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To: Lorraine D. Hunt OIRA BC RPT/OMB/EOP@EOP

cc:
Subject: Comment on Draft Report

Attached is the Mercatus Center's comment on the Office of Management and Budget's "Draft 2003 Report to Congress on the Costs and Benefits of Federal Regulations" prepared in response to OMB's request for comment [Federal Register: February 3, 2003 (Volume 68, Number 22, Notices)].

If you have any problems with this transmission, please contact me directly. All other inquiries should be addressed to Susan Dudley, Senior Research Fellow and Deputy Director, Regulatory Studies Program, Mercatus Center at George Mason University (sdudley@gmu.edu). Thank you.

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April 29, 2003

Dr. John D. Graham
Administrator
Office of Information and Regulatory Affairs
Office of Management and Budget
NEOB, Room 10202
725 17th Street, NW
Washington, DC 20503

Dear Dr. Graham:

Please find enclosed the comments that we have prepared on the Office of Management and Budget's Draft 2003 Report to Congress on the Costs and Benefits of Federal Regulations.

This report offers an important opportunity for government policymakers and the public to gain a better understanding of the impact of federal regulations. We appreciate the opportunity to comment on it and hope that our comments will assist the Office of Management and Budget in its efforts.

Sincerely,

Wendy L. Gramm, Director
Regulatory Studies Program

Susan E. Dudley, Deputy Director
Senior Research Fellow
Regulatory Studies Program

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REGULATORY STUDIES PROGRAM

Public Interest Comment on the Office of Management and Budget's Draft 2003 Report to Congress on the Costs and Benefits of Federal Regulation[1]

The Regulatory Studies Program (RSP) of the Mercatus Center at George Mason University is dedicated to advancing knowledge of regulations and their impacts on society. As part of its mission, RSP produces careful and independent analyses of agency rulemaking proposals from the perspective of the public interest. OMB's sixth Report to Congress on the Costs and Benefits of Federal Regulations offers an important opportunity for government policymakers and the public to gain a better understanding of the impact of federal regulations. RSP's comments on this report do not represent the views of any particular affected party or special interest group, but are designed to protect the interests of American citizens.

After an introductory section that discusses the importance of regulatory oversight and regulatory accounting, this comment evaluates and critiques OMB's estimates of the costs and benefits of federal regulation. Section II.A addresses OMB's estimates of the total costs of regulation issued over the last decade, Section II.B examines OMB estimates of this year's "major" rules, and Section II.C offers recommendations for improving the benefit-cost estimates. Section III responds briefly to OMB's request for comments on (1) guidelines for regulatory analysis, (2) analysis and management of emerging risks, and (3) improving analysis of regulations to protect homeland security. More detailed critiques of the regulatory analysis guidelines and emerging risks are provided in separate comments. Section IV concludes the comments.

I. The importance of regulatory oversight

In our previous comments on OMB draft reports to Congress, we discussed the importance of regulatory oversight, and the regulatory accounting process Congress initiated when it required these annual reports. The federal government has two principal mechanisms by which it diverts resources away from private sector uses towards government-mandated goals: taxation (and subsequent spending) and regulation. While tax revenues are measured, tracked through the federal budget, and subjected to

[1] Prepared by Susan E. Dudley and Brian F. Mannix, Mercatus Center, George Mason University. This comment is one in a series of Public Interest Comments from Mercatus Center's Regulatory Studies Program and does not represent an official position of George Mason University.

Congressional oversight and public scrutiny, there is no corresponding mechanism for keeping track of the costs of regulation. Since the costs of regulation are not paid directly, as taxes are, Americans don't know what this hidden tax actually amounts to each year. This annual report represents a good opportunity to improve regulatory transparency not only by increasing awareness of the magnitude of the hidden regulatory tax, but also by increasing the accountability of regulators to American people.

It is important to recognize that *all* of the regulatory burden ultimately falls on individuals—consumers, workers, entrepreneurs, investors, taxpayers, citizens, and children—and affects the quality of their lives. Businesses (and governments too, for that matter) are merely intermediaries and cannot "absorb" the real costs of regulation. People bear the burden of this hidden regulatory tax.

We continue to support OIRA's renewed attention to the principles embedded in Executive Order 12866, issued by President Clinton in September 1993. We also commend the increased transparency OIRA has brought to the executive oversight process under President Bush. As we noted in previous comments, while openness and public debate are essential to the process of rulemaking and its oversight; internal communication, coordination, and deliberation are also essential for the Executive branch to operate effectively. To this end, the regulatory analysis guidelines included as Appendix C to the 2003 report should prove valuable at facilitating greater coordination and bringing improved analytical vigor to the regulatory process. We comment on specific aspects of those guidelines in section III.A below, and in more detail in separate comments.

OMB's report shows that, despite renewed efforts, compliance with sound regulatory principles remains uneven. Major regulations are not supported by sound regulatory analysis, yet OMB continues to report agency estimates without standardizing assumptions and methodologies. To truly meet the goals of increased transparency and accountability, OMB should, at a minimum, identify the different assumptions and methods underlying the different agency estimates and the effect they have on the resulting overall estimates.

