglas E. Maclean, *Comparing Values in Environmental Policies: Moral Issues and Moral Arguments*, VALUING HEALTH RISKS, COSTS, AND BENEFITS FOR ENVIRONMENTAL DECISION MAKING 83,95 (P. Hammond & R. Coppock eds., 1990)).

<sup>78</sup> Edward R. Morrison, *Comment: Judicial Review of Discount Rates*, 65 U. CHI. L. REV. 1333, 1339. For an excellent discussion of this topic see Heinzerling, *supra* note 58.

<sup>79</sup> Heinzerling, *supra* note 58, at 2028.

agendas. OIRA's proper role is one of oversight, not one of usurping agency expertise or setting regulatory agendas.

We appreciate this opportunity to comment on OMB-OIRA's Draft Report and hope our comments will be carefully considered as OMB-OIRA prepares the Final Report.

Sincerely,

Joan Claybrook  
President, Public Citizen

Frank Clemente  
Director, Public Citizen's Congress Watch

Wendy Keegan  
Regulatory Affairs Fellow

Laura MacCleery  
Counsel for Auto Safety and Regulatory Affairs

## Appendix A

### Letter from Public Citizen to OIRA Administrator John Graham Challenging OIRA's Rejection of NHTSA's Proposal for a Tire Pressure Monitoring System

March 11, 2002

Dear Dr. Graham,

There are so many serious flaws in your recent review and rejection of the National Highway Traffic Safety Administration's (NHTSA's) proposal for a tire pressure monitoring system required by the Transportation, Recall Enhancement, Accountability and Documentation (TREAD) Act, it is hard to know where to begin. I find it difficult to believe, with all your emphasis on "sound science," that your office has returned a rule based on the pure speculation and infirm logic contained in your "return letter"<sup>80</sup> of February 13, 2002.

Let me get this straight. In your capacity as Administrator of the Office of Information and Regulatory Affairs (OIRA) within the Office of Management and Budget (OMB), you have blocked an overdue, lifesaving rule required by Congress in the wake of the nation's most publicized tire safety disaster because, in your view, NHTSA must permit industry to install a marginally cheaper, but far less accurate and beneficial, type of tire pressure monitoring system. Your return letter ignores the record that NHTSA has assembled in the course of the rulemaking and disregards the 191 comments filed in the agency's docket, including two of my own, during the agency's public notice and comment period. The docket includes notice of at least 20 meetings between the agency and industry and other technical experts about the feasibility and cost of various systems. Your return letter also fails to take note of several recent, carefully designed studies conducted by NHTSA which have revealed the sorry state of the typical tire on the highway and the widespread hazards of tire underinflation,<sup>81</sup> including the agency's recent public awareness campaign, entitled *Tire Safety: Everything Rides On It*.<sup>82</sup>

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<sup>80</sup> A "return letter" is a rejection of an agency's rulemaking proposal, which can occur, as here, at the final stages of the rulemaking following a full notice and comment process. According to your testimony Feb. 28<sup>th</sup> before the House Subcommittee on Consumer Affairs, you have signed 20 return letters since taking office. Under the Clinton Administration, no return letters were issued in the last three years and just 25 were issued over Clinton's entire eight-year term. Even outside of the context of your other moves to consolidate power within OMB, such as the list of rules for rescission contained in the final Year 2001 Report to Congress on the Costs and Benefits of Regulations and Unfunded Mandates on State, Local and Tribal Entities, your activism in returning rules constitutes a major increase in the role of OMB and its interference in agency rulemaking. Of the 20 return letters discussed in your testimony, only 5 of the rules have since been passed by your office, meaning that OMB action has delayed issuance of the remaining 15 rules. Of course, as you told *Congressional Quarterly*, the threat of a return letter may be most critical in assuring that you are able to exert power at the early stages of every rulemaking, with leverage over formative decisions that are largely out of sight to the public or to Congress. See Rebecca Adams, "Regulating the Rule-Makers: John Graham at OIRA," *Congressional Quarterly*, Feb. 23, 2002, at 521.

<sup>81</sup> See National Center for Statistics and Analysis, Tire Pressure Special Study, August 2001, DOT HS 809 315 (Methodology); DOT HS 316 (Interview Data); DOT HS 317 (Vehicle Observation Data). As part of this four-part study, NHTSA also conducted extensive surveys at 336 gasoline stations throughout the U.S., see Kristin Thiriez (NHTSA Engineer) and Rakesh Subramanian (NHTSA Mathematical Analyst), Tire Pressure Special

The agency's Notice of Proposed Rulemaking (NPRM) clearly laid open for public comment the question whether the agency should require a direct or indirect system for monitoring tire pressure.<sup>83</sup> Like many others in the record, we urged the agency to require a direct system, given that direct systems are capable of measuring all four tires, and provide consistent and accurate results to the driver. We argued that the great inaccuracy and partial coverage (only three tires at most) of the indirect system would make that system a nuisance which many consumers would learn to disregard, and would be a source of disdain and irritation with inept government rules.

### *There Are Many Serious Deficiencies in Indirect Systems*

As Representative Markey (D-Mass.) forcefully pointed out in the hearing before the House of Representatives Subcommittee on Commerce, Trade, and Consumer Protection on February 28<sup>th</sup>, 2002, the indirect system barely works. Here are some of its many shortcomings:

- C Indirect systems are only available on vehicles with antilock brakes, which are the more expensive vehicles on the highway.
- C Because it measures differences in rotational speed of tires rather than directly measuring inflation levels, it works only if one tire is more than 25 percent less inflated than the others; the direct system, by contrast, provides continuous readouts on the dashboard *in addition to warnings at underinflation levels of 20 percent*, so that conscientious consumers can adjust tire inflation levels to keep them right at the recommended level, thereby preventing the repeated, cumulative damage to tires.
- C Indirect systems do not work if all four tires are equally under inflated, a likely scenario if they are checked or purchased at the same time.
- C It also does not work if two tires on the same axle *or* the same side of vehicle are equally under inflated, but does work if diagonal tires are equally under inflated, a shell game that is certain to confuse and frustrate consumers. By comparison, the direct system monitors inflation changes in all four tires and any tire combination.
- C The vehicle must be moving for the system to work, so it cannot be used to check proper inflation at a gasoline station while consumers are inflating the tire and will only alert consumers once they are already on the road.
- C The indirect system did not work well on the smooth surface of the test track, or on long, straight roads without curves. Enormous areas of the Midwest and West may not be well served by these limitations.

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Study, October 2001, DOT HS 809 359 (Using sample of 10,900 observations of tire pressure of all four tires on vehicle); *see also* Frank Swoboda, "Inaccurate Tire Gauges Can Be a Matter of Safety," *The Washington Post*, Dec. 4, 2001.

<sup>82</sup> *See* <http://www.nhtsa.dot.gov/cars/rules/TireSafety/ridesonit/brochure.html>; NHTSA Press Release, "Many U.S. Passenger Cars Are Driven on "Bald" Tires, NHTSA Research Shows: U.S. Transportation Secretary Mineta Announces Launch of Major Nationwide Campaign to Promote Tire Safety," Nov. 30, 2001.

<sup>83</sup> *See* Tire Pressure Monitoring Systems: Controls and Displays, Notice of Proposed Rulemaking, 66 FR 38982, July 26, 2001, at 38987-96 (discussing differences in direct and indirect systems). In the NPRM, NHTSA stated that its experts doubted whether indirect systems were even capable of complying with the minimum performance requirements of the second the regulatory alternatives the agency proposed. *Id.* at 38996.

C The indirect systems were, overall, less reliable in notifying consumers of serious underinflation levels.

*OIRA Is Obstructing Congressional Intent and Relying on Flawed Analysis*

Indeed, at the same hearing on February 28, 2002, you agreed that the indirect system is inferior, stating that a direct system<sup>84</sup> will provide better safety, and that the quality of indirect systems is still under development. Nonetheless, according to your testimony, OIRA has won this round, and will be announcing that the requirement for a direct system, instead of being phased-in, as the agency proposed, has been put on hold for two additional years until model year 2007, in order to enable NHTSA to further “study” the problem and to consider a standard for anti-lock brake systems (ABS).<sup>85</sup>

This outrageous result, you were informed by Representative Markey, who authored this tire pressure amendment, means that “this amendment, the Markey amendment, is not being implemented.” As Representative Markey observed, the delay could be disastrous for the future of the rule, because industry will “use any scientific or technological hedge that they can” to resist additional safety requirements. Of course, as you are well aware, studying the issue until 2007 means in practical terms that a phase-in of new requirements would not occur until, at the earliest, model year 2011 or 2012. And folding in consideration of the ABS issue, which has long been a complicated data tangle, will doubtless provide ample opportunity for even more delay, obfuscation, and frustration of Congressional purpose.

