



**Testimony of Wesley Warren
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The Role of Science in Regulatory Reform

**Investigations and Oversight Subcommittee
House Science and Technology Committee**

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Good morning and thank you for the opportunity to testify on The Role of Science in Regulatory Reform. My name is Wesley Warren, and I am the Director of Programs for the Natural Resources Defense Council (NRDC). NRDC is a national, nonprofit organization of scientists, lawyers and environmental specialists dedicated to protecting public health and the environment. Prior to joining NRDC I served in the White House as Chief of Staff at the Council on Environmental Quality and as Associate Director for Natural Resources, Energy and Science at the Office of Management and Budget. I previously worked on the professional staff of the House Science and Energy and Commerce Committees.

The role of science in regulatory reform is an important and timely topic and I commend the subcommittee for making it an area of focus early in the 111th Congress. As members of this Committee know, science is at the very core of the work many of our agencies do to fulfill their missions, particularly when those missions involve protecting public health and the environment. How scientific analysis is conducted by those experts within federal agencies, and how science fares in relation to other considerations taken in the regulatory process, can make enormous differences in whether laws passed by Congress are implemented as intended, and how effectively those laws protect the public. It is not an overstatement to say that these questions and how they are resolved can make the difference between life and death, or life and health, for many Americans.

Too often in recent years, proposed agency actions based upon the solid scientific work of agency experts that would have improved protection of public health and the environment have been blocked, delayed, watered down or otherwise weakened based upon ideological-imposed criteria that were never authorized by Congress. An important source of this diversion and delay of public health protections has been the Office of Management and Budget (OMB), and specifically the Office of Information and Regulatory Affairs (OIRA).

Under Executive Order 12866, which succeeds previous Executive Orders, OMB is given substantial authority to review agency actions including rulemaking, guidance, and even propounding information requests. OMB has frequently used this authority, particularly (but not exclusively) in recent years, to interfere with agency efforts to carry out their science-based missions, and to impose consideration of other factors never sanctioned by Congress. Moreover, OMB has frequently used methods to influence regulatory outcomes that run counter to principles of open government and transparency.

This subcommittee held a hearing last summer that considered some examples of these problems, including OMB's revised process for overseeing and interfering with EPA's development of hazard assessments for toxic chemicals through its IRIS program. My NRDC colleague Dr. Linda Greer testified before the subcommittee on that issue.

Less than a year later, these types of problems are receiving renewed scrutiny, prompted in part by the new Administration's request for public comments on whether and how to amend EO 12866. NRDC responded to the Administration's call for comments on how to improve the way our regulatory process functions. Below I provide an overview of the

issues raised by the potential revision or replacement of the Executive Order, followed by a summary of the recommendations NRDC submitted to the administration. I will then outline in some detail the basis for those recommendations.

I. OVERVIEW

On February 26th, the Office of Management and Budget (“OMB”) placed a notice in the *Federal Register* that it would be making recommendations for a new Executive Order of Federal regulatory review. NRDC submitted comments pursuant to that notice as OMB requested submissions on eight specific areas: the relationship between the Office of Information and Regulatory Affairs (“OIRA”) and the agencies; disclosure and transparency; encouraging public participation in agency regulatory process; the role of cost-benefit analysis; the role of distributional considerations, fairness and concern for the interest of future generations; methods of ensuring that regulatory review does not produce undue delay; the role of the behavioral sciences in formulating regulatory policy; and the best tools for achieving public goals through the regulatory process.

In some ways the most significant issue area is the last area listed by OMB for requested comments, namely, identifying the best tools for achieving public goals through the regulatory process. The most important aspect of this issue has to do with the philosophy of government to be used by the administration.

The previous administration had an ideological view of the role of government in the economy which held that, on the face of it, government involvement in regulating economic behavior was necessarily undesirable. An extension of this view was that regulatory policy should have review procedures that would work presumptively against approving regulatory actions. The assumption behind this approach is that since government action so often does more harm than good, then it is better to prevent more regulation as a matter of course and to only allow those that pass an overwhelming burden of proof.

As current events indicate, this ideological view is ill-founded conceptually and poorly documented empirically. In contrast, sound public policy should embrace the concept that it is just as undesirable to under-regulate bad market behavior as it is to interfere needlessly with a well-functioning marketplace. Getting the amount of regulation “just right” should be the goal of public policy, with a presumption that having enough of the right kind of regulation was a sought after outcome.

In environmental policy specifically there is considerable amount of empirical evidence that points to the approaches that are most likely to achieve the right amount of regulation. It should be noted that past reports by OMB have amply documented a highly favorable ratio of benefits to costs resulting from environmental regulations. However, it should also be emphasized that using a cost-benefit test is one of the worst methods on which to rely for environmental decision-making.

As my testimony will discuss later in more detail, cost-benefit analysis (CBA) is an analytical tool that intellectually is designed to prevent too much regulation, and which as a result ends up professing much too little. This highly pronounced asymmetry of results is very undesirable from a public policy perspective and argues both for reforms in CBA procedures and for limitations on its use.

Fortunately the public record abounds with successful alternatives to the use of CBA as the decision-making criteria in environmental policy. In contrast to environmental statutes that rely on cost-benefit or risk assessment requirements, the most successful statutes are those that rely on health-based or technology-based standards. The goals of the latter statutes are much more obtainable and the burdens of proof are much more achievable than the former.

In addition, the precautionary principle acts as an ally to environmental policy and a philosophic alternative to CBA. The precautionary principle formalizes the common sense notion that it's better to be safe than sorry. This approach in effect shifts the burden of proof to those who may engage in undesirable social actions to prove that they are acceptable. This shift acts as an antidote to CBA's overly conservative intellectual framework that is preoccupied with preventing too much regulation. Again the empirical record is filled with statutes that have successfully taken a precautionary approach to public policy to provide a level of protection for society that is much more likely to be just right.

As for the issue concerning the relationship between OIRA and the agencies, it is the view of NRDC that OIRA in particular and the Executive Office of the President (EOP) more generally should respect the statutory authority of the federal agencies and their issue expertise during the rule making process. That means that OIRA should focus its attention on ensuring compliance with statutory requirements, enhancing the efficiency of agency actions, and providing interagency coordination rather than micromanaging the content of agency decision-making in respect to specific policies.

NRDC also strongly supports the principles of transparency and disclosure in government. They provide an essential guarantee to the public that decision making is conducted through the proper channels and informs the public of the true basis of government actions. Executive branch input on proposed agency regulations should be included in the administrative record for judicial review of final agency rules, except where prohibited by law. Because such input is considered by the agency decision-maker, it is properly considered part of the "whole record" for judicial review pursuant to the Administrative Procedure Act, 5 U.S.C. § 706.

Equally important in a democracy is the role of public participation in the decision-making process. This is one of the most critical means by which the people affected by governmental decisions can make sure that their opinions are adequately taken into account by policymakers.

Although details vary, many other recent commentaries generally agree with the views stated herein on the proper role of OIRA, the need to improve the use of cost-benefit analysis, and the virtues of greater disclosure, transparency and public participation.¹

II. SUMMARY OF RECOMMENDATIONS

1. Sound public policy should embrace the concept that it is just as undesirable to under regulate bad market behavior as it is to interfere needlessly with a well-functioning marketplace. Getting the amount of regulation “just right” should be the goal of public policy, with a presumption that having enough of the right kind of regulation was a sought after outcome.
2. It is the view of NRDC that OIRA in particular and the Executive Office of the President (EOP) more generally should respect the statutory authority of the federal agencies and their issue expertise during the rule-making process.
3. NRDC also strongly supports the principles of transparency and disclosure in government. Executive branch input on proposed agency regulations should be included in the administrative record for judicial review of final agency rules, except where prohibited by law. Because such input is considered by the agency decision-maker, it is properly considered part of the “whole record” for judicial review pursuant to the Administrative Procedure Act, 5 U.S.C. § 706.
4. NRDC strongly supports increased public participation in the decision-making process, an important component to democracy.
5. NRDC strongly recommends that CBA not replace or supplement the decisional criteria of the underlying statutory authority, and that to the extent it is used as an informational tool, the administration should work to reduce its serious flaws.
6. NRDC has requested that OMB conduct a review of past estimates of the costs of environmental compliance and compare them to actual costs, and then devise a methodology protocol for adjusting static cost estimates by more accurately adjusting for costs. Additional research can refine this concept over time, but the inclusion of a standard concept for making this adjustment could help to address the overstatement of costs that tends to systematically occur even in government estimates.
7. NRDC has requested that OMB lead a policy process to examine the inherent undercounting of benefits in cost-benefit analysis and to develop a methodology protocol by which decision makers can systematically compensate for this deficiency in their use of the tool for informational purposes.
8. In the interest of both sound regulatory processes and healthful environmental outcomes, NRDC has suggested that OMB review all the Bush administration

