NRDC
THE EARTH'S BEST DEFENSE

NATURAL RESOURCES DEFENSE COUNCIL

June 15, 2006

FILED ELECTRONICALLY
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Re: NRDC Comments on the OMB Proposed Risk Assessment Bulletin

Dear Dr. Beck:

The Natural Resources Defense Council (NRDC), a national non-profit public interest organization, offers these comments in response to the Office of Management and Budget's (OMB) Proposed Risk Assessment Bulletin, release on January 9, 2006,[1] which will be peer-reviewed by the National Academies of Science.[2]

The views expressed herein are presented on behalf of NRDC's over 1 million members and activists, who help us protect our nation's public health, safety, and environmental safeguards. Such safeguards were born from a deliberative public process, and although these protections may come at some cost, they deliver tremendous benefits from decreased risks of cancer, to safer automobiles, and increased energy savings. Thus, we believe those who wish to change these safeguards should engage in the same deliberative process used to create them.

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[1] Office of Info. & Reg Affs., OMB, Proposed Risk Assessment Bulletin (Jan. 2006), available at www.whitehouse.gov/omb/inforeg/proposed_risk_assessment_bulletin_010906.pdf

[2] National Academies. Review of the OMB Risk Assessment Bulletin. BEST-K-06-02-A (E. Mantus) www8.nationalacademies.org/cp/projectview.aspx?key=34282

OMB intends its Proposed Risk Assessment Bulletin to provide, "clear, minimum standards for the scientific quality of federal agency risk assessments."[3] Foreshadowing the broad misgivings about this Bulletin from diverse interests, Members of Congress have already identified issues of general concern in a May, 2006 letter issued by the Ranking Members of the House Science, Energy & Commerce, Government Reform, and Transportation and Infrastructure Committees.[4] Although NRDC supports OMB's stated goal of improving agency risk assessment practices, we too have grave misgivings about this troubling proposal. We, therefore, urge OMB to withdraw it from any further public consideration.

STANDARD DEFINITIONS

Within comments written In March, 1995, the following risk-related terminology was issued by the Office of Science and Technology Policy, Executive Office of the President which may be helpful in discussing the current Bulletin:

- ***Risk Assessment***: A process used to evaluate and describe how dangerous a substance or hazard is (i.e. how big is the problem?)
- ***Risk characterization***: An evaluation of available data on a hazard (including exposure and effects), and their associated strengths, limitations, and uncertainties, resulting in a description of the expected risks associated with the hazard.
- ***Risk Management***: The decision-making process by which the results of a risk assessment are integrated with other information, including social, economic, and legal considerations, as well as the actions taken as a result (i.e. what are we going to do about it?)

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[3] Graham, J as quoted in a press release of the Office of Management and Budget. January 9, 2006

[4] Letter to R. Cicerone, President, National Academies of Science from Congressmen B. Gordon, JD Dingell, HA Waxman, JL Oberstar. May 5, 2006 http://sciencedems.house.gov/press/PRArticle.aspx?NewsID=1103

- ***Risk Communication***: The process by which the risk assessor, policymakers, and other individuals discuss risk with one another, including communication between risk assessors and risk managers, and communication between risk assessors and managers and the public.
- ***Comparative risk analysis***: The comparison of risks to one another, which can include the comparison of individual risks or the comparison of groups of risks (i.e. how big is this problem compared to others?)
- ***Risk Analysis***: A comprehensive term encompassing various risk-related activities such as risk assessment, risk management, risk communication, and comparative risk analysis.

RISK ASSESSMENT NEEDS TO SUPPORT REGULATORY ACTION

Risk assessments are conducted under a wide variety of conditions, for a wide variety of purposes, under numerous federal and state statutes, and in widely varying contexts. Risk assessments involve calculating the increase in risk (e.g. illness, injury, or death) associated with exposure (e.g. acute or chronic) to a hazardous agent (where hazard is a quantitative estimate of potency). An agency's ability to collect robust data on exposure and hazard is often very limited. It cannot, for instance, go out and intentionally expose people to precise, measurable levels of carcinogens and then document the increase in cancer rates. Most often, an agency must collect data through other means, often using experimental data from well-designed animal and non-animal studies conducted under controlled laboratory conditions. Still, uncertainties and data gaps abound when extrapolating experimental data to risk for the general population that includes people of diverse ages, lifestyles, nutritional status, genetic make-up, and health status. This makes quantitative risk assessment something between a science and a guessing game, depending on the reliability of the input data.