II. The Costs and Benefits of Federal Regulations

A. Estimates of the Total Costs and Benefits of Regulations Reviewed by OMB

The costs of regulations are a tax on American citizens, but unlike taxes, they are not accounted for in any systematic way. That is why Congress, through Section 624 of the FY2001 Treasury and General Government Appropriations Act, asked OMB to report each year "an estimate of the total annual costs and benefits (including quantifiable and nonquantifiable effects) of Federal rules and paperwork, to the extent feasible:

> (A) in the aggregate;

(B) by agency and agency program; and

(C) by major rule."

There are admittedly numerous methodological and conceptual obstacles to developing reliable estimates of the total costs and benefits of regulation. However, OMB is in the best position to develop such estimates. We are encouraged that OMB has extended its estimate of total benefits and costs by including estimates of the impacts of rules issued between October 1992 and March 1995, as well as major rules issued between October 2001 and September 2002. As a result, OMB's estimates of total regulatory costs and benefits now cover the major regulations issued over the last ten years. These estimates, however, still suffer from serious shortcomings.

1. OMB continues to report estimates prepared by agencies without independent analysis.

OMB's reported estimates are based, as in previous years, on agency estimates of the costs and benefits of regulations. OMB caveats these estimates by saying:

> "We have not made any changes to agency monetized estimates other than connecting them to annual equivalents. Any comparison or aggregation across rules should also consider a number of factors that our presentation does not address. To the extent that agencies have adopted different methodologies—for example, different monetized values for effects, different baselines in terms of the regulations and controls already in place, different treatments of uncertainty—these differences remain embedded in [the total benefit and cost table]. While we have relied in many instances on agency practices in monetizing costs and benefits, our citation of or reliance on agency data in this report should not be taken as an endorsement of all the varied methodologies used to derive benefits and cost estimates.[2]

Aside from this caveat, OMB offers no independent assessment of the quality or usefulness of agency analyses, and correspondingly, the estimates presented in this report. There is little value added in simply compiling the unverified representations of agency management. Such an approach would be unthinkable when dealing with budget expenditures; OMB should make an effort to impose some discipline on agencies' estimates of regulatory expenditures.

We have suggested in previous comments that OMB's reports to Congress should provide more detailed information about the assumptions underlying the benefit and cost estimates of the individual regulations that comprise the aggregate figures. OMB is in a unique position to provide some useful analysis; it has access to agency analyses, interagency discussions, and public comments on individual rules. In the course of its own reviews of significant regulations under Executive Order 12866, OMB analysts

[2] Draft 2003 report, p. 8.

identify strengths and weaknesses of the methodologies agencies use to estimate benefits and costs. At a minimum, it should include those observations in this report in the form of a "report card" that highlights strengths and weakness of each analysis. OMB could present a table, along the lines of that produced in its 1988 Regulatory Program, that summarizes how each regulatory analysis addressed key criteria.[3]

2. The total benefit estimate is influenced heavily by four EPA rules.

OMB reports estimated annual benefits of regulation over the ten-year period (October 1992-September 2002) of between $135 billion and $218 billion. These benefits are much higher (4-5 times) than estimated costs, which OMB reports to be between $38 billion and $44 billion. However, the OMB report notes that EPA estimates of the benefits of four rules – all of which derive benefits from reducing particular matter (PM) emissions – contribute a substantial fraction of the aggregate benefits. EPA estimates, and OMB reports, benefits ranging from $96 billion to $113 billion per year attributable to PM reductions provided by these four rules; that is more than half of the benefits of all regulations combined.

As reported by OMB, EPA estimates that the benefits of reducing PM exceed the costs ($8 to $8.8 billion per year) by a factor of 12 or 13. In a footnote, OMB summarizes the uncertainties associated with benefits attributed to PM reductions, and many commentators have questioned the methodology EPA uses to derive these high benefits. Indeed, in our comments on OMB's 2001 report to Congress[4], we highlighted problems with EPA's estimates of these benefits, including (1) an unrealistic baseline, (2) uncertainties in the magnitude and causation of effects, (3) improper accounting for latency of effects, and (4) exaggerated valuation of health benefits.

The fact that the benefits reported by OMB are so dominated by the questionable analytical approach used to value reductions in one pollutant illustrates the problem with relying uncritically on agency estimates.[5]

The Congress needs an accurate picture of the benefits and costs of regulation; not only to evaluate the performance of existing regulatory programs, but also to make important decisions about future legislation. On its web page for the Clear Skies initiative, EPA continues to promote a highly questionable estimate of benefits based on the same flawed analysis of the health effects of PM, claiming that: "The monetized benefits of Clear Skies would total approximately $96 billion annually by 2020, substantially outweighing

[3] U.S. Office of Management and Budget, *Regulatory Program of the United States Government*, April 1, 1987-March 31, 1989, pp. xv-xvii.

[4] Available at: http://www.mercatus.org/article.php/69.html.

[5] The cost estimates may have similar problems. In a Mercatus Center working paper, Garry Vaughn, PhD finds that EPA's cost estimates for air quality rules are understated by a factor of 4 or more. EPA's Section 812 report on the costs of clean air regulations between 1970 and 1990 estimates present value costs of $523 billion, while Vaughn found costs were more likely to be close to $2.4 billion (both estimates in 1990 dollars).

the annual costs of $6.5 billion."[6] On further reading, one learns that $93 billion of this is from an estimate of health effects, that an alternative estimate of these same health effects in only $11 billion, and (in a footnote) that even the $11 billion may be too high.