- changes to Circular A-4 and consider completely repealing all the changes made to the Clinton Best Practices document, especially those related to discount rates, the value of statistical life-years, and false thresholds for analysis. OMB should also raise the current quantitative threshold for a major rule from \$100 million and limit review to rules that cost more than this level without regard to qualitative criteria such as novel legal and policy issues.
9. NRDC has asked the Obama OMB to remove the use of these alternative practices from use and the record of analysis, as the whole purpose of these alternative analyses is to put benefit calculations step-by-step on a downward path in part by creating uncertainty about the results of the main analysis.
 10. Any new executive order on federal regulatory review should reinforce the administration's commitment to addressing distributional considerations, especially those that affect minorities, low-income populations, future generations and children. These considerations are particularly important for environmental regulation. NRDC also recommends committed implementation of Executive Order 12898, addressing environmental justice in minority populations and low-income populations, and Executive Order 13045, protecting children from environmental health risks and safety risks.
 11. OMB should establish written, publicly available performance requirements and milestones for OIRA review of agency actions to ensure efficient and timely completion of duties, and there should be an accountability mechanism to ensure that OIRA meets these performance standards. As noted in these comments, these performance requirements should more closely and transparently document exchanges among OIRA, the agencies and outside parties, and should follow a formal process that has clear and reasonable deadlines and a manageable appeals process.

III. GENERAL ISSUES CONCERNING COST-BENEFIT ANALYSIS

CBA can be a useful tool for helping to organize information in the regulatory review process. In some fields, where the costs and benefits are fairly well known and are both of a strictly monetary nature, CBA may even serve as the suitable decision-making test. However, in many areas of social regulation including environmental policy, the flaws of CBA are so serious that they make it inappropriate to use as the decisional criteria. Therefore, NRDC strongly recommends that CBA not replace or supplement the decisional criteria of the underlying statutory authority, and to the extent it is used as an informational tool, that the administration work to reduce its serious flaws.

The limitations on the use of cost-benefit analysis are extensive and in fact quite well known.² Of greatest concern is the extent to which CBA has inherent biases that overstate costs and undervalue benefits. OMB should be commended for inviting input

on the key question that should be considered in the use of cost-benefit analysis: namely, what if anything can be done to compensate for its limitations and biases?

a. Overstatement of Costs

On the cost side, the most serious source of overstatement of costs is the overly static assumption about technology in government projections that overlooks the ability of innovation to lower costs over time. Again and again, dire predictions by industry about the effects of environmental protection on the economy have been shown after the fact to be greatly inflated. The eventual cost of the acid rain control program required by the Clean Air Act Amendments of 1990 is a well-documented case in point, as it fell far below the estimates of either industry or government.³

The prowess of technology to lower costs over time is really driven by the efficiency of a market economy in responding to a new constraint, in this case a regulatory requirement that internalizes an externality. It is at least ironic that many advocates of the use of cost-benefit tests as decisional criteria in decision-making also have great faith in the reliance on free market behavior; and yet they have little regard for efficient, cost-minimizing progress by the market to respond to these internalized externalities.

To the extent that CBA will continue to be produced for decision-makers, it needs to move to a more systematic treatment of the role of technology in lowering costs over time. Therefore, NRDC has requested that OMB conduct a review of past estimates of the costs of environmental compliance and compare them to actual costs, and then devise a methodology protocol for adjusting static cost estimates by more accurately adjusting for costs. Additional research can refine this concept over time, but the inclusion of a standard concept for making this adjustment could help to address the overstatement of costs that tends to systematically occur in government estimates.

b. Undervaluing Benefits

One of the most troubling aspects of cost-benefit analysis is not simply its tendency to misstate costs and benefits, but to systematically overstate the costs while understating the benefits. This bias stems from the fact that in the search for a “net benefits” answer to the cost-benefit test the ruling practice is to first quantify all costs and benefits, and then to reduce them to a common denominator in the form of dollars. Therefore any term that does not lead itself to quantification, and then monetization, tends to fall out of the equation entirely.

Because the costs of regulations are usually the expense of compliance, costs do not generally suffer from the same “dropping out” effect in the net benefits equation, whereas benefits by their nature are often difficult to quantify, much less monetize. Even when we cannot precisely state certain kinds of benefits in monetary terms, we know the value to society is not *nothing*. The Administration must undertake an effort to rigorously correct this deficiency as noted below.

There are numerous reasons why the many different kinds of benefits that exist are difficult to either quantify or monetize. This difficulty is serious in estimating the benefits of reducing pollution, but it especially skews our ability to sensibly estimate the benefits of protecting natural resources. Values like preventing the degradation to landscapes, extinction of species, or loss of wilderness are notoriously problematic when it comes to assigning dollar values to them. It may be a fundamentally flawed concept to even try in some cases. However, to the extent that CBA is going to be performed, OMB must develop a better approach for presenting these benefits in the analysis.

Therefore, NRDC has requested that OMB lead a policy process to examine the inherent undercounting of benefits in cost-benefit analysis and to develop a methodology protocol by which decision-makers can systematically compensate for this deficiency in their use of the tool for informational purposes.

c. Implications for Environmental Policy

Past annual OMB reports to Congress regarding federal regulations have documented the overwhelming social benefits of environmental regulations compared to the costs. It is noteworthy that even the Bush OMB reports showed this result even though the techniques used to measure benefits have clearly failed to capture them all through proper quantification. The most recent OMB annual report on the costs and benefits of regulations showed once again that environmental benefits by themselves accounted for most of the benefits of social regulations over the last decade. Therefore, it is essential to understand that regulatory review policy is first and foremost environmental policy.

OMB generally divides the regulations it analyzes into three substantive areas: social regulations, tax compliance and economic regulations. Environmental regulations, including those issued by the EPA, fall under social regulations, which in FY 2007 accounted for 45% of all the regulation analyzed by OMB.

OMB analyzed 93 regulations over the ten-year period from October 1997 to September 2007, 40 of which came from EPA.⁴ Of the EPA rules OMB analyzed 27 implemented by the Office of Air and Radiation and 10 rules from the Office of Water. The monetized benefits of these rules ranged between \$83,298 and \$529,567 million, with costs ranging from \$32,252 and \$35,058 million. The majority of large estimated benefits for EPA rules are accounted for the reduction in public exposure to a single air pollutant- fine particulate matter. Overall, OMB estimated that the 97 analyzed regulations in this ten year period garnered between \$122,190 and \$655,556 million in benefits, compared to \$46,219 and \$53,894 million in costs.⁵

For the most recent fiscal year, ranging from October 2006 to September 2007, OMB analyzed the benefits and costs of 40 major final rules. Of these, 18 final rules were categorized as 'social regulations,' with benefits estimated to range between \$122,190 and \$655,556 million, and costs ranging from \$46,219 and \$53,894 million. EPA continues to be responsible for the majority of estimated benefits and costs generated by Federal regulation, as shown by the three rules promulgated by the EPA. The benefits of

the EPA rules range from \$21,143 and \$170,391 million, with costs estimated between \$7,475 and \$7,584 million. There were three other environmental regulations promulgated, although two issued by the Department of Interior (DOI) were not monetized and therefore not included. The remaining rule, mandating energy efficiency standards for electric distribution transformers by the Department of Energy (DOE), has estimated benefits of \$490 to \$865 million, and costs of \$381 to \$428 million.⁶

Thus, the Environmental Protection Agency (EPA) by itself accounts for as much as 90% of the benefits all social regulations from a span of agencies that includes the Departments of Agriculture, Education, Energy, Health and Human Services, Housing and Urban Development, Justice, Labor, and Transportation. In absolute terms the upper end of the range of estimated benefits to society from EPA regulations over this 10-year period is an impressive \$593 billion. Furthermore, even by the OMB report's admission, these EPA regulations in the aggregate yield a highly favorable ratio of benefits to costs. Even using the high-end estimate of costs, the ratio of benefits to costs ranges from over 2:1 to an astonishing 17:1.

Keeping in mind that even the lower end of this range is highly beneficial, what explains the large size of this range? The 2008 OMB report points to five factors, but one of the most disturbing is uncertainty about the value to be placed on saving lives.⁷ Indeed the greatest contribution by EPA to total social benefits is derived specifically from air pollution controls that reduce such premature mortality. This point is notable not only because of the philosophic importance of preserving life, but also because it underscores the significance of getting the methodology right for estimating the value of protecting it. It also helps to explain the motivation of the Bush administration in devising new methods for lowering the value attributable to preventing premature mortality, so that it could justify its repeated attempts to weaken air pollution regulations.

d. Bush Administration's Undermining of CBA

The Bush administration took a multi-faceted approach to warping the use of cost-benefit analysis. Here NRDC would like to highlight two examples which the Administration should consider correcting as part of its review of the regulatory process. One example is the set of "best practices" that the OMB instructs agencies to follow in its calculations of the benefits of regulations (e.g. Circular A-4). The other is distorted estimates of the benefits of air pollution regulations that the Bush administration left on the books.