The statute authored by Representative Markey under the Transportation, Recall Enhancement, Accountability and Documentation (TREAD) Act, specifically delegated authority to issue the rule to the Secretary of Transportation and provided an extremely short (one-year) statutory deadline for “a warning system in new motor vehicles to indicate to the operator when a tire is significantly under inflated.”<sup>86</sup> The statute makes no mention of ABS.

Your 2001 Report to Congress states that one of the external peer reviewers of that report questioned OMB’s legal authority to issue return letters, arguing that even if they were lawful, they should be “done with care.”<sup>87</sup> In response, according to the report, your Office of General Counsel reviewed these concerns and found that there was authority for OIRA to issue return letters, although you provide not a hint of the origins of this considerable power. The report does note, however, that “[w]e share the view of the reviewer that OIRA should not return a rule to an

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<sup>84</sup> In your terminology, the “direct” system was called a “4-tire standard.”

<sup>85</sup> I hope, in arriving at this so-called “compromise,” that your office performed a meaningful analysis of the cost of this additional research to society, in terms of government expenditures, expertise, and the agency’s diversion from other pressing priorities, as well as in terms of the loss of the saved lives and other safety benefits that would have accrued in the interim from a requirement for direct systems. Your return letter lacks such self-reflection.

<sup>86</sup> See Transportation, Recall Enhancement, Accountability and Documentation Act, PL 106-414, 114 Stat. 1800 (Nov. 1, 2000).

<sup>87</sup> It is clear that withdrawal of a published final rule and suspension of the effective date of a published final rule are both actions constituting rulemaking under the Administrative Procedures Act and require notice-and-comment procedures. See *Alaska Professional Hunters Association, Inc. v. FAA*, 177 F.3d 1030 (D.C. Cir. 1999); *Natural Resources Defense Council, Inc. v. EPA*, 683 F.2d 752 (3d Cir. 1982).

agency for reasons that would compel an agency to act in ways that are inconsistent or incompatible with the statute under which the agency is operating.”<sup>88</sup>

NHTSA was not charged by Congress with examining the safety benefits of ABS, and, because of long-standing doubt about their safety effects, has never issued a safety standard that would require them. NHTSA did, however, undertake considerable preparation for its actual assignment regarding whether to require direct or indirect tire pressure monitoring systems. A 136-page technical report by NHTSA drafted by three agency experts and ten other advisors, who conducted extensive testing of both systems, corroborated the agency’s preference for direct measuring systems:

Through its testing, NHTSA found that systems that use sensors to directly measure tire pressure (pressure-sensor based systems) were better able to detect underinflation, had more consistent warning thresholds, and were quicker to provide underinflation warnings than the systems that infer tire pressure from monitoring wheel speeds (wheel-speed based [or “indirect] systems).<sup>89</sup>

In view of this ample record and the agency’s years of building technical expertise in the area of tire inflation and safety, NHTSA wisely decided to permit only the installation of direct systems.

Your office demurred. After once revising the rule for content, including at least one previous round of edits of the agency’s NPRM on cost and benefit issues,<sup>90</sup> your office has again returned the agency’s proposal. Inexcusably, your return letter employs only the most bare-bones and unproven assumptions about the cost and market effects of combining indirect systems with a requirement for anti-lock brakes (ABS) (a long-controversial area outside the focus of the agency’s current rulemaking mandate), which, in turn, has only statistically insignificant and highly disputed safety effects.<sup>91</sup> In order to make even the sparsest case for indirect systems, it appears that OIRA must find some shred of benefits any place that it can.

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<sup>88</sup> See *Making Sense of Regulation: 2001 Report to Congress on the Costs and Benefits of Regulations and Unfunded Mandates on State, Local and Tribal Entities* (Office of Management and Budget, Dec. 2001). The objections of this peer reviewer as to the return letter’s underlying legitimacy throws serious doubt on your use of the return letter to assure early OMB access to the formative stages of the rulemaking process, as you told *Congressional Quarterly* was your goal. In an interview, you told the reporter that agencies are now operating under a thinly veiled threat of such letters: “What we’ve been working on is to create an incentive for agencies to come to us when they know they have something that in the final analysis is going to be something we’re going to be looking at carefully. And I think that agencies that wait until the last minute and then come to us – well, in a sense, they’re rolling the dice.” See Rebecca Adams, “Regulating the Rule-Makers: John Graham at OIRA,” *Congressional Quarterly*, Feb. 23, 2002, at 521. Your centralization of an OMB power that remains controversial even for experts in this area is of deep concern to me. If it is dubious to issue return letters, surely it is far more pernicious to use them as a threat to alter processes at the heart of statutorily assigned agency discretion and judgment.

<sup>89</sup> See *An Evaluation of Existing Tire Pressure Monitoring Systems*, DOT HS 809 297, July 2001.

<sup>90</sup> See Memorandum in Response to Section 6(a)(3)(E) of Executive Order 12866, Docket NHTSA-2000-8572-69 (showing edits requested by OMB in strike and add format to pre-publication NPRM).

<sup>91</sup> Indirect systems may only be used on cars with ABS.

In fact, your reasons for rejecting the rule are marked by fallacious assumptions, disingenuous statements and cost-benefit sophistry. Taking the word of only one manufacturer as evidence for the economic decisions of every manufacturer, you argue that “manufacturers can reduce the cost of compliance” by allowing indirect systems, accompanied by a requirement or manufacturer program to install anti-lock brake systems (ABS) across the entire vehicle fleet. You present no evidence that requiring direct systems will *discourage* manufacturers or consumers from installing ABS; nor is there any evidence that even suggests that every manufacturer will make a decision similar to the one cited above. Yet the very survival of your conclusions depends upon assumptions regarding the installation of ABS in every vehicle on the highway.

In fact, linking the availability of a functioning, direct tire pressure monitoring system to ABS makes no sense whatsoever, as the more expensive direct systems cost \$66 per vehicle (not including benefits such as increased tread life, increased fuel economy and reductions in crashes), whereas ABS and the indirect system impose costs of \$240 for the ABS and an additional \$13.29 for the indirect monitoring system, a total of \$253.29. Because ABS is currently not installed in the cheapest sector of the vehicle fleet, imposing an ABS requirement would essentially inflict an unnecessary \$187 of costs<sup>92</sup> on those customers who can least afford it and who should not have to pay for a brake system which, after years of use, has an unproven safety record.

What will these consumers, who have not chosen to pony up for ABS now, get for their enforced outlay? The only study cited by you in support of the safety “benefits” of ABS was a recent study undertaken to examine, ironically, the historical over-involvement of vehicles with ABS in certain kinds of crashes. In the past, while ABS had been found to reduce fatalities in two-vehicle crashes, other evidence suggested that, perhaps due to differences in handling, ABS actually increased run-off-the-road crashes and crashes with fixed objects.

In the study you cite as the only “best estimate” available on ABS and safety, safety researcher Charles Farmer found that ABS *had no statistically significant effect on crash fatalities*.<sup>93</sup> Farmer was unable to determine whether ABS ultimately saved or cost lives across the vehicle fleet, making the “between 4 and 9 percent reduction” in crash fatalities you cite as evidence for your position a statistical blip that may actually be zero percent. The Insurance Institute for Highway Safety summarized the results of the same study by Farmer as follows:

. . .the real-world advantages of antilock brakes are unproven. Over the long term, vehicles with such brakes have fared no better in overall fatal crash experience than vehicles without antilocks. “Despite their impressive

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<sup>92</sup> This cost is calculated by adding the cost of ABS (\$240) to the cost of installing an indirect system on a vehicle with ABS (\$13.29) (=253.29) and subtracting the cost of a direct system (\$66.50), which would have been imposed on all consumers under NHTSA’s rulemaking proposal ( $253.29 - 66.50 = 186.79$ ). Therefore, an ABS requirement tied to this rulemaking would tax consumers with \$187 in potentially worthless additional costs for the dubious combined benefits of ABS and an indirect system.