It is understandable that agencies try to portray their programs and initiatives in the best possible light. Because health-benefits estimation is subject to considerable uncertainty, there is typically a wide margin between what an agency thinks is "best" for public relations and what a statistician would define as a "best estimate" for scientific purposes. OMB must work to eliminate these biases, which have a disturbing tendency to persist and "bioaccumulate," even as caveats and footnotes tend to disappear.

3. Other estimates of costs and benefits are questionable.

In Table 3 of the report, OMB presents estimated benefits and costs of regulations by selected programs and agencies. Regulations directed at energy efficiency and renewable energy are reported to produce benefits nearly twice the costs. (The benefits range from $4.7 to $4.8 billion compared to costs of $2.5 billion.) However, such a result is inconsistent with economic principles. Energy efficiency regulations restrict consumer choice by forcing consumers to purchase more energy-efficient appliances than they would choose in the absence of federal restrictions. While DOE consistently estimates net benefits from these standards, its analysis derives those benefits by substituting DOE-selected discount rates for consumer discount rates and preferences. In the absence of a significant market failure (which DOE does not identify to justify its regulations), it is implausible that restricting consumer choices will increase net benefits.

4. Costs and benefits of rules issued before 1992 could significantly increase total estimates.

OMB suggests that "the total costs and benefits of all Federal rules now in effect (major and non-major, including those adopted more than 10 years ago) could easily be a factor of ten or more larger than the sum of the costs and benefits" it reports. It recommends more research "to provide a stronger analytic foundation for comprehensive estimates of total costs and benefits by agency and program."[7]

We concur. However, several recent analyses may offer the foundation OMB seeks.

Probably the most dependable estimate of the total costs of regulation is presented in a recent report for the Small Business Administration, by Professors Mark Crain and Thomas Hopkins. They estimate that Americans spent $843 billion in 2000 to comply with federal regulations.[8] This suggests that OMB's factor of 10 estimate (indicating total costs between $380 and $438 billion per year) may understate the actual costs.

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[6] See http://www.epa.gov/air/clearskies/benefits.html , accessed April 28, 2003.

[7] Draft 2003 report, p. 7.

[8] W. Mark Crain and Thomas D. Hopkins, *The Impact of Regulatory Costs on Small Firms*, Office of

In September 2001, the Mercatus Center released a working paper on the costs of workplace regulation.[9] Based on a careful review of available literature, including academic studies, agency regulatory impact analyses, and private sector analyses on the costs associated with 25 major statutory and executive provisions, the study conservatively estimates that workplace regulations cost at least $91 billion per year in 2000 dollars. In contrast, OMB's estimate of the costs of labor regulations issued since 1992 is slightly over 1 billion per year.

B. Estimates of Benefits and Costs of this Year's "Major" Rules

Table 4 of OMB's report presents information on each of the "major rules" issued in final form between October 1, 2001 and September 30, 2002. This table illustrates the range of approaches and the degree of analytical rigor used by agencies in estimating the benefits and costs of economically significant rules pursuant to E.O. 12866. Of the 31 economically significant rules reviewed by OMB and included in this report, OMB classifies the vast majority (25) as "transfers," i.e., they simply shift money from one segment of society to another. OMB reports neither costs nor benefits for transfer rules. Of the remaining six "social regulations," issuing agencies estimated benefits for five, and costs for only three. Thus, of the 31 major rules issued during fiscal year 2002, OMB presents costs for only three, and benefits for only five.

These statistics highlight several problems with relying solely on information reported by agencies.

1. The most obvious is the lack of information on the impacts (costs and benefits) of the major rules issued last year. By definition, an economically significant or major rule has an annual impact of $100,000,000 or more,[10] yet costs are presented for less than ten percent of these rules.

2. There are real costs associated with regulations that effect large "transfers" from one group to another. OMB should investigate and report these costs.

Advocacy, U. S. Small Business Administration, RFP No. SBAHQ-00-R-0027.

[9] Joseph M. Johnson, *A Review and Synthesis of the Cost of Workplace Regulations*, Mercatus Center at George Mason University, Working Paper Series, September 2001.

[10] E.O. 12866 (available at: http://www.whitehouse.gov/omb/inforeg/eo12866.pdf) defines a significant regulatory action as one that "is likely to result in a rule that may:

(1) Have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities;

(2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;

(3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or

(4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in this Executive order.

3. For 2 of the rules, agencies report only expected benefits, not expected costs, which is likely to overstate any net benefit estimate

Scholars in the Regulatory Studies Program of the Mercatus Center at George Mason University have commented on 3 of the 6 regulations summarized in Table 4. These comments raised questions about the benefit and cost estimates developed in the draft Regulatory Impact Analyses and relied on in OMB's table, and are summarized below. [11]

1. DOE's Energy Conservation Standards for Central Air Conditioners and Heat Pumps[12]

DOE's benefit estimates are based almost exclusively on cost savings to the average consumer estimated using unrealistic discount rate assumptions, without adequately considering either different usage patterns, or the value consumers place on reliability, performance (especially dehumidification), or esthetics. The standards would require consumers in northern states to purchase high-cost air conditioners, and residents of southern states to purchase high-cost heat pumps, even though they would not likely recoup those up-front costs in lower energy bills over the life of the unit. DOE's static comparison of up-front costs to operating costs also ignores the fact that once the initial investment is made, lower operating costs will encourage more usage of the unit, leading to increased energy use (less conservation). Since air-conditioning usage is highly elastic, forcing consumers to use higher efficiency units may increase energy consumption instead of decreasing it. Rather than providing net benefits of almost $2 billion per year, as estimated by DOE and reported by OMB, these standards will likely impose net cost on consumers.