In 2003 the Bush OMB revised Clinton administration regulatory review procedures set out pursuant to Executive Order ("E.O.") 12866. The Clinton procedures were set out in detail in a 1996 OMB document that described best practices for agencies to follow in their calculations of the costs and benefits of regulations, and an OMB 2000 guidance issued to agencies concerning how to implement these practices.⁸ The Bush administration's changes were quite subtle but significant.

Three changes in particular represent the worst changes of the best practices:

- First, OIRA changed the way in which the discount rate is applied for purposes of discounting streams of future benefits.⁹
- Second, OIRA gave greater emphasis to the Value of a Statistical Life-Year (VSLY) as the measure of the benefit of reducing the risk of loss of life, as opposed to the standard Value of a Statistical Life (VSL).¹⁰
- Third, OIRA imposed without justification a completely new set of statistical requirements for rules with impact above a \$1 billion threshold.¹¹

In making changes to the Clinton administration's Best Practices guidance, the Bush OMB made two claims in its defense: (1) the changes are not really any different than the policies of the Clinton administration; and (2) OMB policies are just suggestions and agencies are free to do what they want. If valid, these two arguments taken together would completely obviate the point of making any changes in the first place. The reality was that the changes were specifically meant at least in part to undermine the effectiveness of environmental policy.¹²

The Bush administration's Circular A-4 demonstrates once again how dramatically the environmental policies and the regulatory approaches of the Bush administration were entwined. In Circular A-4, of the 35 examples given of how to do a regulatory review procedure or why the procedure is necessary to do, 32 were in the field of environmental policy, and 25 of those were EPA-specific.¹³

Therefore, in the interest of both sound regulatory processes and healthful environmental outcomes, NRDC has suggested to this Administration that OMB review all the Bush administration changes in Circular A-4 and consider completely repealing all the changes made to the Clinton Best Practices document.

1. The Rate of Discounting Future Benefits

Before the Bush administration, OMB policy on intra-generational benefit streams regarding the use of a discount rate recommended a seven percent rate based on its claim that seven percent is close to the average before-tax rate of return to capital in the U.S.¹⁴ This directive was plainly out of line with more recent actual rate of return experience and was in need of an update. Even now the 10-year Treasury rate hovers stubbornly below three percent.

The fix of the Bush OIRA, however, was wholly inadequate to the task; it directed agencies to provide net benefits estimates using both the out-of-date seven percent rate and added to it a new three percent discount rate. However, in the past agencies were never really barred from looking at rates other than seven percent as long as they also included an analysis with OMB's seven percent number. As EPA's 2000 guidelines for preparing economic analysis notes after recommending the use of a consumptive rate of interest: "EPA economic analyses therefore should provide estimates of the present

values of costs and benefits using both a two to three percent rate and OMB's guidance on discounting [using a seven percent rate]."¹⁵

Thus, the Bush revision had the effect of further enshrining the dictate that the flawed seven percent rate must be included in agency analysis. Also it puts an implied floor on the lower discount that can be used at three percent, even though one could argue that at times even that rate is too high. OMB should instead take a hard look at what a more reasonable discount rate should be, and allow agencies much greater flexibility in choice of a suitable discount rate for the specific policy under review.

NRDC and many others have profound ethical, pragmatic, policy, and legal concerns about OMB's approach to discounting the value of future lives lost. In particular, OMB should revise the way in which it views the practice of discounting the value of lives that are lost in the future from exposures to hazards in the present. The discounting of future lives (especially if insupportably high discount rates such as seven percent are applied) amounts to an incredible vanishing act where the calculations of such values are concerned.

Not surprisingly, a substantial body of research related to the social rate of time preferences supports the view that individuals discount the value of future lives by a rate far below the seven percent rate set by OMB in Circular A-94. In fact, given the low level of interest rates for the last several years, it would be surprising if up-to-date research on social time preference did not provide a robust endorsement of the view that the discount rate for the loss of future lives should be extremely small if not zero. Therefore, as a way of helping to correct the systematic biases in cost-benefit analysis, NRDC has requested that OMB recommend the use of a discount rate of zero for the value of future lives until the technical and ethical issues related to this practice are satisfactorily resolved.

For issues that have especially long time horizons that are inter-generational in nature, Circular A-4 has suggested a different approach. While still requiring the use of the three percent and seven percent rates as in the case of intra-generational benefits, Circular A-4 would allow rates as low as one percent in certain cases. Although this approach is better than simply limiting the analysis to three percent and seven percent rates, it again falls short of the mark that OMB should set for this analysis. Indeed, it may be worse than current agency practice.

The OMB 1996 best practices document and its 2000 guidelines are somewhat circumspect on the issue of the correct discount rate for inter-generational analysis and allow agencies some leeway. Specifically, these documents allow the agency either to use the same discount rate analysis that it would use for intra-generational benefits while addressing equity issues separately, or to use "a special social rate of time preference."¹⁶ In implementing this advice, the EPA guidance document has recommended that analyses should include a "no discounting" scenario by displaying a stream of costs and benefits over time (which EPA notes is not the same as a discount rate of zero). It also recommends the inclusion of other scenarios beyond the seven percent and three percent

rates, namely, those “in the interval one-half to three percent as prescribed in optimal growth models.”¹⁷

Over long time horizons, even the relatively low discount rate of one percent can drive the net present value estimate of benefits down to almost nothing. This statistical obliteration of the value of protecting future lives becomes exaggerated in the extreme when policies with extended timelines like nuclear waste disposal or climate change are involved. The inevitable but insupportable conclusion seems to be that anything the present generation does that adversely affects future generations is acceptable because the value of the benefit to future lives does not amount to much.¹⁸

2. Shift from Value of a Statistical Life to Life-Years

One of the standard ways for agencies to measure the benefit from reducing the risk of premature mortality is the use of the Value of a Statistical Life (VSL). The estimate for the VSL can be calculated using a number of different kinds of willingness-to-pay surveys, such as those that rely on labor market (i.e., wage-risk) studies or contingent valuation. The standard use of VSL has itself been subject to the criticism that it underestimates the benefit of reducing the risk of mortality because of income, age, and occupational biases that are built into some of the kinds of studies used to construct a value for it.

An alternative to the use of VSL is the concept of the Value of a Statistical Life-Year (VSLY). VSLY in effect measures the benefit of reducing the risk of premature death based on the number of years a hypothetical person has to live, instead of assigning an average VSL to everyone.

VSLY deserves particular attention because it is one of the most controversial proposed changes to the guidelines. Under VSLY, all else being equal, the older a target population is, the lower the calculated benefit of protecting them. Therefore, protections for the elderly would be subjected to a special devaluation under this technique. VSLY also serves as the basis for another technique for lowering the value of life, the Quality Adjusted Life Year (QALY). Once one establishes VSLY as a method for calculating the value of reducing the risk of mortality, then one can take the additional step of adjusting the calculation of the value of remaining life-years by their “quality.” Again, since the quality of life of the elderly can be said to be less than younger people, the life of the elderly can be lowered again.

The discussion of the value of a human life and which measure for it is appropriate is at times troubling and often analytically slippery. The troubling aspect comes from the fact that it is an issue that is not economic in nature but rather philosophic. NRDC holds the view that all life is precious and therefore deserves equal protection under the law. This view by itself is a sufficient argument against using VSLY or QALY analysis and NRDC has urged the administration to adopt this view.

Nonetheless, the value of life as it relates to age is a subject matter of economic study, and therefore it is imperative that the right kind of economic analysis be brought to bear on it. Because the analytical framework for this discussion is so slippery, it is critical to ask the question in the right way so that the thinking about it is also correct.

The supporters of VSLY like to frame the question around a true if partial notion that generally speaking one would rather die later rather than sooner. This notion is so common-sensical that it is the basis of an old joke, in which the robber tells his victim that it's either his money or his life, to which the victim says, "Take my life, I'm saving my money for my old age."

The proposition that one would rather die later than sooner is valid as far as it goes, but one can also stretch it too far. It's true that society has an interest in ensuring that social investments will get younger people to an older age. It's not true that the premise of this conclusion is that the lives of younger people are more valuable to save because they have more years left in them. That incorrect premise leads to following a fair question about when you would rather die with a false one, namely: if you could only save a single person, should it be an older person or a younger person?

There are many wrong premises to this second question as posed, one of which is that society cannot afford to make the investments needed to extend the life of both younger and older people. But the main faulty premise comes about by not asking the right second question after the question about whether you would die sooner or later. The proper follow up question to ask is: now that it's later, are you more willing to die than you were before?