<sup>93</sup> See Charles M. Farmer, New Evidence Concerning Fatal Crashes of Passenger Vehicles Before and After Adding Antilock Braking Systems,” *Accident Analysis and Prevention* 33 (2001), at 361.

performance on the test track, there is still no evidence that antilock brakes are producing overall safety benefits, “ says Institute president Brian O’Neill.<sup>94</sup>

Since the remainder of your argument about the “benefits” of an indirect system rests on this blip of “4 to 9 percent,” your benefits calculus is actually a castle in the air.

Essentially, you need whatever sliver of benefits you can eke out of the data on ABS to add to the poor performance statistics of indirect systems in order to make your implausible claim that the addition of ABS to the remainder of the vehicle fleet *plus* the modest safety benefits of indirect systems would save more lives than a direct system alone. However, the breach of normal statistical practice you commit by relying on statistically insignificant data has devastating consequences for the validity of your conclusions. Rather than quibbling at NHTSA about yet more benefit details, as the remainder of your letter does, you should have performed your own sensitivity analysis<sup>95</sup> of these conclusions before holding the agency hostage to your arbitrary demands.

Due to the lack of statistical significance, as above, the “benefit” from ABS *could just as easily be zero as four or nine percent*. At zero benefits, a decision to require ABS would tax lower-income consumers with an undesired and valueless extra expenditure of \$187 for ABS systems and indirect monitors per vehicle, or \$935 million per year across the number of vehicles annually produced without ABS (some 5 million vehicles). A sensitivity analysis might have shown you that well-founded uncertainty about ABS yields you *either and equally probably* benefits or losses of this amount. Given that these benefits would accrue only if all your unsupported suppositions about manufacturer and market behavior are correct, and that consumers who choose to value ABS can purchase the system in this marketplace, one might think that you would yield to the agency’s mandate and exercise of judgment in this case.

If forcing consumers to pay \$187 for nothing was not enough, an ABS requirement would enable manufacturers to continue to install slipshod, lousy tire pressure monitoring systems, stunting the continued development of direct measurement technologies. Furthermore, manufacturers would, predictably, be able to charge a mark-up for those consumers annoyed by the imprecision of indirect systems with money to expend on safety “extras,” thus further disadvantaging lower-income consumers.

Without OMB’s intervention, on the other hand, direct systems that truly warn of dangerous conditions would be available to all consumers at the lowest cost due to the ability to manufacture them in mass production as standard equipment, and the systems’ capacity for continuous monitoring of all four tires on the dashboard might trigger a cultural sea-change in attention to tire safety.<sup>96</sup> In addition, manufacturers of these systems would take the risk of further investments to perfect future direct systems. Consumers who regularly monitored their

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<sup>94</sup> See Insurance Institute for Highway Safety Status Report, Vol. 35, NO. 4, April 15, 2000.

<sup>95</sup> Sensitivity analysis is used to reinforce a finding by demonstrating that an outcome is robust, *i.e.*, that the conclusion is not very sensitive to potential changes in the variables upon which the result rests.

<sup>96</sup> Statistical evidence collected by the agency suggests that this is quite possible, as 85 percent of drivers of the 11,530 vehicles surveyed were “concerned about maintaining proper tire inflation.” See Preliminary Analysis of Findings, 2001 NASS Tire Pressure Special Study, Aug. 3, 2001, Docket No. NHTSA-2000-8572-74.

tire conditions would see cost savings in gas from improved fuel economy, cost savings on the longer tread life of their tires, and, most importantly, fewer tire-related crashes.

Nor does it matter, as your analysis suggests, that the cost of inflicting ABS on the remainder of the vehicle fleet *plus* the cost of indirect systems for the whole fleet is cheaper than the cost of a direct system requirement. NHTSA already determined that the cost savings from allowing an indirect system were *not worth it* on safety grounds. Given the total uncertainty of any safety benefits flowing from ABS, there is literally no reason to doubt the agency's informed decision.

Other unexamined assumptions and errors also plague your re-hashing of NHTSA's hundred-page economic analysis. Here are just two examples: 1) The number of crash fatalities used as a multiplier of your fanciful "4 to 9 percent" was 40,000, an extremely rough number that actually includes some 10,000 annual pedestrian, large truck occupants, bus occupants, and bicyclist fatalities,<sup>97</sup> which are outside the scope of the rule and which should, at the least, be considered separately; 2) You failed to account for the time it takes to alter vehicle manufacturing processes, instead assuming that 1.1 million vehicles currently produced without ABS would suddenly be manufactured with this feature. NHTSA avoids these pitfalls because the agency does not base its benefit estimates on overall fatality statistics, but instead looks at specific benefits.

In sum, your agency has embarrassed itself by getting in over its head. How many mechanical engineers are on staff at OIRA, who can fairly evaluate the merits of the agency's decision? The expertise of your office in this arena is unclear, at best. What is clear is that you are choosing to trade a known quantity of lives that will be lost by allowing indirect systems in exchange for highly dubious ABS benefits and assured increases in costs for lower-income consumers. This line of reasoning would not have passed the laugh test if it had originally been submitted by NHTSA to your office, and would be far more comical now if the precedent your action sets, and the human lives that will be lost from allowing a much less effective system, were not so grave.

### *Conflicts of Interest Impugn Your Involvement in this Rule*

Nor have you chosen to recuse yourself from this decision, as you should, because of your well-documented and specific conflicts of interest. The OIRA docket shows that you held a meeting regarding tire pressure monitoring systems with auto industry representatives on October 26, 2001, just before the agency's pending rulemaking mandate would become past due.<sup>98</sup> Attending that meeting were three representatives of the Alliance of Auto Manufacturers

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<sup>97</sup> Occupant fatalities in passenger cars and light trucks actually totaled 31,910. *See* Traffic Safety Facts 2000 – Overview, National Center for Statistics and Analysis (2001). Using your methodology, this error alone subsumes your conclusions. Confusingly, you do not use benefits numbers comparing it to the whole fleet with ABS, but only 7.4 percent. Reducing 7.4 percent of the total number of fatalities (2,308) by 4 to 9 percent would reduce fatalities by 92-207, a number solidly in the range of the number of fatalities averted by the direct system (141). Of course, the agency's calculations regarding number of fatalities averted by a direct system requirement was substantially justified by NHTSA, whereas the "4 to 9 percent" figure you utilize for the add-on benefits of ABS could just as easily be zero.

<sup>98</sup> *See* Meeting Record Regarding: Tire Pressure Monitoring Systems, Oct. 26, 2001,

(Alliance), as well as lobbyists for Toyota, Ford, DaimlerChrysler and Volkswagen of America.<sup>99</sup> Under your tenureship as Director of the Harvard Center for Risk Analysis (HCRA), a post which you left only months before this meeting, the center received unrestricted funding, in undisclosed amounts, from Ford, Volvo and General Motors, as well as the American Automobile Manufacturers Association, the predecessor organization of the Alliance.<sup>100</sup>

Unsurprisingly, OIRA's return letter mirrors the reasoning of the Alliance,<sup>101</sup> which appears to be disappointed by NHTSA's decision, as manufacturers would not have the option of charging consumers a premium for the luxury of an accurate tire monitoring system. The Alliance has loudly clamored for its right to get by with a shoddy, indirect system, despite all the evidence of the potential harm that would result and the unfairness of this option for lower-income consumers.<sup>102</sup> Fearing they might not prevail in the public comment process, the industry came to you.

You conducted an additional meeting with industry after the return letter was issued, and according to your statements at the House hearing, while "negotiations" with NHTSA were ongoing. The OMB docket reflects a meeting on February 21, 2002, between yourself, a few officials from OIRA and three representatives of the Rubber Manufacturers Association (RMA). According to letterhead submitted to the NHTSA docket, the RMA includes Goodyear Tire and Rubber Company, which was a former source of unrestricted funding in undisclosed amounts under your direction of HCRA.<sup>103</sup>

Unlike the former meeting, NHTSA officials were apparently not invited or chose not to attend your meeting with RMA. While NHTSA provides substantive notes of *ex parte* meetings with industry and others as a part of the rulemaking docket, your meeting docket simply notes the date and subject of the meeting and its attendees. We do know that, in its official comments

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<http://www.whitehouse.gov/omb/oir/2127/meetings/78.html>; Meeting Record Regarding: Tire Pressure Monitoring Systems, Feb. 21, 2002, <http://www.whitehouse.gov/omb/oir/2127/meetings/94.html>.