2. EPA's Rule to Control Emissions from Nonroad Large Spark-Ignition Engines and Recreational Vehicles[13]

EPA's analysis supporting this rule did not show that nationwide standards will be effective at meeting air quality in the urban regions that are out of attainment, but instead justified the rule on cost-per-emitted-ton measures that do not inform policy makers as to whether the restrictions will actually contribute to air quality goals. EPA also justified the stricter emission standards on alleged fuel cost savings to purchasers of these vehicles without recognizing that purchasers value other qualities that would have to be forfeited in these machines.

Instead of economic costs, the Agency estimated the engineering costs that producers would face in modifying engine designs and developing new technologies needed to meet the emission standards. Our review of EPA's analysis also revealed an inconsistent and

[11] For a complete list of regulations on which scholars at the Mercatus Center have commented, go to www.Mercatus.org and click on Regulatory Studies.

[12] Available at the Mercatus web site: http://www.mercatus.org/research/RSP200113.htm.

[13] Available at the Mercatus web site: http://www.mercatus.org/research/RSP200116.htm.

inappropriate treatment of research and development costs, flawed "learning curve" treatment of variable costs, and a flawed treatment of fixed costs.

3. DOT Light Truck Average Fuel Economy Standards[14]

The Department of Transportation was restricted from analyzing the costs and benefits of CAFE standards for model year 2004, so the OMB report includes no estimates for this rule. However, NHTSA's economic model supporting its CAFE standards for 2005-2007 shows large net benefits to consumers even if markets are assumed to operate perfectly, i.e., without counting any externalities. We know this must be false, because the fundamental premise of benefit-cost analysis is that all benefits and costs must be valued according to the consumers' own preferences. Any regulatory constraint that forces consumers away from their preferred choices must have negative net benefits. NHTSA's results prove that its model must be wrong.

The model year 2004 standards are thus likely to impose net costs on consumers. Errors like this should not be incorporated into OMB's report uncritically.

C. Recommendations for Improving Total Benefit-Cost Estimates

1. OMB should hold agencies accountable for analysis that complies with its economic analysis guidelines.

OMB's guidelines for regulatory analysis reflect generally accepted principles for evaluating the impacts of regulation. In the course of E.O. 12866 review, it should hold agencies accountable for following the guidelines.

2. The report should present OMB's objective estimates of the benefits and costs of individual regulatory actions.

In many cases agencies are required by law to issue regulations whose costs exceed the benefits—although the agencies are understandably reluctant to say so. Nonetheless, in its report to Congress, OMB should report benefits and costs honestly and without deliberate bias. OMB should report best (i.e., expected value) estimates of aggregate benefits and costs, in addition to ranges. OMB should identify in a concise but comprehensive manner variations in agency methodologies used to estimate benefits and costs of individual regulations. It should present a "report card" for agency analyses that highlights their strengths and weaknesses.

[14] Comments on the light truck CAFÉ standards for 2005 are available at: http://www.mercatus.org/article.php/208.html.

3. OMB should continue to build its regulation-by-regulation database of the costs and benefits of regulations issued before 1992.

The report recognizes that "the total costs and benefits of all Federal rules now in effect (major and non-major, including those adopted more than 10 years ago) could easily be a factor of ten or more larger than the sum of the costs and benefits" it reports. OMB should be commended for providing estimates for a ten-year period in this report. It is in the best position to continue to extend its estimates to include costs and benefits of regulations issued before 1992.

4. OMB should attempt to estimate the dead-weight loss associated with "transfer rules"

There are real costs associated with regulations that effect large "transfers" from one group to another. At the very least, OMB should estimate the deadweight loss associated with the transfer (as it has done in previous years' reports). OMB has estimated the "excess burden of taxation" at 25 percent of revenues. It would be surprising if transfers effected by regulation had a deadweight loss any less than that. In addition, regulations that transfer wealth are typically the product of lobbying and other rent-seeking behavior on the part of the beneficiaries. Such rent-seeking will dissipate the benefits, so that costs assumed to be transfers may in fact represent real resource costs.[15] OMB should investigate and report these costs.

III. Recommendations for Reform

In this report, OMB has taken a different approach to eliciting recommendations for reform, as required by Congress. It asks for comment on (1) draft guidelines for regulatory analysis, (2) approaches for analyzing and managing emerging risks, and (3) improving the analysis of regulations related to homeland security. We address these briefly below. In separate comments, we provide a more detailed review and critique of the draft Guidelines for Regulatory Analysis.