It should not be surprising that the answer that most often comes back to this question is, "Not really." The fact that there is a smaller amount of years left in your supply seems not to have reduced the demand you still have for continuing to use the ones you have left. In some ways it has made the value much higher of each scarce remaining year.

One way economists look at the issue is to consider the social rate of time preference. Reliable empirical data in this field do not support the premise of either QALY or VSLY. One study by some of the leading experts on this subject concluded quite simply that the data do not support discounting the value of life based on the numbers of years someone has remaining to live.¹⁹

Yes, society has an interest in helping younger people to live longer, so they can "enjoy their money in their old age." However, since individuals continue to want to die later rather than sooner even as they age, it is fundamentally wrong-headed to assume that society can only afford to invest in saving either the young or the old. Once we save the lives of the young, we should not allow ourselves to fall victim to the other side of the robber's choice, telling them as they approach their old-age, there's no more money left to invest in saving them.

3. False Thresholds

E. O. 12866 already requires a regulatory impact analysis (RIA) for major rules above \$100 million a year or under certain qualitative conditions. There are several problems with these criteria.

- First, while it is reasonable to have a threshold figure for what is a major rule, the \$100 million figure has become out of date and needs to be revised upward based on changes to inflation since the time of the data used to set the original threshold level. A procedure should also be put into place that will automatically allow this figure to rise according to an established price index.
- Second, it is sufficient for the minimum threshold to be limited to costs alone. After all, if the costs are below \$100 million and the benefits are above, what difference does it matter how much higher the benefits are above that level?
- Third, the qualitative criteria should be deleted since they are overly vague and put almost no constraints on the potential reach of the review process, whether it makes sense or not. The qualitative criteria that a review can be necessitated by novel legal or policy issues is especially troublesome, and gives OIRA an almost unlimited reach into agency processes in a way not contemplated by Congress. Maximum Available Control Technology proposals are often caught in this net even if they do not exceed \$100 million a year in costs and are quite beneficial in their result.

In addition to the threshold for regulatory review contained in E.O. 12866, the Bush administration required a whole new form of uncertainty analysis for rules costing more than \$1 billion a year, even though RIAs under E.O. 12866 already had to address issues of uncertainty in that analysis.²⁰ This new requirement appears completely arbitrary and serves simply to clog the regulatory process.

No reason was ever given by OMB for why the existing analysis requirement would be deficient for rules of a larger size. Moreover, no justification was given for hinging a formal analysis on the level of cost as opposed to level of cost combined with the ratio of benefits to costs. It is a form of false precision and a waste of resources to do a formal analysis of the exact distribution of the range of uncertainties if you already know the benefits are going to exceed the cost at any level. Finally, no justification was provided for the \$1 billion figure being the correct threshold, although it is likely that environmental regulations would be disproportionately impacted by this requirement and therefore it is reasonable to conclude that was the motive.

EPA already had a method for addressing uncertainty analysis. As EPA noted in its 2000 guidelines: “If, however, the implications of uncertainty are not adequately captured in the initial assessment then a more sophisticated analysis should be undertaken.... However, these methods can be difficult to implement, often requiring more data than are available to the analyst.”²¹ Instead of relying on an arbitrary figure to determine whether a higher standard for analysis should apply (e.g. the \$1 billion threshold), EPA applied a more reasonable approach by determining first whether the initial assessment passed a

test of adequacy in capturing the implications of uncertainty. Where the benefits far exceed the costs and the data are lacking for additional formal analysis, EPA could reasonably decide that the initial assessment was more than adequate.

The effect of the Bush administration change is to threaten rulemakings with delay by sending the agency back to collect data that may not be available, even if the available data are sufficient to determine the results of the rule would be positive. As OMB ominously notes in its guidelines, “For example when the uncertainty is due to a lack of data, you might consider deferring the decision, as an explicit regulatory alternative, pending further study to obtain sufficient data.”²²

The connection to the potential for tying up environmental controls is not accidental. In its 2003 proposal to change the Clinton guidelines, the Bush OMB explicitly pointed to analysis of air pollution regulations as an example of the problem with uncertainty about future emissions, changes in air quality, resulting health effects, and the “economic and social value of the change in health outcomes.” In reality, it was never made clear what other type of rules would even meet this threshold test for extra uncertainty analysis.²³

The Bush administration’s decision to single out regulations for unfavorable treatment simply on the basis of the size of costs, seems to have been an attempt by the Bush White House to justify after the fact a policy it already had in place. In at least one significant case, EPA’s rule to control polluted runoff from construction and development sites, the Bush OMB deleted the most effective and beneficial provision of the rule drafted by EPA simply based on the size of the costs of the provision. The Bush administration took this indefensible action despite the fact that this action had no basis in the statute as part of its decisional criteria and that even so the provision would have clearly passed any reasonable cost-benefit test.²⁴ Furthermore some rules like this one may have total costs that seem large in dollars, but that are in fact quite small in comparison to the total size of the industry.

Thus the implication of uncertainty requirements in the hands of a hostile OMB is that arbitrary procedures can be institutionalized as a reason for blocking rules regardless of statutory directives or overall benefits to society. The Obama OMB should avoid new uncertainty concepts that could lead to such results by raising the current \$100 million threshold and eliminating the formal uncertainty requirement for rules that exceed \$1 billion in costs.

4. Faulty “Alternative Analysis” Left on the Books

It is instructive to consider the implications of the Bush administration’s changes to the regulatory review process in the context of specific applications during administration policy reviews. Once again, air pollution controls offer a keen illustration of the point of what can happen when the government manipulates the price tag put on human life.

In the fall of 2002 the Bush OIRA insisted that EPA begin to include an “alternative analysis” in its environmental reviews that employed some new techniques to drive down

the calculation of benefits. In these alternative analyses, when the entire range of techniques was employed, the estimated benefits of controlling air pollution astonishingly dropped by over an order of magnitude. Three cases in which EPA used a variation of this alternative analysis include the technical justification for the Clear Skies Initiative (CSI), the off-road engine rule (a.k.a. the snowmobile rule), and the off-road diesel rule.²⁵

Requiring an alternative analysis by the agency could be a valuable exercise if it were done with the intention of providing a more balanced range of information to policy makers. Such an effort would be directed to correcting the existing biases of CBA, in this case the underestimation of benefits. There are many ways in which OIRA could direct its efforts to correcting these biases, as has been suggested in prior comments submitted to OIRA by NRDC and others.

Unfortunately, the Bush OIRA made no attempt to produce a set of techniques or alternative analyses that would have the effect of raising estimates of benefits by reducing built-in biases. In fact, OIRA does not even attempt to provide a symmetrical pair of alternative analyses, one that reduces the estimate of benefits in the way OIRA would prefer and one that raises estimates of benefits by correcting anti-benefit biases. Either of these approaches would produce a more complete range of benefit estimates for policy makers to consider than the Bush OIRA's alternative approach by itself. Of course, the best approach is to simply correct the bias toward underestimation without including OIRA's new analysis, and therefore provide the most honest set of numbers to be used by policy makers.

In the alternative analysis advocated by OIRA, EPA used three principal steps to lower its own original benefit estimate. In each instance, the approach in the original analysis is a far more reliable calculator of benefits than the alternative analysis. We can see how this process will work over time by going through the alternative analysis in the EPA air pollution proposals step-by-step.

In the first step of both the standard and the alternative analysis, EPA estimates the value of reducing the risk of fatalities in terms of statistical lives. For the standard analysis, this estimate is based on 26 studies, 21 of which are labor market/wage-risk studies and five of which are contingent valuation studies. The alternative analysis, however, only based its estimate on the contingent valuation studies, reducing the VSL almost in half from \$6.1 million to \$3.7 million. The second step in the alternative analysis adjusts the VSL estimate even further downward based on the fact that many of the people saved by the rule would be elderly, dropping the value to \$2.3 million for seniors. The last step shifted the entire analysis from a VSL to a VSLY analysis, which in its worst case scenario can ultimately end up with a valuation of \$130,000.

One could also argue that there is no real harm in leaving these alternative analyses and their techniques on the books, since EPA could always ultimately rely on its main analysis. However, the whole purpose of these alternative analyses is to put benefit calculations step-by-step on a downward path in part by creating uncertainty about the results of the main analysis. In addition, it makes no sense to waste staff time and

resources performing unhelpful and misleading analyses. Therefore, NRDC has asked that the Obama OMB remove the use of these alternative practices from use and the record of analysis. Indeed, the Bush OMB apparently no longer considered its alternative analysis to be the “alternative,” but rather equal or more reliable from their point of view. Proof of this attitude can be seen in the 2003 OMB Annual Report to Congress in the section explaining OMB’s method for summing up the cost and benefits of regulations.²⁶ In most cases, OMB simply accepted the calculations submitted by the agency. However, in the case of EPA estimates concerning air pollution benefits OMB created a new lower figure for the range of estimates using its new technique for lowering the value of life.²⁷

Thus we can see how the regulatory review procedures adopted by the Bush administration were meant to set the stage for a more far reaching undermining of environmental protection in general and air pollution controls in particular. It would start by using the Bush OMB alternative analysis to lower benefits and then to argue there is uncertainty about the regulations. Next, the regulation may be subjected to a formal uncertainty analysis for which there would be insufficient data. Then, the agency’s rule would be delayed until more data are collected, perhaps endlessly. The approach is an unbalanced trap even for rules that are quite beneficial, with weaker environmental protections one of the results.