<sup>99</sup> According to letterhead submitted in comments to the docket, the present membership of the Alliance includes DaimlerChrysler, Ford, Volvo, the BMW Group, Fiat, Ford, General Motors, Isuzu, Mazda, Mitsubishi Motors, Nissan, Porsche, Toyota, Volkswagen and Volvo

<sup>100</sup> As was made clear in two letters sent by prominent academic scholars in opposition to your nomination to OIRA, many, if not most, academic researchers shy away from accepting unrestricted funding due to the multiple and serious problems it poses for conflicts of interest, both apparent and actual. Instead, researchers typically seek funding under the rubric of restricted funding research contracts, which explicitly spell out the terms of the grant and conditions for review of result by funders. *See* Letter from 32 Scholars Opposing Graham and Raising Conflicts of Interest Concerns, May 17, 2001, <http://www.citizen.org/congress/regulations/graham/chivian.html>; 53 Scholars and Academics Write the Senate Governmental Affairs Committee Opposing the Graham Nomination, May 9, 2001, <http://www.citizen.org/congress/regulations/graham/academics.html>.

<sup>101</sup> *See* Letter from Vann H. Wilbur, Alliance of Automobile Manufacturers Director for Vehicle Safety And Harmonization, Mar. 23, 2001 to NHTSA ("The Alliance believes that both wheel-speed [indirect] based and pressure-sensor [direct] based TPMS [tire pressure monitoring systems] have merit and should be permitted under pending requirements. Our proposal will allow the further development of both types of systems."), Docket no. NHTSA-2000-8572-16.

<sup>102</sup> Other than the typical resistance offered by industry on cost grounds, we presume that the industry is unwilling to offer the more preferable system for tire monitoring on cars which lack ABS, which are the less expensive cars across one-third of the vehicle fleet.

<sup>103</sup> *See* Comments of the Rubber Manufacturers Association on NPRM Federal Motor Vehicle Safety Standards; Tire Pressure Monitoring Systems; Controls and Displays, Sept. 6, 2001, at 1.

to the docket and meetings with NHTSA officials, the RMA consistently supported a strong rulemaking, arguing that NHTSA should use a stringent definition for the amount of underinflation that would produce a warning, and that an adequate warning system was necessary because consumers would “rely heavily on the [Tire Pressure Monitoring Systems] and ignore routine tire maintenance.”

### *A Meaningful Tire Safety Rule Is Necessary for Public Health*

In testimony before the House Subcommittee on Commerce, Trade, and Consumer Protection, NHTSA's Administrator Dr. Jeffrey Runge, made it clear that OMB is squashing the agency's judgment on this issue:

The NPRM to require a warning system to indicate to vehicle operators when a tire is significantly under inflated was published on July 26, 2001. The NPRM drew extensive comments. We have sought to resolve the issues raised by the comments and devise a system that will meet the intent of the TREAD Act in a manner that best serves safety. In the belief that we had devised such a system, we sent a final rule to OMB on December 18, 2001. On February 12, 2002, OMB returned the rule to us for reconsideration based on concerns it had identified.<sup>104</sup>

In overriding the outcome of the public process in this rulemaking, you are also infringing upon the expressed will of Congress. In addition to the mandate for this rulemaking, in the Transportation, Recall Enhancement, Documentation and Accountability (TREAD) Act, Congress went out of its way to signal the importance of tire safety and to grant NHTSA wide-ranging authority to enact measures that will result in enhanced public awareness of tire-related problems.<sup>105</sup>

And the facts bear out their concern. Unlike the spare analysis in your return letter and accompanying evaluation, NHTSA supported its regulatory decision with meticulous research into existing systems, consumer habits, and tire conditions. Using the National Automotive Sampling System (NASS), extensive driver attitude and vehicle tread and tire pressure surveys were conducted at 336 gasoline stations throughout the U.S., including some 11,530 vehicles.<sup>106</sup>

When a tire is under inflated, its sidewalls flex more than they should and the air temperature inside the tire increases, making it more prone to failure. In addition, under inflation reduces the tread life of tires and the fuel economy of vehicles, both of which are costly for consumers. The facts unearthed by the agency in preparing for the rulemaking are alarming and

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<sup>104</sup> Testimony of Jeffrey W. Runge, M.D., Administrator, National Highway Traffic Safety Administration, Before the Subcommittee on Commerce, Trade, and Consumer Protection, Committee on Energy and Commerce, U.S. House of Representatives, February 28, 2002, at 6-7.

<sup>105</sup> See Transportation, Recall Enhancement, Accountability and Documentation Act, P.L. 106-414, Sec. 11. Improved tire information. “(b) Inflation levels and load limits. In the rulemaking conducted under subsection (a), the Secretary may take *whatever additional action* is appropriate to ensure that the public is aware of the importance of observing motor vehicle tire load limits and maintaining proper tire inflation levels for the safe operation of a motor vehicle...” [emphasis added].

<sup>106</sup> See Preliminary Analysis of Findings, 2001 NASS Tire Pressure Special Study, Aug. 3, 2001, Docket No. NHTSA-2000-8572-74.

suggest there is a dire need for a rule that will heighten consumer awareness of tire hazards as Congress intended:

- Seventy-four percent of the on-road fleet has at least one tire that is under inflated.<sup>107</sup>
- Thirty-six percent of passenger cars and 40 percent of light truck vehicles (minivans, pick-up trucks and sport utility vehicles) have at least one tire that is 20 percent or more below the recommended tire pressure.<sup>108</sup>
- While 85 percent of the population of drivers are concerned about maintaining proper tire inflation in their vehicles, only 25 percent use the correct method to determine the manufacturer's recommended tire pressure, and 43 percent fail to actively maintain their tire pressure.<sup>109</sup>
- Worn tire tread may reflect continuous driving on under inflated tires; nine percent of vehicles sampled had at least one tire that was bald, that is, with tread wear at or below two 32<sup>nds</sup> of an inch.<sup>110</sup>
- Radial tires, which are standard equipment on most new cars, can lose much of their air pressure and still appear to be fully inflated,<sup>111</sup> yet between 6 and 16 of drivers admitted to checking their tire inflation levels visually.<sup>112</sup>
- While more than 90 percent of gas stations have air pumps, nearly 10 percent are out of order; 50 percent lack gauges to measure air pumped into the tire; and 20 percent of those that do have pumps give inaccurate readings, reflecting an inflation level that is as much as 4 psi more than the air pressure actually in the tire.<sup>113</sup>
- Eighty-five percent of all tire air pressure losses are the result of slow leaks that occur over a period of hours, days, or months.<sup>114</sup>

How much more research money and expert time will taxpayers have to spend to overcome your paralysis by analysis and to get this relatively simple, lifesaving measure implemented?

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<sup>107</sup> See National Center for Statistics and Analysis, Tire Pressure Special Study, August 2001, DOT HS 809 315 (Methodology); DOT HS 316 (Interview Data); DOT HS 317 (Vehicle Observation Data). As part of this four-part study, NHTSA also conducted extensive surveys at 336 gasoline stations throughout the U.S., see Kristin Thiriez (NHTSA Engineer) and Rakesh Subramanian (NHTSA Mathematical Analyst), Tire Pressure Special Study, October 2001, DOT HS 809 359 (Using sample of 10,900 observations of tire pressure of all four tires on vehicle); see also Frank Swoboda, "Inaccurate Tire Gauges Can Be a Matter of Safety," *The Washington Post*, Dec. 4, 2001.

<sup>108</sup> See Tire Pressure Monitoring Systems: Controls and Displays, Notice of Proposed Rulemaking, 66 FR 38982, July 26, 2001.

<sup>109</sup> See Kristin Thiriez (NHTSA Engineer) and Rakesh Subramanian (NHTSA Mathematical Analyst), Tire Pressure Special Study, October 2001, DOT HS 809 359.

<sup>110</sup> See National Center for Statistics and Analysis, Tire Pressure Special Study, August 2001, DOT HS 317 (Vehicle Observation Data).

<sup>111</sup> See Frank Swoboda, "Inaccurate Tire Gauges can Be a Matter of Safety," *The Washington Post*, Dec. 4, 2001.

<sup>112</sup> See Preliminary Analysis of Findings, 2001 NASS Tire Pressure Special Study, Aug. 3, 2001, Docket No. NHTSA-2000-8572-74.

<sup>113</sup> *Id.*

<sup>114</sup> See Tire Pressure Monitoring Systems: Controls and Displays, Notice of Proposed Rulemaking, 66 FR 38982, July 26, 2001.