A. Regulatory Analysis Guidelines

As recommended above, developing clear analytical guidelines, and holding agencies accountable for complying with them, would be an important step toward regulatory reform. Appendix C of the draft 2003 report presents draft guidelines for regulatory analysis. The draft revises guidelines first issued during the Reagan administration in 1988, and then revised by the Clinton administration in 1996 and 2000.[16]

[15] Gordon Tullock. "The Welfare Costs of Tariffs, Monopolies and Theft" *Western Economic Journal*, 5, pp. 224-232. (1967).

[16] The 1996 guidelines were not called guidelines but "Best Practices."

The draft guidelines provide more detailed guidance than its predecessors in several key areas, including the conduct of cost-effectiveness analysis as well as benefit-cost analysis, and treatment of uncertainty using formal probabilistic analysis. It is also refreshing that they encourage agencies to be transparent in their analysis and assumptions so that reviewers can understand and reproduce results. The guidelines should ensure greater consistency across agency analyses, and should facilitate more accurate annual reporting of regulatory costs and benefits as required by Congress.

Despite these good qualities, the draft also takes some curious turns that seem inconsistent with an administration philosophy that embraces markets and limited government. For example, the draft is arguably less demanding than either the Reagan or Clinton guidelines in its requirement that, before considering regulatory intervention into private markets, an agency must first identify a significant market failure (why the private sector can't address the issues without regulation). The new guidelines cite "other possible justifications" for regulatory action, including "promoting privacy and personal freedom." It provides no example of when regulation (which, almost by definition, *restricts* personal freedoms) would be necessary to *promote* personal freedom.

The draft also suggests "harmonization of U.S. and international rules may require a strong Federal regulatory role." What this means is unclear. Would the new guidelines endorse restrictions on promising new therapeutic or agricultural products to "harmonize" with European Union members who resist biotechnology techniques? U.S. foreign policy ought to stress our objective of exporting freedom, not importing government regulations—particularly regulations that lack any economic rationale apart from "everybody does it."

1. Discounting inter-generational effects

The draft guidelines venture into some controversial areas. On "ethical grounds," yet without any economic or empirical rationale, it advocates applying discount rates as low as one percent for measuring long-term (inter-generational) benefits and costs.

OMB refers to a conference volume published by Resources for the Future[17] as justification for annual discount rates as low as 1 percent. Yet, a careful review of the papers in this volume does not offer clear support for a low intergenerational discount rate. As discussed more fully in our companion comment on OMB's guidance, as many of the papers in the volume offer evidence that a low rate would be *inappropriate*. Most of the authors who expressed concern that the results of traditional discounting violate ethical intuition were unable to defend making decisions based on an arbitrarily low discount rate.

We believe it is a mistake to vest the discount rate with moral significance. It is simply a price, formed by the interaction of supply and demand and strongly influenced by the

[17] Paul R. Portney and John P. Weyant (eds.), *Discounting and Intergenerational Equity,* Washington, D.C.: Resources for the Future, 1999.

state of technology. It should reflect the opportunity cost of the investment, or the foregone benefits of other projects not undertaken as a result of a mandated government expenditure, which could have provided value for future as well as current generations.

In comments on a paper in the volume, Jerome Rothenberg notes that abatement (of future problems, like climate change) takes two forms: prevention or adaptation. A subset of adaptation "is to make provision for a general subsidizing of those [future] generations in terms of overall productivity—in effect, a reimbursement to them for sustaining unmitigated climatic damages." Thus, the opportunity cost of preventive abatement actions is the lost productivity of adaptation/reimbursement investments, which can be approximated by market rates of return on capital.[18]

Looking hundreds of years into the future is difficult; so let's examine a low-discount-rate approach by looking to the past. If we could go back in time, would we really ask our (relatively poorer) ancestors to set their money aside at a one percent return for our benefit? Indeed, would we even be better off if they had done so? They would have had to forsake many higher return investments to make this "investment in the future" and as a result, our standard of living would likely be lower today, even with the "inheritance" they left us invested at a one percent rate.

As OMB recognizes, rates of return that are required for private investments are already much higher than those routinely accepted by government agencies, in part because of the burden of taxation. This distortion will be exacerbated if government agencies are permitted to justify proposals that return benefits of only one percent, and do that only after decades or centuries pass. Such low-value government-mandated projects will displace ever greater amounts of private investment, raising the question of how the CEA can forecast long-term economic growth in excess of one percent annually, when it is so willing to displace the high-value private investment that drives economic growth.

2. Use of contingent valuation surveys for estimating non-use values

The draft, like the Clinton guidelines before it, supports the use of the controversial benefit-valuation technique known as contingent valuation (CV). Noting that CV may be the only method available to estimate "non-use" values, the guidelines attempt to address its problems by enumerating "best practices" for conducting CV. But, as Boudreaux, Meiners & Zywicki[19] show, the practical problems of CV cannot be resolved with better surveys because the technique itself is conceptually flawed. CV studies rest on the assumption that values are absolute and static, when in reality they are relative and dynamic, formed by the interaction of market forces.

[18] Rothenberg also notes that when investments come at the expense of investment and consumption, a social discount rate, rather than the private cost of capital, is appropriate (p. 107).

[19] Donald J. Boudreaux, Roger E. Meiners and Todd J. Zywicki. "Talk is Cheap: The Existence Value Fallacy," *Environmental Law.* Northwestern School of Law of Lewis and Clark College. Vol. 29, No. 4 (1999).