IV. ACTION IN THE FACE OF UNCERTAINTY

Because of the inherent biases of CBA, it is a defective tool to use in decision-making on the environment. Regulations that are based on health or technology standards are much more reasonable and effective approaches on which to rely for decision-making.

One of the reasons opponents of regulatory protections often argue for the use of CBA as the decisional criteria in rulemakings is because of its extensive and at times oppressive requirements for information. The CBA technique lends itself readily to the endless argument that more information is needed or that scientific understanding is imperfect. Special interests often try to commandeer the risk assessment process to create an impenetrable labyrinth of procedures or political atmosphere of uncertainty. Ultimately the success of the system requires that opponents of regulation not be allowed to relentlessly demand an unobtainable level of knowledge as a precondition for action.

a. Too Little Precaution, Too Much Time

The desire to have a high degree of certainty in regulatory decision-making prior to taking action builds an overly conservative presumption into the system that is very deep. This presumption is not necessarily reasonable on the face of it. It would be admittedly expensive and inefficient for society to endure a regulatory burden that was not supported by sufficiently positive results. Yet it could also be expensive and inefficient for society not to adopt a level of regulation sufficient to reap all of the positive results potentially available. After all, pollution externalities for example impose a huge and inefficient cost

on society in terms of public health and ecological effects, some of which can be irreversible.

Judging from the information provided in past OMB reports on the costs and benefits of regulations, we seem to be in little danger of erring on the side of too much environmental regulation, given the extremely high ratio of benefits to costs that have resulted from existing social regulations. Indeed, the conservative presumption of the system has most likely denied society the benefits that would accompany additional, well-designed regulations to address social externalities like environmental degradation.

One of the principal ways in which the excessively biased nature of the system can be partially offset is through the use of precaution in regulatory policy. The concept of precaution recognizes that knowledge is never perfect, and yet there is often a need to take action before certainty is complete. Precaution introduces into this decision-making process the common sense notion that in some matters it is better to be safe than sorry. The precautionary principle is a statement of the fact that regulatory policy needs to explicitly incorporate a measure of precaution into the decision-making structure in order to reduce risk to society, since that structure left to itself is much more likely to have too little precaution and too much risk.

Another EOP office, the Council on Environmental Quality (CEQ), published a groundbreaking monograph on the subject of risk analysis in 1989, Risk Analysis: A Guide to Principles and Methods for Analyzing Health and Environmental Risks.²⁸ In that publication, CEQ catalogued a long list of different “dimensions” of risk, showing how different the nature of risk can be in different situations. These dimensional traits include severity, potential for catastrophe, reversibility, impact on future generations, voluntariness, and controllability. This catalogue shows that it is not sufficient to focus simply on generic ways that precaution may be used in risk assessment and management; rather it is necessary to start with an understanding of the different kinds of risk that need to be assessed or managed, and then separately analyze the way in which precaution applies in each case.

The failure to appreciate that a one-size-fits-all approach to risk assessment and management does not work well is one of the main ways in which risk policy goes wrong. The Office of Science and Technology Policy (OSTP), yet another EOP office historically active on risk management issues, noted in a 1995 white paper: “[E]ach law establishes somewhat different criteria for making risk management decisions. The extent to which such an analysis is permissible or productive in light of statutory provisions must influence a decision to undertake a risk assessment. There are advantages to having some degree of consistency in the statutory provisions that guide risk reduction activities in the federal government.... However, the specific methods to be used in evaluating risks are best developed in agencies on a statute-by-statute basis so that the analytical approach is appropriate to the types of risks addressed.”²⁹

Indeed, the Executive Office of the President (EOP), which includes OMB, CEQ, and OSTP, generally lacks legal power to dictate risk-based decision-making to the agencies.

In most cases, such policy is properly rooted instead in the statutory requirements of different agencies. When courts assess whether an agency has acted lawfully, primary consideration is given to whether Congress has already expressed the answer regarding the decision-making criteria through legislation. Agencies interpret this as a mandate to regulate in protection of the public health – even when there is less than absolute certainty as to the probability that a given harm will occur.

Congress and agencies must constantly consider how much precaution to use in regulation. Moreover Congress typically has remedied ineffective health and safety statutes by *increasing* the amount of precaution in a statute. From decades of trial and error, we have learned two important lessons: regulation that accommodates uncertainty succeeds, and regulation dependant upon absolute proof of risk or a rigid cost-benefit test fails to protect the public sensibly.

Congressional mandates to protect health in the face of uncertainty have been consistently upheld in the Supreme Court. In both the *Lead Industries Association* and *American Trucking* decisions, the Court held that the executive may not deviate from the degree of public health protection mandated by congress when implementing a regulation.

b. Case Studies

Many legitimate opportunities to protect public health and safety are hampered by the requirements of *too much* proof of harm, *too much* balancing of environmental risks with “other factors,” and *too little* requisite precaution. Examples include the regulation of hazardous air pollutants, lead and other toxics. Based on these case studies, one can see that the alternative to reasonable regulation ends up as inaction, delay, and irreparable harm to the public health and the environment.

As a result of this harsh history lesson, Congress has routinely mandated by statute the standard required for agencies to act under a particular law. Courts have consistently held that a margin of safety adequate to the task of protecting the public health as prescribed by Congress is one that enables an agency to regulate without meeting an unreasonable threshold of certainty.³⁰

In this section, NRDC gives examples as case studies on how to and how not to regulate social risks.

1. Air Toxics: Congress Learns Its Lesson

Before the 1990 amendments to the Clean Air Act, EPA was charged by Congress with creating National Emission Standards for Hazardous Air Pollutants (NESHAPs) for the air pollutants listed within the Toxic Release Inventory. Due to the uncertainty about the amount of toxic exposure required to produce harm, EPA assumed the exposure standard to be zero. But EPA was highly reluctant to justify action regarding a zero risk exposure based on risk analysis. As of 1990, only eight of 650 toxic materials had been

successfully regulated – this despite reams of data supporting their toxicities. With an unreasonable burden of proof put in place regarding certainty, NESHAPs was a plain failure in practice.

As a result of the agencies' inability to meet its congressional mandate, Congress was compelled to act. Congress took notice of the slow rate of progress, identified the inability to regulate in the face of uncertainty as the problem, and instead mandated toxic standards be generated using technology-forcing requirements. Since the 1990 amendments, 46 air toxics standards have been set for 82 different types of major industrial sources.

The NESHAPs story ends with a happy ending: Congress realized that more action was necessary and responded appropriately. But note that once again it was beyond the scope of EPA (or, for that matter, OMB) to alter the *degree* of precaution mandated by the statute – only Congress could alter the legislated level of risk and uncertainty.

2. Lead: When Agencies Resist Precautionary Regulation

In contrast, neither Congress nor executive agencies were able to regulate environmental exposures to lead before nearly a century of debilitating exposure had taken its toll. The use of lead in gasoline is therefore the single best example of the need for government regulation in the face of uncertainty.³¹

Lead in gasoline was hazardous from the get-go: within a year of first producing leaded gasoline in 1923, eighty percent of workers at DuPont's New Jersey factory were poisoned, resulting in more than three hundred cases of death or severe nerve damage. Although lead production was temporarily halted in 1925 due to overwhelming opposition from the scientific community, production of lead gasoline resumed the following year after the Surgeon General declined to restrict its use, citing the need for more definite proof.

A half-century later, even after lead was regulated as a hazardous fuel additive because lead was “reasonably anticipated to endanger the public health or welfare,” EPA nevertheless resisted classifying lead as an air pollutant until NRDC successfully sued to compel its phase-out.³² Now, lead is accepted by the agency as a significant environmental threat, including especially to the health of children.