## *NHTSA Was Right On the Money*

Although the cost difference, once benefits are factored in, amounts to a mere \$15 per vehicle, the difference in the number of injuries and deaths prevented by the two systems is considerable.<sup>115</sup> While direct tire pressure monitoring systems would prevent an estimated 10,635 injuries and 79 deaths, the indirect system would, in the agency's best estimates, fail to prevent 4,050 of those injuries and 30 of those deaths.<sup>116</sup> The real numbers are likely to be even worse, given that consumers using the shoddy, indirect system, which fails to show drivers which tire is under inflated, or if more than one is under inflated (as well as failing in other confusing permutations), and is more frequently in error, would quickly learn to disregard the warnings.

Put another way, the agency estimated that direct systems would result in 38 percent of light vehicle operators being warned of low tire pressure, while indirect systems would result in only 24 percent of operators currently on the highway being warned, due to the imprecision of that system.<sup>117</sup>

Even with the agency's badly inflated cost numbers,<sup>118</sup> the net cost per life saved is \$1.9 million for the direct system and \$1.1 million for the indirect system, well below the \$6.3 million value assigned to human life in the type of ghastly arithmetic practiced by regulatory actuaries such as those in your office.<sup>119</sup>

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<sup>115</sup> *Id.*

<sup>116</sup> That is, it would prevent only 6,585 injuries and 49 deaths. *Id.*

<sup>117</sup> See Tire Pressure Monitoring System, Preliminary Economic Assessment, July 2001, Docket No. NHTSA-2000-8572-57.

<sup>118</sup> Public Citizen's individual comments to the docket pointed out that the agency overweights its cost estimate by a factor of 1.5, as it inflated the costs to reflect a retail markup rather than using a societal cost figure. See Tire Pressure Monitoring System FMVSS No. 138, Preliminary Economic Assessment, Docket No. NHTSA-00-8572-57, p.VI-1. Because the retail markup is a transfer payment from consumers to industry rather than a net social cost, and because some part of the cost to industry is likewise a transfer payment among industries, the real cost figures are actually lower than the agency's estimates. See Office of Management and Budget, "Economic Analysis of Federal Regulations Under Executive Order 12866," (January 11, 1996), which reads in part "[a]n important, but sometimes difficult, problem in cost estimation is to distinguish between real costs and transfer payments. Transfer payments are not social costs but rather are payments that reflect a redistribution of wealth;" See Public Citizen, Re: Tire Pressure Monitoring Systems: Notice of Proposed Rulemaking 66 FR 38982 *et seq.*, July 26, 2001, Docket No. NHTSA 2000-8572-148.

<sup>119</sup> These figures rendering the value of human life in monetary terms remain highly controversial, *see, e.g.*, Frank Ackerman and Lisa Heinzerling, "If It Exists, It's Getting Bigger: Revising the Value of a Statistical Life," *Global Development and Environment Institute Working Paper No. 01-06*, Oct. 2001; Lisa Heinzerling, "The Rights of Statistical People," 28 *Harv. Envtl. L. Rev.* 189 (2000); Richard L. Revesz, "Environmental Regulation, Cost-Benefit Analysis, And the Discounting of Human Lives," 99 *Colum. L. Rev.* 941 (May 1999); Lisa Heinzerling, "Regulatory Costs of Mythic Proportions," 107 *Yale L.J.* 1981 (1998); Lisa Heinzerling, "Reductionist Regulatory Reform," 8 *Fordham Envtl. Law J.* 459 (1997); David A. Wirth & Ellen K. Silbergeld, "Book Review: Risky Reform," 95 *Colum. L. Rev.* 1857 (Nov. 1995); Douglas E. MacLean, "Comparing Values in Environmental Policies: Moral Issues and Moral Arguments," in *Valuing Health Risks, Valuing Health Risks, Costs, and Benefits for Environmental Decision Making* (1990); Mark Sagoff, *The Economy of the Earth* 46 (1988).

*OIRA's Over-Reaching Must Stop*

OIRA had one bite at the agency's NPRM, and the agency kindly obliged you. Nowhere in statute does your office retain the authority to delay an overdue rule mandated by Congress and subject to the Administrative Procedures Act notice-and-comment rulemaking process, much less to force OIRA's will upon the agency, in violation of an express delegation of decision-making power to the Secretary of Transportation.

It is far past time, as you promised at your nomination hearing, to leave behind your role as industry advocate and try on your civil servant hat. These problems with OIRA's peremptory refusal to let this rule become final are serious and should be addressed. My hope is that you will review our objections with more care than it appears you have allocated to NHTSA's well-developed position requiring direct monitoring systems, and that sound science exercised in its true form – with humility – as well as the interests of public health and democracy, will ultimately prevail.

Sincerely,

*Joan Claybrook*  
President  
Public Citizen

## **Appendix B**

### **Stuck in Neutral: Recommendations for Shifting the Highway and Auto Safety Agenda into High Gear**

Appendix B will be submitted separately via email, and together with our comments in hard copy. This report is also accessible on the internet at:  
[http://www.saferoads.org/press/press2001/pr\\_sin3.htm](http://www.saferoads.org/press/press2001/pr_sin3.htm)

## Appendix C

### **“High Priority” Rules Nominated by the Mercatus Center Are Well Supported by the Record**

The following rules were targeted by the Mercatus Center for rescission or reform because, the Mercatus Center asserts, agencies did not adequately assess their costs and benefits or properly evaluate the underlying facts. However, as demonstrated, each of these rules was the subject of a full and robust public notice and comment period. It is unclear how or why OIRA allowed the Mercatus Center’s shallow analysis to supercede the extensive scientific and factual record on which these rules are based.

#### *New Source Review Rules*

The Clean Air Act, enacted in 1970, contains a grandfather clause that exempts hundreds of the nation’s oldest and dirtiest power plants, oil refineries and chemical and manufacturing plants from complying with current pollution clean-up rules.<sup>120</sup> Specifically, New Source Review (NSR) provisions require new facilities to install pollution control equipment when they are built, and require old facilities to install state of the art pollution reducing equipment when they expand their operations in a manner that increases pollution emission significantly.<sup>121</sup> The purpose of the NSR program is to “protect public health and welfare, as well as national parks and wilderness areas.”<sup>122</sup>

According to EPA estimates, over the period from 1997 to 1999, the NSR program has reduced emissions by over 4 million tons.<sup>123</sup> The unhealthful effects of these emissions are breathtaking. EPA estimates the annual health bill from 7 million tons of SO<sub>2</sub> and NO<sub>2</sub> at “more than 10,800 premature deaths, at least 5,400 incidents of chronic bronchitis, more than 5,100 hospital emergency visits and over 1.5 million lost work days.”<sup>124</sup> Another study by Abt Associates, a private research group that does work for the EPA, found that 31,000 deaths a year are caused nationwide by power plant emissions.<sup>125</sup> Add to this human toll the irreparable damage to our national parks, watersheds, wildlife and natural resources, and it is clear that rigorous enforcement of NSR is essential to our national health and well-being.

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<sup>120</sup> “Rewriting the Rules: The Bush Administration’s Unseen Assault on the Environment,” National Resources Defense Council, p. 9 [hereinafter, NRDC Report].

<sup>121</sup> “New Source Review 90-Day Review Background Paper,” June 22, 2001, Environmental Protection Agency, p. 2 [hereinafter NSR Background].

<sup>122</sup> NSR Background, p. 2.

<sup>123</sup> *Id.* at 8. This estimate represents emission reduction resulting from Best Available Control Technology (BACT) required by only one of the two programs comprising NSR. Thus, actual emissions reduction is significantly higher.

<sup>124</sup> Data provided to the Senate Environment Committee by EPA, February 27, 2002 letter from Eric V. Schaeffer, former Director of EPA’s Office of Regulatory Enforcement, to Administrator Christine Todd Whitman [hereinafter, Schaeffer Letter].

<sup>125</sup> Eric Pianin, “White House Warned on Easing Clean Air Rules,” *Washington Post*, January 9, 2002 [hereinafter, Post January 9].

In 1999, the Clinton Administration launched a series of lawsuits against power plants and oil refineries for violating NSR requirements.<sup>126</sup> Two of these suits were successfully settled, resulting in an annual emissions reduction of SO<sub>2</sub> and NO<sub>2</sub> of a quarter million tons.<sup>127</sup> Unfortunately, under the Bush Administration, all momentum in these cases has been lost due to the occurrence of two events.