Kahneman, Ritov, and Schkade find that willingness to pay estimates derived from CV studies, though denominated in dollars, "are better viewed as expressions of attitudes than as indications of economic preferences," and that "the anomalies of CV are inevitable manifestations of known characteristics of attitudes and attitude expressions."[20] They find that stated preferences derived from CV studies are analogous to juries' punitive damage awards, and are not consistent with economists' rational models.

Both jury awards and CV results seem to reveal a normative notion of what should be, divorced from actual behavior or revealed preferences. But how much weight should these prescriptive notions carry in designing government policy? Boudreaux *et. al.* point out,

> In market transactions, we can assume that all individual trades increase individual utility, because the occurrence of the trade itself suggest that the individual values the good received more highly than the good surrendered. Thus, it is only through the process of actual exchange of one good for another that we can know for sure that an individual values one option over another… Divorced from the discipline of making actual choices, the hypothetical choices presented by contingent valuation have little value.[21]

Kahneman *et al* and Boudreaux *et al,* through very different paths, reach the conclusion that stated preferences divorced from any expectation of actually having to pay the stated values, are not accurate proxies for revealed economic preferences. The similarities Kahneman *et al* find between jurors and CV respondents suggests that, like jurors determining civil damage awards, CV respondents view the values they assign as imposing costs on someone other than themselves. They know they will never have to pay the values they profess to place on different amenities. Indeed, it strikes us as unrealistic to think that individuals would give up more than a small amount of income or other use value in exchange for a non-use value. It is equally unrealistic to assume that it is in society's interests to pursue government policies that would divert society's scarce resources based on these subjective, stated preferences.

B. Analysis and Management of Emerging Risks

The report notes that "US regulators rely on various science-based precautionary approaches in assessing potential hazards and taking protective actions." "For purposes of collecting and analyzing current risk assessment and management practices in federal agencies, with an emphasis on the role of precaution in risk policy and regulation, the

[20] Daniel Kahneman, Ilana Ritov, and David Schkade, "Economic Preferences or Attitude Expressions?: An Analysis of Dollar Responses to Public Issues," in *Journal of Risk and Uncertainty,* 19:1-3; 203-235 (1999).

[21] Boudreaux, *et. al., Op. Cit.* p. 785.

Administration has formed an Interagency Work Group on Risk Management,"[22] and requests comment on several questions, which we address below.[23]

Before we address the specific questions however, a brief introduction to the concept of "precaution" in risk policy and regulation is in order. The essence of OMB's question is how should regulators behave when there exists uncertainty about the likelihood or magnitude of potential harm associated with human action. Some advocate the "precautionary principle" as the guiding principle for policies directed at public health and the environment. There is no widely endorsed definition of the precautionary principle, but one that is often cited is the January 1998 Wingspread Statement on the Precautionary Principle:

> When an activity raises threats of harm to human health or the environment, precautionary measures should be taken even if some cause-and-effect relationships are not fully established scientifically.[24]

Variations on this principle have appeared in several international environmental agreements and declarations and have been used to justify international controls or bans on various technologies.[25] Concerned that the "burden of scientific proof has posed a monumental barrier in the campaign to protect health and the environment,"[26] proponents turn to the precautionary principle to avoid having to justify decisions based on available evidence, but instead based on a "better safe than sorry" approach.

The problem with this approach is that it does not recognize that inaction, as well as action, bears risks. Sunstein points out that "risks of one kind or another are on all sides of regulatory choices, and it is therefore impossible, in most real-world cases, to avoid running afoul of the principle.[27]

In his book, *The Precautionary Principle: A Critical Appraisal of Environmental Risk Assessment*, Indur Goklany[28] shows that the current use of the precautionary principle is flawed in that it focuses simplistically on potential dangers associated with new technologies and ignores the very real risks that could be mitigated by those technologies.

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[22] 2003 draft p. 19.

[23] In separate comments on this draft report, other Mercatus scholars provide additional feedback on this issue.

[24] Wingspread Statement: A Common Sense Way to Protect Public Health & the Environment, Prepared by the Science & Environmental Health Network, January 25, 1998 <<http://www.sehn.org/wing.html>>

[25] For example, Principle 15 of the Rio Declaration (UN 1992:10), Convention on Biological Diversity, Article 3.3 of the U.N. Framework Convention on Climate Change (UNFCC, 1992). See Goklany 2001 for a discussion of these declarations.

[26] Joel Tickner, Carolyn Raffensperger, and Nancy Myers. *The Precautionary Principle In Action: A Handbook,* First Edition. Science and Environmental Health Network. (1998) Available at http://www.sehn.org/rtfdocs/handbook-rtf.rtf

[27] Cass Sunstein, "The Paralyzing Principle." *Regulation* Vol. 25, No. 4 (Winter 2002-2003) Cato Institute. Available at www.regulationmagazine.com.

[28] The Cato Institute, 2001.

For example, advocates of applying the precautionary principle to new genetically modified organisms interpret it as requiring that a new substance not be introduced "unless you have proof it will do no harm to the environment."[29] This approach would apply precaution only to the unknown risks a new technology might introduce, without regard to the benefits to health or the environment that will be foregone if it is banned.