Regulation of lead provided the watershed legal challenge to uncertainty in environmental regulation. This challenge culminated in two separate appeals by the lead industry to the D.C. Circuit, each attempting to require EPA to provide more definite causality before lead could be regulated.³³

In *Ethyl Corp. v. EPA*, Judge Skelly Wright warned that effective regulation would be “impossible” if courts demanded a “rigorous step-by-step proof of cause and effect.” As a result, agencies may now regulate in the face of uncertainty if they use “available evidence to make rational assessments” concerning potential risks.³⁴ The threshold

question was NOT what quantity of lead caused the harm, nor what percentage of that quantity was from gasoline, but whether the lead posed a “significant risk of harm” to the public health.³⁵

The requirement to follow statutory mandates for precautionary regulation found further support in *Lead Industries Association v. EPA*.³⁶ Here, Judge Wright again agreed with EPA that setting a standard under the Clean Air Act with “an absence of adverse effects” does not require showing that “the effects on which the standards are *clearly* harmful or *clearly* adverse” (emphasis in original).³⁷

3. *Toxics: Failing to Protect Public Health*

In theory, the Toxic Substances Control Act (“TSCA”) authorizes the EPA to obtain information on the risks of industrial chemicals and to regulate usage of those chemicals that the agency determines present an unreasonable risk to public health and safety. However, EPA has yet to achieve either of these goals due to a severe lack of regulatory authority to carry out these tasks. There have been approximately 83,000 chemicals currently listed in EPA’s TSCA inventory since its implementation in 1979.³⁸ About 21,000 of these chemicals are new to TSCA’s Chemical Substances Inventory since 1976.³⁹ Of these, 67% do not have any test data on file regarding the safety and health effects of the chemical, and 85% do not have any data relating to the chemical’s effects on public health. EPA has used its authority to test chemicals for unreasonable risk less than 200 times due to the cumbersome process of rulemaking required to commence testing.

While the agency has the authority to regulate chemicals under Section 6 of TSCA, the ‘unreasonable risk’ threshold that the agency must meet is extremely high. The cost-benefit analysis required to meet this standard is extensive, with substantial evidence involved to justify regulation and withstand judicial review. As a result, EPA has only issued regulations to limit the use or production of five existing chemicals to date out of 83,000.⁴⁰ This failure to regulate dangerous substances is most pronounced in EPA’s effort to regulate and ban asbestos, a known deadly chemical. In *Corrosion Proof Fittings v. EPA*,⁴¹ the Court ruled that EPA did not have sufficient evidence to out-right ban the use of asbestos and therefore did not meet its burden in demonstrating that banning the substance was the least burdensome regulatory action. This was after ten years of data gathering by the agency.⁴²

In order to remedy these shortcomings, a timetable should be established for all manufacturers to provide chemical data to EPA and other relevant agencies for proper risk assessment. What’s more, the burden of proof needs to be shifted so that chemical manufacturers are required to prove the safety of substances, rather than requiring EPA to prove a substance poses an unreasonable risk. Furthermore, the regulatory hurdles EPA faces before being able to take action to address unsafe substances are too high, and must be lowered to allow EPA to protect public health and the environment from unsafe chemicals.

V. DISTRIBUTIONAL CONSIDERATIONS, FAIRNESS AND FUTURE GENERATIONS

Science should play a critical role in reinforcing the administration's commitment to addressing distributional considerations, especially those that affect minorities, low-income populations, future generations and children. Such considerations are particularly important for environmental regulation. E. O. 12898,⁴³ adopted in 1994, directs each agency, to the greatest extent practicable and permitted by law, to make environmental justice part of their mission by identifying and addressing disproportionately high and adverse human health or environmental effects of their programs, policies, and activities on minority populations and low-income populations in the United States. Unfortunately, despite the executive policy on environmental justice set forth in this order, it has not been implemented in any meaningful way in recent years.

Under the Bush administration, the EPA paid only superficial attention to the directive of E. O. 12898. For example, in promulgating regulations pursuant to the Clean Air Act, EPA frequently failed to undertake any actual analysis of environmental justice implications and typically just adopted one or two sentences, often boilerplate language, disavowing any distributional impact.⁴⁴

In other cases, such as EPA's 2006 rulemaking for the National Emission Standards for Organic Hazardous Air Pollutants from the Synthetic Organic Chemical Manufacturing Industry (also called the "HON Rule"),⁴⁵ EPA simply ignored significant evidence of environmental justice concerns. In that rulemaking EPA opined: "The fact that low-income and minority citizens may represent a larger percentage of the population exposed to HON HAP emissions compared to their percentage within the overall U.S. population does not in itself indicate that there is an environmental justice concern."⁴⁶ In declining to impose stricter emissions limitations on chemical manufacturing facilities—facilities that are heavily clustered alongside other industrial facilities in minority and lower-income communities such as New Orleans and the Houston Shipping Channel—EPA relied primarily on "consideration of the additional costs of further control."⁴⁷ EPA's decision to ignore scientific, health-based considerations and its attendant failure to adopt additional controls has left poor and minority communities located near the fence lines of chemical manufacturing facilities exposed to cancer risks 300 hundred times greater than the acceptable risk level identified by Congress for toxic air pollution.⁴⁸ The new administration should make a greater commitment, across all agencies, to comply with E. O. 12898 as well as principles of reasoned rulemaking and sound science.

Science should similarly be the animating force behind the administration's concern for the interests of future generations, including today's children. Children face different and more severe health and safety risks than adults:

"A growing body of scientific knowledge demonstrates that children may suffer disproportionately from environmental health risks and safety risks. These risks arise because: children's neurological, immunological, digestive, and other bodily systems are still developing; children eat more food, drink more fluids, and breathe more air in proportion to their body

weight than adults; children's size and weight may diminish their protection from standard safety features; and children's behavior patterns may make them more susceptible to accidents because they are less able to protect themselves."⁴⁹

With respect to environmental and safety regulations, an existing E. O.⁵⁰ provides some guidance. E.O. 13045 declares that "each Federal agency: (a) shall make it a high priority to identify and assess environmental health risks and safety risks that may disproportionately affect children; and (b) shall ensure that its policies, programs, activities, and standards address disproportionate risks to children that result from environmental health risks or safety risks."⁵¹ For regulatory actions that are "economically significant," as defined under E. O. 12866, and that pertain to an environmental health or safety risk that an agency has reason to believe may have a disproportionate effect on children:

"the issuing agency shall provide to OIRA the following information developed as part of the agency's decisionmaking process, unless prohibited by law: (a) an evaluation of the environmental health or safety effects of the planned regulation on children; and (b) an explanation of why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives considered by the agency."⁵²

Unfortunately, in the same way that agencies have failed in recent years to account fully for the impacts of regulatory action and inaction upon minority and low-income communities, during the Bush administration they likewise failed to account for the unique vulnerability of children.⁵³ For example, EPA has previously denied that E. O. 13045 applies to its rulemakings by arguing that a rule does not pose special risk to children, despite contradictory evidence.⁵⁴ In light of such recent failures, there is a pressing need for the new administration to make a greater commitment to the scientific procedures and decision-making guidelines outlined in E.O. 13045.

VI. TRANSPARENCY AND OTHER PROCESS IMPROVEMENTS

NRDC also strongly supports the principles of transparency and disclosure in government. They provide an essential guarantee to the public that decision-making is being conducted through the proper channels and informs the public of the true basis of government actions. Executive branch input on proposed agency regulations should be included in the administrative record for judicial review of final agency rules, except where prohibited by law. Because such input is considered by the agency decision-maker, it is properly considered part of the "whole record" for judicial review pursuant to the Administrative Procedure Act, 5 U.S.C. § 706.

Under historic and ongoing OIRA practices, OIRA desk officers and other officials exercise outsized influence over agency rulemakings and other activities that either never become transparent to the public, or become transparent in rare circumstances where a statute (like the Clean Air Act, see CAA 307(d)(4)(B)(ii)) requires OIRA written

comments to be disclosed. Even in those latter circumstances, however, the OIRA influence and comments (on proposed or final rules) are made public only when a proposed or final rule is signed, severely limiting and undermining the public's ability to learn about the OIRA influence in a timely and effective fashion.

Under the prior administration, OIRA even managed to circumvent the minimal transparency safeguards built into the rare statute like the Clean Air Act that required documentation of OMB written comments. The surreptitious nature of this conduct makes it difficult to prove, which is precisely the problem, but plenty of reliable if anecdotal information exists of such practices. Rather than provide written comments on EPA rulemakings to the agency, OIRA would insist that their comments be accepted on phone calls or during in-person meetings. In at least one situation OIRA staff reportedly insisted that an EPA political appointee transcribe written edits and notes on a draft Clean Air Act rulemaking during a phone call. It is impossible to see these steps as anything other than circumvention of statutory transparency requirements. These are precisely the types of practices that we have urged this administration to abandon.

Another objectionable practice by OIRA in the recent past involved an informal, pre-review "review" process, in which OIRA staff pressured EPA officials to adopt OIRA-preferred provisions even before the rule entered the official review. The adverse consequences of this procedure were that (1) OIRA could maintain that it did not make changes during the formal OMB review process (they had already been made); (2) any OIRA staff written comments made during the pre-review period were not included in the administrative rulemaking records or the certified record for judicial review, meaning there was no transparency or accountability to the public; and (3) OIRA staff did not consider themselves bound by the deadlines governing OMB's formal review, and these informal reviews sometimes led to rules or proposals being delayed for far longer than the formal review period deadlines would have allowed.