First, in May 2001, the Bush Administration directed EPA to initiate a 90-day review of NSR requirements (which review continues today, one year later). As a result, the EPA and the Department of Energy have engaged in very public wrangling regarding “proposed revisions” to NSR requirements.<sup>128</sup> The second event was the Bush Administration’s announcement of its “Clear Skies Initiative” on February 14, 2002, which addresses emissions of SO<sub>2</sub>, NO<sub>2</sub> and mercury from power plants. If enacted, the “Clear Skies Initiative” would apply to both old and new plants, thus apparently replacing NSR requirements for power plants.<sup>129</sup> There are serious uncertainties as to the effectiveness of the “Clear Skies Initiative,” among them, how facilities will achieve the emissions reductions required to meet the ambitious caps proposed by the plan and the level of long term limits emissions.<sup>130</sup> According to an EPA analysis prepared for Vice President Cheney’s task force, the existing Clean Air Act programs would reduce power plant emissions in almost half the time as Bush’s “Clear Skies Initiative.”<sup>131</sup>

These two developments undermine the integrity of current NSR requirements and send a clear signal to power companies and refineries that the Bush Administration intends to relax emissions controls, thus removing any incentive to come to the table to negotiate a settlement or comply with the law in the short term. Indeed, Administrator Whitman herself acknowledged this fact on March 7, 2002 at a Senate Committee on Governmental Affairs hearing on the Bush Administration’s environmental record. Administrator Whitman stated, “If I were a plaintiff’s attorney, I wouldn’t settle anything until I knew what happened with [the Tennessee Valley Authority] case.”<sup>132</sup> Not surprisingly, two defendants have refused to sign consent decrees to which they agreed fifteen months ago, “hedging their bets while waiting for the Administration’s Clean Air Act reform proposals.”<sup>133</sup>

Adding fuel to the NSR controversy, the Mercatus Center nominated NSR regulations for

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<sup>126</sup> Eric Pianin, “EPA Veteran Resigns Over Pollution Policy,” *Washington Post*, March 1, 2002 [hereinafter, Post March 1].

<sup>127</sup> Schaeffer Letter.

<sup>128</sup> Post January 9.

<sup>129</sup> See McGarity Testimony.

<sup>130</sup> See McGarity Testimony. Many plants already switched from high sulfur coal to cleaner burning lower sulfur coal and natural gas to meet the less ambitious caps established by the acid rain program created by the 1990 Clean Air Act amendments. As a result, companies will likely have to install costly pollution reduction equipment, or acquire the necessary permits to forgo pollution controls, large capital expenditures they will be loath to undertake. Further complicating the issue, the “Clear Skies Initiative” as proposed requires Congress to set caps only for 2010 targets. EPA would later establish 2018 caps after reviewing “new scientific, technology and cost information, and if necessary, adjust[ing] the phase two targets.”

<sup>131</sup> Andrew Goldstein, “For Bush, It’s Not Easy Being Green,” *Time*, February 25, 2002.

<sup>132</sup> Katharine Q. Seelye, “E.P.A. Chief Says Pollution Will Probably Stay Unsettled Until Related Case Is Decided,” *New York Times*, March 8, 2002. It should be noted however, that under the current Administration, the EPA has not filed any new enforcement lawsuits.

<sup>133</sup> Schaeffer Letter

“review or rescission” and, in its 2001 Costs and Benefits Report to Congress, OIRA identified the regulations as “high priority” for review. Mercatus supported the nomination of the NSR regulations asserting that they are a “deterrent to investment in new oil refinery and power generation capacity” and that “EPA’s aggressive application of NSR provide[s] perverse incentives and encourage litigation.” Mercatus suggested that EPA use the “settlement process to alter its NSR policy.”<sup>134</sup>

Mercatus’ comments are entirely without merit. First, the Justice Department has already determined that enforcement of NSR is not overly aggressive. In May 2001, the National Energy Development Group, headed by Vice-President Dick Cheney, recommended that President Bush direct the Attorney General to “review existing enforcement actions regarding New Source Review to ensure that the enforcement actions are consistent with the Clean Air Act and its regulations.”<sup>135</sup> In response to this directive, on January 15, 2002, the Justice Department announced its conclusion that EPA was “justified in suing operators of scores of aging coal-fired power plants that were illegally polluting the atmosphere” and Attorney General John Ashcroft vowed to continue to “vigorously” pursue those cases.<sup>136</sup>

Second, as described above, relying on the “settlement process” to amend NSR policy is a joke given the Bush Administration’s undermining of NSR regulations with phantom proposed regulations and Administrator Whitman’s statement advising defendants against settlement. OIRA’s unexplained acceptance of Mercatus’ unfounded arguments supporting “review or rescission” of NSR regulations underscores the pervasive influence of industry in shaping OIRA’s agenda.

In OMB-OIRA’s notice and request for comments on its “Draft Report to Congress on the Costs and Benefits of Federal Regulations,” the agency notes that the “EPA is considering whether revisions to these regulations and guidance documents are appropriate.”<sup>137</sup>

### *HHS Standards for Privacy of Individually Identifiable Health Information*<sup>138</sup>

The Department of Health and Human Services (HHS) issued a final medical privacy rule (Standards for Privacy of Individually Identifiable Health Information) in December 2000 in response to a mandate from Congress dating back to 1996. This privacy rule has been the subject of a lengthy, thorough, and robust rule-making process – both before its December 2000 release in final form and since that release – a process that continues to this day. On April 26, 2002, the comment period closed for proposed revisions to these standards that would, among other

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<sup>134</sup> OMB 2001 Report on the Cost of Regulations.

<sup>135</sup> NSR Review, Appendix A.

<sup>136</sup> Eric Pianin, “Suits Against Power Firms Justified, Justice Department Says,” *Washington Post*, January 16, 2002.

<sup>137</sup> Office of Management and Budget, “Draft Report to Congress on the Costs and Benefits of Federal Regulations,” 67 FR 15014 *et seq.*, March 28, 2002.

<sup>138</sup> We thank Georgetown University’s Health Privacy Project for their assistance in preparing this testimony. Much of the following is adapted from *Comments on Final Federal Standards for Privacy of Individually Identifiable Health Information*, submitted to HHS by Georgetown University’s Health Privacy Project and endorsed by 31 additional organizations (dated March 29, 2001).

changes, revoke patients' right to prohibit the use or disclosure of their personal health information without their consent.<sup>139</sup>

The 1996 law, called the Health Insurance Portability and Accountability Act (HIPAA), imposes upon HHS the legal duty to adopt and implement a series of "Administrative Simplification" rules to improve the "efficiency and effectiveness of the health care system by encouraging the development of a health information system through the establishment of standards and requirements for the electronic transmission of certain health information."<sup>140</sup> In addition to ensuring the privacy of individually identifiable health information, other rules required by HIPAA establish uniform standards for electronic health care transactions and security rules to safeguard the data. Representatives of health care consumer groups, health plans, and health providers all reached consensus in 1996 that the movement toward an electronically based health care system should not go forward without adequate federal protections in place for the confidentiality of health information. Congress agreed and HIPAA reflects this consensus.

Pursuant to its congressional mandate, HHS issued a proposed privacy rule in November 1999. In response to requests from industry representatives and consumer advocates, HHS extended the initial 60-day comment period by an additional 45 days, giving the public more than 3 months to submit comments. Of the over 52,000 comments eventually submitted,<sup>141</sup> more than half came from consumers and their representatives. After the comment period closed, HHS spent 10 months engaged in extensive fact finding prior to releasing the final rule. The thoroughness with which HHS considered these comments is reflected in the preamble to the final rule. Indeed, almost 200 pages of the preamble are devoted to summarizing and responding to these comments.

Overall, the final product of that extensive rule-making process was a balanced rule. HHS made many significant changes sought by consumer groups, as well as many of the changes urged by health care providers, health plans, clearinghouses, researchers, and others operating in the health care arena. HHS described the three pronged purpose of the final regulation: (1) to protect and enhance the rights of consumers by providing them access to their health information and controlling the inappropriate use of that information; (2) to improve the quality of health care in the U.S. by restoring trust in the health care system among consumers, health care professionals, and the multitude of organizations and individuals committed to the delivery of care; and (3) to improve the efficiency and effectiveness of health care delivery by creating a national framework for health privacy protection that builds on efforts by states, health systems, and individual organizations and individuals."