Goklany proposes an alternative approach to "precaution" in policy making that considers the risks of inaction as well as the risks of action. While we do not endorse all aspects of Goklany's formulation of a precautionary principle, we highly recommend his thoughtful book to OMB and the task force. He offers a set of criteria on which to construct a precautionary framework:

1. The *public health criterion* suggests that threats to human health take precedence over threats to the environment.

2. The *immediacy criterion* requires that more immediate threats be given priority over threats that could occur later.

3. The *uncertainty criterion* calls for threats that are more certain to take precedence over less certain threats.

4. The *expectation-value criterion* says that for threats that are equally certain, the one with the higher expected value should receive greater weight.

5. The *adaptation criterion* states that "if technologies are available to cope with, or adapt to, the adverse consequences of an impact, then that impact can be discounted to the extent that the threat can be nullified."

6. The *irreversibility criterion* requires that greater priority be given to outcomes that are irreversible, or likely to be more persistent.[30]

Rather than using these criteria one at a time, as Goklany suggests, we find them very useful factors to consider when conducting benefit-cost analysis. Examining the benefits and costs of different policy options with these criteria in mind would help policy makers balance the risk of accepting new products or technologies too quickly and without complete information against the risks of delaying or foregoing new products or technologies.

We now turn to the specific questions posed by OMB in the draft report.

1. Ways in which "precaution" is embedded in current risk assessment procedures through "conservative" assumptions in estimation of risk, or through explicit "protective" measures in

[29] Goklany, quoting Leggett of Greenpeace, p. 2.

[30] Goklany pp 9-10.

management decisions as required by statutory requirements as well as agency judgments. [31]

Precaution is embedded in current risk assessment procedures, particularly those directed at human health risk assessments, but such precaution may harm, rather than protect, public health. Risk assessments based on animal studies, in particular, present policy makers with only the high end of the range of possible risk outcomes. This is a problem because when agencies focus their efforts on regulating insignificant risks, they may forsake more significant risks, or inadvertently create even greater risks.

Most estimates of human risk from exposure to a substance come from extrapolating risks from animal studies, or from studies of human populations exposed to very high doses of the substance. This raises difficult questions, including how to treat differences between species (e.g., rats and humans) and how to extrapolate the effects of very high doses to the relatively low exposure levels encountered by Americans. Currently, the assumptions used to make these extrapolations are very cautious, resulting in exaggerated estimates of risk. Generally, the risk estimates derived from these conservative assumptions are treated as expected values, rather than upper bounds, leaving regulators poorly informed about how effective regulation will be.

2. **Examples of approaches in human and ecological risk assessment and management methods addressed by US regulatory agencies (e.g., consumer product safety, drug approval, pesticide registration, protection of endangered species) which appear unbalanced.** [32]

As discussed above, risk assessments methods in the U.S. systematically overstate estimated risks. EPA's regulation limiting arsenic in drinking water to 10 ug/l, for example, likely overstates the risk to exposures in the U.S. significantly.

- The 10 ug/L standard was based largely on Taiwan studies which linked long-term exposure to arsenic levels that are 10 times higher than the current U.S. standard to increased risk of lung and bladder cancers.

- These study populations differ in important ways from the U.S. population, for example they had a higher incidence of smoking and poorer nutrition. By ignoring these differences, EPA likely overstated by a significant amount the risk of arsenic ingestion in the U.S.

- The assumption of a linear dose-response function to extrapolate effects at 500 ug/L down to levels of 50 ug/L, 20 ug/L and 10 ug/L is not consistent with either National Academy of Science (NAS) findings or available evidence on the mode of action for arsenic-associated cancers and is likely to overstate risk at low doses.

[31] 2003 draft p. 20.

[32] 2003 draft p. 20.

- EPA improperly discounted an epidemiological study of Latter Day Saints in Utah (Lewis et al., 2000), which found no statistical evidence linking the amount of arsenic ingested in drinking water with elevated risks of bladder or lung cancer.[33]

The Food and Drug Administration's new drug and devise approval process is another example where precaution can imperil Americans' health. According to one medical doctor who studies FDA policy, "the average number of clinical trials performed on an average drug increased from 30 in the early 1980s to 68 during 1994-95, while the average number of patients in clinical trials for each drug more than tripled. Furthermore, the average time required for clinical trials of a new drug increased from 85 to 92 months from the first half of the 1990s to the second half."[34] The time and cost involved in bringing a new drug to the market prevents new life-saving treatments from reaching people who need them and ends up costing lives.

Another commentator illustrated this problem with the 15 years FDA took to approve an artificial valve, which significantly reduces embolism risk. Approved by the FDA in 2001, the valve had been available since 1986 or earlier in Italy, Germany, France, Switzerland, and Japan. "Given the fact that approximately 16,000 heart valve recipients per year in the U.S. experience bleeding complications, many of them fatal, the Omnicarbon valve offers major life-saving benefits—benefits which were denied to the American public due to the FDA's 15-year delay."[35]

3. How the US balances precautionary approaches to health, safety and environmental risks with other interests such as economic growth and technological innovation.[36]

In 1983[37] the National Academy of Sciences codified the process by which regulators should quantitatively evaluate risks and make policies to reduce those risks. It suggested separating the process into two parts: risk assessment and risk management. *Risk assessment* is a purely scientific process that measures the risk of an activity. For example, risk assessment could estimate the risk of contracting cancer from exposure to a certain chemical over a certain length of time. Risk assessment cannot tell whether that risk is too high, or what should be done about it. That decision is made in the risk management phase. *Risk management* takes scientific risk assessment information and combines it with other information, such as the cost and feasibility of reducing risks, to determine what action to take.