These practices permit OIRA staff to exert hidden and potentially undue influence over EPA rules during these informal review periods and delay important public health and environmental measures. These informal reviews sometimes led OMB's subsequent formal reviews to be mere formalities that lasted no more than a few days after the formal review began; the real work and influence had been accomplished during the improper informal reviews, during which OIRA had already won the changes to the rules it was seeking, so the formal review amounted to rubber stamping a pre-negotiated outcome.

Under the prior administration, OMB would routinely engage in informal reviews of EPA rules – quaintly dubbed "consultations" – outside of the strictures and deadlines provided under E.O. 12866. In some cases, these informal OIRA "consultations" delayed the EPA rule far beyond the time period provided for under the executive order, delaying the rule's important health benefits. For example, EPA's rule governing "PM2.5 De Minimis Emission Levels for General Conformity Applicability," EPA-HQOAR-2004-0491, underwent an informal OIRA consultation for over 6 months before the rule was re-submitted to OIRA for formal review under E.O. 12866 on July 6, 2006, OMB completed its formal Executive order review on July 7, 2006, making quite clear that the formal

review process was a charade and OMB had effectively substituted a drawn out, unaccountable, non-transparent, and informal “consultation” for the formal review process and strictures.

It is also worth noting that a significant number of the rules subject to informal OIRA “consultation” fell well below the \$100 million threshold in E.O. 12866. Indeed, it is our understanding that OIRA has long insisted on reviewing every EPA MACT rule, regardless of whether those rules met the quantitative or qualitative significance criteria in E.O. 12866.

Then there are the numerous instances in which OIRA simply granted itself lengthy and nearly open-ended extensions to formally review EPA rules. See, *e.g.*, EPA-HQOAR-2005-0163 (EPA rulemaking proposal sent to OMB for formal review on August 18, 2006, OMB review formally extended on November 16, 2006, and OMB review completed on April 19, 2007). In addition, there are examples of OIRA conducting lengthy informal “consultations,” followed by lengthy extensions of its formal review period. See, *e.g.*, EPA-HQ-OAR-2001-0004 (EPA rule provided to OIRA for informal “consultation” on April 11, 2005, submitted for formal review on September 8, 2006, formal review extended on December 7, 2006, and OMB formal review completed on February 28, 2007); see also EPA-HQ-OAR-0173.

These documented abuses just cover EPA rules adopted under the Clean Air Act, but we have every reason to believe these same abuses have been practiced by OMB with respect to other EPA rulemakings and actions carried out by other federal agencies. We have urged OMB to abandon these abuses of Executive Order 12866, and to adopt new practices that will provide the expected timely and formal review of agency rules – without resorting to non-transparent and abused informal consultations.

In general terms OMB should establish written, publicly available performance requirements and milestones for OIRA review of agency actions to ensure efficient and timely completion of duties, and there should be an accountability mechanism to ensure that OIRA meets these performance standards. More specifically, these performance requirements should include the following:

- Provide all comments on draft rulemaking proposals and draft final rules and other agency actions (*e.g.*, guidance) in writing, and make those writings available to the public *in real time* either on the OMB web site or in the publicly available electronic rulemaking record for the underlying agency action(s);
- Avoid to the greatest extent possible oral comments on draft proposals and final rules and other actions that could be seen as an attempt to circumvent the written comment condition above or “fingerprinting” requirements in statutes like the Clean Air Act;
- Allow officials *only* at the branch chief level or higher to take actions that have the effect of delaying or blocking the agency action past the formal review period, and then only by making written comments on draft proposals and final rules and

other actions. This would remedy or lessen the potential for abuse in which OIRA desk officers exercise effective veto power over agency actions by refusing to release those actions.

- Make the comments and identities of all agencies and departments during the inter-agency review process on a given agency's rule, publicly available and available to the agency in question in real time. This will provide greater information to the public policy process and offer greater accountability for all of the parties involved
- Hew to the review deadlines in the Executive Order, and only seek extensions where strictly necessary. If and when the formal OMB review period expires, there should be a presumption that OMB review is complete unless formal written objections are lodged at the branch chief level or above, and those written objections are again made available in real time to the agency and the public. If OMB does need to seek an extension, there should be only one such extension and it should be of limited, specified duration. Both of these conditions are needed to reform the current practices which can unjustifiably hold up agency actions by allowing OIRA to either fail to provide written reasons for refusing to release an agency action, or grant itself open-ended extensions.
- Establish an appeals process in situations in which OMB objections to an agency action may be appealed by the agency. This appeal process should be less draconian than the current process calling for elevation to the Vice President's office, since that process discourages appeals and creates undue leverage on the part of OMB. As part of this alternative it could be helpful to involve formally other EOP offices with special expertise and responsibility over the subjects and source of disagreement, *e.g.*, the Council for Environmental Quality for disputes between OMB and EPA and the other environmental and natural resource agencies.
- Finally, we have urged OIRA to provide better detailed summaries of its meetings with outside stakeholders, whomever they might be, rather than the cursory meeting summaries that OIRA currently provides, in which the meeting participants are listed along with only the briefest mention of the subject of the meeting. Members of the public (or fellow agencies for that matter) would benefit from a more meaningful explication of the discussion of issues affecting them.

CONCLUSION

Thank you again for the opportunity to testify before the Subcommittee. We look forward to working with the subcommittee and full committee, as well as the administration, to ensure that efforts to protect public health and the environment based upon agency expertise are successful. I would be happy to answer any questions you may have.

¹ For example, see American Rivers et. al., Transition to Green: Leading the Way to a Healthy Environment, a Green Economy and a Sustainable Future, pp. 2-11 – 2-20, available at <http://www.saveourevironment.org/assets/transition-to-green-full-report.pdf>; see also Richard L. Revesz & Michael A. Livermore, Fixing Regulatory Review: Recommendations for the Next Administration, Institute for Policy Integrity, Report No. 2 (New York University School of Law, Dec. 2008); Gary Bass et. al., OMB Watch, Advancing the Public Interest Through Regulatory Reform (2008), available at www.ombwatch.org/regulatoryreformrecs.pdf.

² See Lisa Heinzerling and Frank Ackerman, Pricing the Priceless: Cost-Benefit Analysis of Environmental Protection (Georgetown Law Institute, 2002).

³ *Id.*, p. 30.

⁴ Office of Information and Regulatory Affairs, Office of Management and Budget, 2008 Report to Congress on the Benefits and Costs of Federal Regulations, and Unfunded Mandates on State, Local, and Tribal Entities, 2008, p. 4 (hereafter the OMB 2008 report). These were analyses of major rules, or rules that generated costs or benefits of at least \$100 million. All amounts are stated in 2001 dollars.

⁵ *Id.*, pp. iii – 5.

⁶*Id.*, pp. 7-11.

⁷ *Id.*, pp. 7-8.

⁸ Office of Management and Budget, Economic Analysis of Federal Regulations Under Executive Order 12866, January 11, 1996; and Jacob J. Lew, Office of Management and Budget, Guidelines to Standardize Measures of Costs and Benefits and the Format of Accounting Statement, March 2000.

⁹ Office of Information and Regulatory Affairs, Office of Management and Budget, 2003 Report to Congress on the Benefits and Costs of Federal Regulations, and Unfunded Mandates on State, Local, and Tribal Entities, 2003 (hereafter the OMB 2003 report), pp. 150-153.

¹⁰ *Id.*, p. 147.

¹¹ *Id.*, p. 157.

¹² To rebut fully the first claim above that the Bush changes were not much different from the Clinton policy, one must carefully compare the Bush language to Clinton language that it revised, since changes in context at times altered the meaning of key passages in certain sections. Also, to understand the implications of the Bush changes for environmental regulatory review, one must contrast the revised OMB directives with the existing EPA guidelines on economic analysis from September 2000. (See EPA, Guidelines for Preparing Economic Analyses (Sept. 2000)). The EPA guidelines are an outstanding summary of currently accepted approaches to economic analysis. Following a review of the revised guidelines, EPA's Environmental Economics Advisory Committee of the Science Advisory Board described the guidelines as "excellent" and concluded that the guidelines "succeed in reflecting methods and practices that enjoy widespread acceptance in the environmental economics profession." *Id.*,

¹³ OMB 2003 Report, Circular A-4, *passim*.

¹⁴ OMB, Economic Analysis of Federal Regulations Under Executive Order 12866, Section III.A.3.a. (1996), and OMB, Special Case: Intergenerational Analysis, Section A.5.b (2000).

¹⁵ See *supra* note 12, Section 6.3.1.5, p. 48.

¹⁶ See *supra* note 14, Section III.A.3.c; and OMB 2000, A.5.b. Special Case: Intergenerational Analysis.