Originally scheduled to go into effect on February 26, 2001, the privacy rule's effective date was delayed to April 14, 2001. On February 28, 2001, HHS published a notice opening the final health privacy rule for a 30-day public comment period.<sup>142</sup> HHS received over 24,000

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<sup>139</sup> 67 FR 14776.

<sup>140</sup> 65 Fed. Reg. At 82463 (December 28, 2000).

<sup>141</sup> See 66 Fed. Reg. at 12739 (February 28, 2001).

<sup>142</sup> See 66 Fed. Reg. at 12738-39 (February 28, 2001).

comments during that 30-day period.<sup>143</sup> After the comment period ended, HHS allowed the rule to go into effect on April 14, 2001. Most entities that must comply with it have until April 14, 2003 to do so; small health plans have an additional year.<sup>144</sup>

HIPAA expressly provides a mechanism for HHS to modify the privacy rule. Under Section 262 of HIPAA (adding Section 1174 to the Social Security Act), the Secretary of HHS has the authority to modify the privacy standards during the first 12 months after the standard is adopted (*i.e.*, becomes effective) when such modification “is necessary in order to permit compliance with the standard.” After that first 12-month period, the Secretary may issue modifications as needed, but not more frequently than once every 12 months. Thus, HIPAA anticipates and provides a statutory mechanism for resolving any implementation problems that may arise, making it clear that Congress did not envision a substantive role for OIRA in revising the rule.<sup>145</sup>

The federal health privacy rule represents a significant and decisive step toward restoring public trust in our nation’s health care system. It gives people more information about and more control over how their health information is used and disclosed. It also gives people important new rights, including the right to obtain a copy of their medical records and request necessary corrections to them.

Opponents in the industry object to the cost of complying with the rule. Indeed, the Mercatus Center cited cost as the basis for its nomination of the rule for “review or rescission,” stating that the “cost of compliance could reduce access to health care by increasing the cost of treatment.”<sup>146</sup> Privacy advocates however, point out that the costs of *not* implementing this rule far outweigh the costs of implementing it. If federal privacy protections are not in place, millions more people will engage in privacy-protective behaviors – to the detriment of their own health and the integrity of research – and confidence in our health care system will continue to erode. According to a national survey released by the California HealthCare Foundation in 1999, 15 percent of adults say they have done something out of the ordinary to keep medical information confidential. These privacy-protective measures include paying out-of-pocket despite having insurance coverage, changing doctors to avoid a consolidated medical record, not seeking care to avoid disclosure to an employer, and giving incomplete or inaccurate information in a medical history.<sup>147</sup>

It makes no sense to look at the cost of implementing the privacy rule in isolation, as did the Mercatus Center did in its recommendation for rescission. The privacy rule is an integral – and necessary – part of a package of Administrative Simplification rules contained in HIPAA.

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<sup>143</sup> See Statement of HHS Secretary Thompson released on April 12, 2001.

<sup>144</sup> On July 6, 2001, HHS issued guidance to the privacy rule to clarify key provisions of the rule and respond to questions. In that guidance, HHS indicated that it intended, in the future, to propose some modifications to the final rule. It is those modifications that are expected any day.

<sup>145</sup> Congress has not taken any action to delay or modify the privacy rule. Late last year, Congress enacted a law to delay by one year the compliance time frame for the HIPAA transaction and code sets regulation, but that new law states clearly that it does not impact the compliance time frame for the privacy rule. See Pub. L. No. 107-105.

<sup>146</sup> OMB 2001 Report on the Cost of Regulations

<sup>147</sup> This survey is available at the California HealthCare Foundation’s Web page: [www.chcf.org](http://www.chcf.org).

The goal of standardizing electronic health care transactions is to create efficiencies and save money. HHS estimates that the cost associated with implementing the privacy rule (approximately \$17 billion over ten years) will be greatly offset by the cost savings associated with implementing HIPAA's transactions standards (approximately \$29 billion saved over ten years).<sup>148</sup> If implemented together, as contemplated by Congress, consumers will benefit, health care organizations will benefit, and the health of our communities will benefit. Even assuming, *arguendo*, that the Mercatus Center's increased cost estimate for the privacy rule is accurate, a net savings will be achieved when the privacy rule is implemented along with the transactions standards, as Congress intended.

Moreover, contrary to the Mercatus Centers' assertion otherwise, the privacy rule is not a "one-size-fits-all" approach. HHS intends the administrative requirements of the privacy rule to be both flexible and scalable, depending on the size, function and organization of the covered entity.<sup>149</sup> For example, smaller health plans have an additional year to comply with the privacy regulation. This evenhanded approach should allow covered entities to comply with the regulation for a fairly minimal cost.

In OMB-OIRA's notice and request for comments on its "Draft Report to Congress on the Costs and Benefits of Federal Regulations," the agency notes that the "HHS has issued guidance clarifying the requirements of this rule and has publicly committed to making regulatory changes to certain aspects of the rule."<sup>150</sup>

### *Hours of Service Rule*

The Federal Motor Carrier Safety Administration (FMCSA) has completed its analysis of docket comments and is now considering regulatory options in its revision of Hours of Service (HOS) regulations. A Notice of Proposed Rulemaking was published on May 2, 2000.<sup>151</sup> The appropriations bill for 2001 (H.R. 4475) prevented the DOT from spending any money to adopt a final rule. In its recommendation for reconsideration of the proposed rule, the Mercatus Center alleges that the DOT did not present data supporting its conclusions that driver fatigue contributes to highway fatalities and did not address either driver fatigue or highway accidents in its proposal. As illustrated below, this is patently untrue.

The FMCSA's revision of its hours-of-service regulations was directly related to the dire need to reduce the risk of crashes involving commercial motor vehicles (CMVs) and the result of much careful study by the agency. The FMCSA estimates that 755 fatalities and 19,705 injuries occur each year on the Nation's roads because of drowsy, tired, or fatigued CMV drivers.

Although basic HOS regulations have been in place since 1938, changes in the transportation system and the construction of the Interstate Highway System have contributed to significantly higher traffic speeds and volumes. The HOS regulations must be revised to reflect

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<sup>148</sup> See 65 Fed. Reg. at 82760 (December 28, 2000).

<sup>149</sup> See 65 Fed. Reg. at 82471 (December 28, 2000).

<sup>150</sup> Office of Management and Budget, "Draft Report to Congress on the Costs and Benefits of Federal Regulations," 67 FR 15014 *et seq.*, March 28, 2002.

<sup>151</sup> 65 FR 25540.

the increased exposure to risks of accidents that follows automatically from annual increases in the number of trucks and other vehicles on the road and in total vehicle miles of travel (VMT) cannot be overstated. Revision of the HOS regulations is in the proposed rulemaking phase.

More than 23,000 comments were received in response to the agency's notice of proposed rulemaking. An NPRM to amend HOS regulations in 1996 alone prompted 1,650 comments, with the strongest support for amending the rules coming from truck drivers, those most directly affected by the rule.

The FMCSA has documented the relationship between fatigue and fatalities extremely well. Present HOS regulations do not adequately ensure that drivers are rested. The agency tentatively estimates that 15 percent of all truck-involved fatal crashes are "fatigue-relevant," that is, fatigue is either a primary or secondary factor. A June 1, 1999, letter from Jim Hall, Chairman of the NTSB to DOT Secretary Rodney E. Slater states that "fatigue has remained a significant factor in transportation accidents since the Safety Board's 1989 recommendations" on improving HOS regulations.

Clearly, risk increases with time driven, as several studies cited by FMCSA have shown. There is a dramatic and consistent increase in crash risk after 8 hours of driving, while approximately 20 percent of the fatal crashes per year involve drivers who have been behind the wheel for 13 or more hours.<sup>152</sup> Long-haul operations account for two-thirds of all fatalities.<sup>153</sup> Fatigue peaks between 4 a.m. and 6 a.m., at which time fatigue-related fatalities increase dramatically.<sup>154</sup>

Of the five options considered,<sup>155</sup> the net benefit ranges from \$1.721 to \$3.359 billion dollars, including paperwork benefits.<sup>156</sup> When paperwork benefits are excluded, option 5 results in a net benefit of \$153 million dollars.<sup>157</sup> Option 5 is a variation of revised options 2 and 4 (14-hour work/drive/break/nap period), with the added provision that both Type 1 and 2 drivers would be required to use an EOBR. The estimated baseline crash reduction from the regulatory changes is 5 percent, while the reduction for motor carriers using Electronic On-Board Recording devices (EOBRs) is 20 percent.<sup>158</sup> A 10 percent reduction in fatigue-related crashes through the use of EOBRs alone results in a net benefit of \$1,816 million dollars.<sup>159</sup> The benefits of this rule would continue, as crashes are avoided, and paperwork reduced, every year the rule is in effect. Over a 10-year analysis period, all options would yield substantial benefits, ranging from \$4.4 billion to almost \$6.8 billion dollars.<sup>160</sup>

In OMB-OIRA's notice and request for comments on its "Draft Report to Congress on the Costs and Benefits of Federal Regulations," the agency notes that the "DOT is considering

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<sup>152</sup> 65 FR 25540.