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[33] Robert S. Raucher, PhD Comment on EPA's Proposed National Primary Drinking Water Standards: Arsenic, Mercatus Center at George Mason University, RSP 2000-18. 2000 Available at http://www.mercatus.org/article.php/87.html.

[34] Henry Miller. "Strong Bush Prescription Needed to Cure an Overactive FDA" Guest Op-Ed *Findlaw.com.* January 12, 2001.

[35] Competitive Enterprise Institute press release. "CEI Criticizes FDA Delay In Approving New Heart Valve." June 27, 2001.

[36] 2003 draft p. 20.

[37] National Academy of Sciences. *Risk Assessment in the Federal Government: Managing the Process.* Washington, DC: National Academy Press. 1983.

This appears to us to be a sound process. It relies on most-likely estimates of risk based on available scientific evidence, and explicitly considers tradeoffs of different actions. Unfortunately, as discussed above, the results of the risk assessment phase tend to be systematically biased, which confounds the risk assessment/risk management division. Because of that systematic bias, uncertain risks are likely to be weighed more heavily than more certain risks of harm.[38] Whatever its merits, precaution is a risk-*management* technique, and there is no place for it in risk *assessments*.

C. Analysis of Regulations Related to Homeland Security

OMB observes that it expects a significant number of homeland-security proposals in the future and requests comment on how best to evaluate their benefits and costs. OMB is asking important questions. The nation suffered a massive blow after the attacks of September 11, 2001. Much like the pattern Higgs describes in *Crisis and Leviathan*,[39] the nation has responded emotionally, and political priorities have changed. New government machinery has been designed and installed, and older programs have been expanded. Unlike past ratchet-like responses that led to a larger federal establishment and expenditures, the new ratchet will likely be built only partly of larger employment levels and increased expenditures of tax money. Regulation will form the other, and perhaps most significant, part.[40] Thus, it is essential that OMB continue to fulfill its functions under Executive Order 12866 to ensure these new regulations are truly in the public interest.

D. Other Recommendations

In future reports, OMB should consider expanding its interpretation of "recommendations for reform." Several commentators have suggested the development of a regulatory budget, and that is part of the rationale for this annual report to Congress on the Benefits and Costs of Federal Regulations. What other changes in regulatory procedures might provide more accountability to the public? For example, Supreme Court Justice Stephen Breyer once suggested that agency-issued regulations should not have the force of law until enacted into law by the Congress. Others have suggested that some regulatory standards could be developed as recommendations by federal agencies, to be enacted by state legislatures. The Toxic Substances Control Act of 1976 asked the EPA to consider whether the government should compensate individuals for the costs imposed by EPA's regulatory programs.[41] It would be useful for OIRA to assemble a catalog of ideas for generic regulatory reform, including some that have been tried in other nations, and begin a public discussion of their merits and weaknesses. Even if some of the ideas seem

[38] See "The Perils of Prudence" by Albert Nichols and Richard Zeckhauser, *Regulation* Nov/Dec 1986 for a discussion of how deliberately bias risk assessments can backfire.

[39] Robert Higgs. *Crisis and Leviathan: Critical Episodes in the Growth of American Government.* Oxford: Oxford University Press. 1987.

[40] Susan Dudley & Bruce Yandle. *Is 9/11 a Crisis to be followed by a Leviathan?* Mercatus Center at George Mason University (2002) Available at: http://www.mercatus.org/article.php/52.html.

[41] Section 25(a).

impractical, such a discussion would help advance our understanding of the nature of government regulation and the pathologies that afflict it.

IV. Conclusions

We strongly support efforts by OMB and the respective agencies to assess regulatory costs and benefits, and are encouraged by OMB's extension of its regulation-by-regulation estimates back to 1992. However, the data as presented are still inconsistent and fragmentary and may not offer the American public an accurate picture of the benefits and costs of regulation. As illustrated above with rules Mercatus scholars have studied, individual estimates are not made in accordance with the Administration's Guidelines. Moreover total cost and benefit estimates are not based on a consistent and objective review of available information.

Holding agencies accountable for basing policy on sound regulatory analysis grounded in accepted scientific and economic principles is an important step. The revised guidelines for the conduct of regulatory analysis and the format of accounting statements, presented in draft as Appendix C of the draft report should support this, though we note here and in more detail in comments on those guidelines that some aspects of the guidelines may undermine the ability of regulators to ensure their initiatives do more good than harm.

Regulations impose a hidden tax on Americans, a tax that ultimately falls on individuals—consumers, workers, entrepreneurs, investors, taxpayers, and citizens—and affects the quality of their lives. In order for the Legislative and Executive branches to understand better the effects of regulations on society, a sober and rigorous analysis of regulatory costs and benefits is vital. We therefore urge OMB to continue this process and include the refinements to the annual report and guidelines that we have suggested.