¹⁷ See *supra* note 14, Section 6.3.2.4, p. 52.

¹⁸ For a discussion of the implications of discounting on decision making on climate policy see Richard Newell and William Pizer, Discounting the Benefits of Climate Change Mitigation: How Much do Uncertain Rates Increase Valuations? (The Pew Center on Global Climate Change, December 2001).

¹⁹ See Anna Alberini, Maureen Cropper, Alan Krupnick, and Nathalie B. Simon, Resources for the Future, Discussion Paper 02-19, April 2002.

²⁰ See *supra* note 8, p. 158.

²¹ See *supra* note 12, Section 5.5.1, pp. 27-28.

²² See *supra* note 8, p. 156.

²³ OMB Draft 2003 Report to Congress on the Costs and benefits of Federal Regulations, 68 Fed. Reg. 5,492, 5,524 (Feb. 3, 2003).

²⁴ For more information on this issue see Dr. Frank Ackerman, Uses and Abuses of Economic Analysis in Setting Stormwater Regulations, December 18, 2002.

²⁵ For references in this section see: EPA, Technical Addendum: Methodologies for the Benefit Analysis of the Clear Skies Initiative (September 2002); and EPA, Final Regulatory Support Document, Final Rule for Cleaner Large Industrial Spark-Ignition Engines, Recreational Marine Diesel Engines, and Recreational Vehicles, 67 FR 217 (November 8, 2002).

²⁶ See *supra* note 9.

²⁷ In the report, OMB notes that it has revised the benefits from reductions in nitrogen oxide (“NOX”) emissions to reflect a range of estimates from these recent EPA analyses. It then acknowledges: “Because of the importance of this endpoint and the considerable uncertainty among economists and policymakers as to the appropriate way to value reductions in mortality risks, EPA has developed alternative estimates for its ‘Clear Skies’ legislation that show the potential importance of some of the underlying assumptions.... OMB has used this analysis to identify an alternative estimate of the benefits from NOX reductions,... a difference in the estimates of roughly a factor of five.” This is a huge reduction in the estimated level of benefits, stated under the guise of uncertainty and submitted to Congress as if it is a figure that should be considered with equal merit as the one relied on by the agency.

²⁸ Council On Environmental Quality, Risk Analysis: A Guide to Principles and Methods for Analyzing Health and Environmental Risks, 1989, pp. 10-11.

²⁹ See Office of Science and Technology Policy, Science, Risk, and Public Policy, March 1995, p. 7.

³⁰ Examples of Legislated Standards in Environmental Statutes:
Clean Air Act
§108 requires NAAQS for pollutants with “an adverse effect on public health or welfare,” meaning proof of actual harm before agency action may be taken. Ethyl Corp v. EPA, 541 F.2d 1, 14 (D.C. Cir 1976) (Wright, J.) In other words, demonstration of an effect is required; but demonstrating the *certainty* of the effect is not, as the *Ethyl* case described below proves. The minimum level of certainty required to regulate a chemical was established by the Supreme Court in the so-called Benzene decision. Industrial Union Department, AFL-CIO v. American Petroleum Institute, 448 U.S. 607 (1980). The Court held that a mere

showing of harm is insufficient cause to regulate a chemical, that the agency, in this case OSHA, must first demonstrate “significant” risk, and then demonstrate that the proposed alternative would cause a significant risk reduction.

Whitman v. American Trucking Associations, 531 U.S. 437, 465 (2001)(Scalia, J.): “The language, as one scholar has noted, “is absolute.” D. Currie, *Air Pollution: Federal Law and Analysis* 4-15 (1981). The EPA, “based on” the information about health effects contained in the technical “criteria” documents compiled under § 108(a)(2), 42 U.S.C. § 7408(a)(2), is to identify the maximum airborne concentration of a pollutant that the public health can tolerate, decrease the concentration to provide an “adequate” margin of safety, and set the standard at that level.”

“Did congress pass the Clean Air and Clean Water Acts out of concern that pollution hurts the economy, or out of a fundamental concern for the health of the citizenry?” Rancho Viejo v. Norton, 2003 WL 1699326 (2003) (Garland, J.).

See also:

§109(b)(1) (codified at 42 USC §7409): “National primary ambient air quality standards... the attainment and maintenance of which in the judgment of the Administrator, based on such criteria and allowing an *adequate margin of safety*, are requisite to protect the public health.”

§109(b)(2): “Any national secondary ambient air quality standard...shall specify a level of air quality the attainment and maintenance of which...is requisite to protect the public welfare from *any known or anticipated adverse effects* associated with the presence of such air pollutant in the ambient air.”

Occupational Safety and Health Act § 6(b)(5) : requires agency to “set the standard which most adequately assures, to the extent feasible, on the basis of the best available evidence, that no employee will suffer any impairment of health.”

Industrial Union Dept., AFL-CIO v. American Petroleum Institute, 448 U.S. 607, 646 (1980): “Congress was concerned, not with absolute safety, but with the elimination of significant harm.”

Safe Drinking Water Act

§300g-1(b)(4)(A): “Each maximum contaminant level goal established under this subsection shall be set at the level at which *no known or anticipated adverse effects* on the health of persons occur and which allows an *adequate margin of safety*.”

Natural Resources Defense Council, Inc. v. E.P.A., 824 F.2d 1211, 1216 (D.C. Cir. 1987):

“The Drinking Water Act, by contrast, directs the Administrator to establish a recommended level for “each contaminant which, in his judgment ... *may have any* adverse effect on the health of persons.” 42 U.S.C. § 300g- 1(b)(1)(B) (emphasis added). This language is inconsistent with a requirement that the Administrator make a threshold finding of significant risk.”

³¹Background on lead in gasoline taken from Peter Montague, Precautionary Action Not Taken: Corporate Structure And the Case Study of Tetraethyl Lead In the U.S.A., in Carolyn Raffensperger and Joel Tickner, Eds., *Protecting Public Health and the Environment: Implementing the Precautionary Principle*, at pp. 294-303 (Washington, D.C.: Island Press, 1999).

³² NRDC v. Train, 545 F.2d 320 (2d Cir. 1976).

³³ Ethyl Corp v. EPA, 541 F.2d 1 (D.C. Cir. 1976).

³⁴ *Id.*, at 28.

³⁵ *Id.*, at 7.

³⁶ Lead Industries Association v. EPA., 647 F.2d 1130 (D.C. Cir. 1980).

³⁷ *Id.*, at 1153.

³⁸ GAO Report, Toxic Substances Control Reform, p. 3 (Feb. 26, 2009).

³⁹ *Id.*

⁴⁰ *Id.*, at 10.

⁴¹ 947 F.2d 1201 (5th Cir. 1991).

⁴² There is extensive independent research that demonstrates asbestos's high toll on public health and safety. A Rand study estimated that the industry liability costs alone could reach \$200 billion. The human costs are considerable. Between 1985 and 2009, 225,000 people are estimated to prematurely lose their lives due to asbestos-related cancers.

⁴³ 59 Fed. Reg. 7,629 (Feb. 16, 1994).

⁴⁴ *See, e.g.*, "Prevention of Significant Deterioration, Nonattainment New Source Review, and Title V: Treatment of Certain Ethanol Production Facilities Under the 'Major Emitting Facility' Definition," 72 Fed. Reg. 24,060, 24,077 (May 1, 2007).

⁴⁵ 71 Fed. Reg. 76,603 (Dec. 21, 2006).

⁴⁶ EPA Response to Comments (EPA Doc. ID EPA-HQ-OAR-2005-0475-0164).

⁴⁷ *Id.*

⁴⁸ Section 112(f)(2)(A) of the Clean Air Act states that if, upon completion of an 8-year review, the existing MACT standards for a carcinogenic pollutant do not reduce lifetime cancer risks to less than 1-in-1 million, then EPA "shall promulgate standards" under § 112(f) for sources emitting that pollutant. 42 U.S.C. § 7412(f)(2)(A). EPA's risk analysis found that hazardous organic emissions from one facility resulted in a lifetime cancer risk of 340-in-1 million. SOCMR Residual Risk Assessment (EPA Doc. ID EPA-HQ-OAR-2005-0475-0108) at A-15, N-3, N-4.

⁴⁹ E.O. 13045, 62 Fed. Reg. 19,885 (Apr. 23, 1997).

⁵⁰ *Id.*

⁵¹ *Id.*

⁵² *Id.*, Section 5, 62 Fed. Reg. 19,887.

⁵³ *Id.*, Section 5, 62 Fed. Reg. 19,887.

⁵⁴ *See, e.g.*, HON Rule, 71 Fed. Reg. at 76,613. In the HON Rule, EPA found that the rule did not present a disproportionate risk to children despite the agency's admission that some of the chemicals of concern regulated by the rule are potentially carcinogenic by a mutagenic mode of action, necessarily a concern for children.