<sup>153</sup> *Id.*, Chart 4, NPRM.

<sup>154</sup> *Id.*, Chart 2, NPRM.

<sup>155</sup> *Id.*, Table 5, FMCSA Revised Regulatory Options.

<sup>156</sup> *Id.*, Table 15.

<sup>157</sup> *Id.*, Table 16.

<sup>158</sup> *Id.*, Table 6.

<sup>159</sup> *Id.*, Table 19.

<sup>160</sup> *Id.*, Table 10.

revisions to these regulations which were proposed in 2000. Any final rule will reflect public comments in response to the notice of proposed rulemaking.”<sup>161</sup>

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<sup>161</sup> Office of Management and Budget, “Draft Report to Congress on the Costs and Benefits of Federal Regulations,” 67 FR 15014 *et seq.*, March 28, 2002.

## Appendix D

### Additional Analytical Issues in Need of Reconsideration

#### *Willingness to Accept Is the Appropriate Measure of the Value of Most Environmental Goods*

It is outrageous that OMB-OIRA still uses a seven-percent discount rate for environmental and public health benefits, and that it uses willingness-to-pay estimates to value benefits in many cases where an economic consensus exists that higher, willingness-to-accept numbers would be more appropriate. A final analytic suggestion is that OMB-OIRA should adopt a “willingness to accept” standard as the measure for valuing environmental goods. According to the 2000 Final Report, “[t]he benefits of environmental protection are represented by the value that society places on improved health, recreational opportunities, quality of life, visibility, preservation of ecosystems, biodiversity, and other attributes of protecting or enhancing our environment.”<sup>162</sup> We agree. However, the 2000 Final Report next asserts, without explanation, that “[t]his value is best measured by society’s willingness to pay (WTP) for these attributes.”<sup>163</sup> In this section, we assert that society’s willingness-to-accept (WTA) environmental harms is generally the best measure of the value of environmental protection. We argue that by using the WTP measure the 2000 Final Report grossly underestimated the value of environmental goods. Although these comments concentrate on how use of WTP rather than WTA undervalues environmental goods, the same analysis is equally applicable to valuing the benefits of other public health and safety protections.

Responding to this same argument by Public Citizen in 2000, the 2000 Final Report acknowledged that WTA can be greater than WTP, and WTA is the appropriate measure when the public – not the polluter or potential polluter – owns the good in question. However, OMB-OIRA argued that WTA is very difficult to estimate.<sup>164</sup> While this may be true, it is an unacceptable reason to use lower WTP numbers, which, we note, are also very difficult to estimate for health, safety, and environmental goods. Since WTA is the appropriate measure for environmental and other public goods, OMB-OIRA and the agencies are obligated to estimate its value as well as they can.

For goods traded in markets, WTP equals WTA. However, as one scholar has explained, for goods not traded in markets, such as health, safety, and environmental goods:

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<sup>162</sup> 2000 Final Report at 8.

<sup>163</sup> *Id.* at 8.

<sup>164</sup> *Id.* at 9:

As we stated in the “Best Practices” guidance we issued in 1996, either WTP or WTA can provide an appropriate measure of benefits, depending on the allocation of property rights. We also indicated then that the common preference for WTP over WTA measures was based on the empirical difficulties in estimating the latter. In theory, the two can diverge if income effects are large, if there are no substitutes for the amenity in question, or if there is a substantial degree of “loss aversion.” Empirical support for these theories is not robust, and empirical difficulties in disentangling these effects from other factors have yet to be resolved.

the two measures are not necessarily the same. For example, the amount that a person might demand to allow someone to expose him to one-in-one-thousand risk of death (under the willingness-to-sell measure)<sup>165</sup> probably exceeds the amount that he is prepared to pay someone to reduce an existing risk by an equivalent amount (under the willingness-to-pay criterion). The latter measure depends upon the resources available to the person; the former measure is limitless.<sup>166</sup>

Indeed, this intuition has been borne out by empirical studies. It has been found that “WTA questionnaires generate values from 3 to 19 times greater than those elicited by WTP questionnaires, as reported by one source. For environmental goods, the ratio of WTA to WTP may be as much as 142 to 1, according to another source.”<sup>167</sup> These results are unsurprising, since the poorer the substitutes for the good, the greater the divergence between WTP and WTA,<sup>168</sup> and many, if not most, environmental goods have no close substitutes.<sup>169</sup>

Willingness to Accept more accurately reflects the true value of precious environmental goods. As one scholar points out:

[a] fundamental assumption underlying most health and environmental legislation is that each individual is entitled to some minimal level of security from risks posed by others, and that commonly held resources are likewise protected. Potentially affected individuals or their governmental representatives must be persuaded to accept additional risks; *they cannot be imposed with impunity up to the point at which the potentially affected individuals are willing to pay to prevent the risk producing conduct.*<sup>170</sup>

In other words, the use of the WTP measure assumes that the polluter has extortion rights, and can demand of society, for example, “how much are you willing to pay to avoid further air pollution?” when the question should actually be, “how much would you have to be offered before you would allow more air pollution?”<sup>171</sup> The use of the WTP measure erroneously ignores the public’s ownership interest in the natural environment.<sup>172</sup>

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<sup>165</sup> As used by McGarity, the expression “willingness-to-sell” has the same meaning as “willingness-to-accept.” McGarity, *supra* note 5, at 68.

<sup>166</sup> *Id.* at 67-68.

<sup>167</sup> Zerbe, *Is Cost-Benefit Analysis Legal? Three Rules*, *supra* note 13, at 441 (citing Daniel S. Levy and David Friedman, *The Revenge of the Redwoods? Reconsidering Property Rights and the Economic Allocation of Natural Resources*, 61 U. CHI. L. REV. 493, and Don L. Coursey and Russell D. Roberts, *Aggregation and the Contingent Valuation Method for Evaluating Environmental Amenities*, Working Paper, Olin School of Business Washington University, St. Louis, MO. (1992)).

<sup>168</sup> *Id.* at 442 (citing Michael W. Hanneman, *Willingness to Pay and Willingness to Accept: How Much Can They Differ?*, 81 Am. Econ. Rev. 635 (1991)).

<sup>169</sup> *See id.*

<sup>170</sup> McGarity, *supra* note 5, at 68 (internal citation omitted) (emphasis added).

<sup>171</sup> *See id.* at n.321 (quoting Douglas R. Williams, *Valuing Natural Environments Compensation, Market Norms, and the Idea of Public Goods*, 27 CONN. L. REV. 365, 455 (1995)).

<sup>172</sup> Zerbe explains that:

The standard benefit-cost approach in which losses are valued according to the WTA and gains according to the WTP is consistent with the empirically derived asymmetrical value function of Tversky and Kahneman [1981]. This function reflects a state in which individuals value losses more highly than they value gains. Individuals appear to place a significantly higher value on the units of a good they already have and might

This point is further developed by another scholar:

The logic of using the WTA to measure loss rests on a normative decision to recognize ownership. The WTA recognizes the initial or reference position as one that incorporates already having the good. The WTP incorporates an initial position in which one does not have the good and asks what the good is worth from this position.<sup>173</sup>

Thus, OMB-OIRA should recognize the public's ownership of public goods and use the WTA measure for most environmental goods. In the absence of data to the contrary, OMB-OIRA must assume that WTA will be 3 to 142 times greater than WTP for environmental good.

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lose or have to give up than they place on getting additional units of the same good.  
Zerbe, *Is Cost-Benefit Analysis Legal? Three Rules*, *supra* note 13, at 443.  
<sup>173</sup> *Id.* at 440 (internal citation omitted).