As a practical matter, however, a regulatory agency must protect the public from preventable risks. To do this in a systematic and scientifically supported manner, an agency collects the available data, and then fills in identified data gaps with adjustment factors, estimates, extrapolations from the

observed range of data to the unobserved range, and with the use of mathematical models. All of these approaches rely heavily on expert judgment, assumptions, and extrapolations. The final risk assessment, including model results, can vary widely depending on the built-in judgments, assumptions, and data. For example, a model may assume an average resting breathing rate, or a heavier breathing rate to capture a working or exercising scenario; the choice may produce widely divergent predictions for the amount of an air pollutant that enters the lungs in a given time.

Regulatory agencies know that the realities of constantly emerging new science and the frailties inherent in available evidence dictate that it will never eliminate all major assumptions and judgments from its decision-making. Our public health and environmental programs, however, would not be effective if incontrovertible evidence of harm were a prerequisite of regulatory action. To quote Bradford Hill, the father of knowledge criteria for epidemiology:

> "*All scientific work is incomplete-whether it be observational or experimental. All scientific work is liable to be upset or modified by advancing knowledge. That does not confer upon us a freedom to ignore the knowledge we already have, or to postpone the action it appears to demand at a given time*." (Bradford Hill, 1965)

However, without *any* scientific support for regulatory decisions, courts will strike down any proposed protections for lack of sufficient evidence. The terrible paradox is that waiting for "evidence" is usually a matter of waiting for an increase in disease and death among the exposed population. Thus, a significant issue for agencies is how much analysis is necessary before promulgating a rule. Courts have consistently acknowledged the need to proceed without full evidence, citing the precautionary goals of most environmental statutes, see Reserve Mining, Ethyl, recent DC Cir Clean Air opinion. In the legal decision of American Trucking on remand, the DC Cir affirmed the propriety of "err[ing] on the side of caution". American Trucking Assns. v. EPA, 283 F.3d 355, 369 (D.C. Cir. 2002).

NRDC CONCERNS WITH THE OMB PROPOSED RA BULLETIN

The Bulletin is mandatory, rather than guidance, thus forcing increased burdens on the issuance of regulations and on information supporting regulatory actions

Because the OMB Risk Assessment proposal is a "Bulletin" rather than guidance it has a prescriptive force behind it; it's mandatory. It dictates rather than suggests. Protestations about flexibility notwithstanding, in fact the bulletin says, "Shall" rather than "may". It dictates to the Agencies what they must do without fail. In fact, each section of the Bulletin begins with the word "shall". For example:

- "…all agency risk assessments available to the public shall comply with the standards of this Bulletin" (II.2)
- The scope and content of each risk assessment "shall" consider the "benefits and costs of acquiring additional information before undertaking the assessment" (III.2).
- All influential agency risk assessments "shall compare the results of the assessment to other results published on the same topic…" (V.1).

It is unreasonable to expect a one-size-fits-all risk assessment approach to be appropriate for all risk assessments across all agencies and under all conditions, as we detail in the following comments. The prescriptive nature of this Bulletin suggests that its goal is not to improve risk assessment across all federal agencies, but instead to force an increasingly burdensome workload on agencies as a means of shackling agencies from taking regulatory action.

The Bulletin re-defines risk assessment to force itself upon all activities that assemble and synthesize scientific information

The Bulletin does not adopt the standard definitions long used by risk assessors, but instead broadens the definition of risk assessment "for purposes of this Bulletin" to include, "a scientific and/or technical document that assembles and synthesizes scientific information to determine whether a potential hazard exists and/or the extent of possible risk to human health, safety or the environment" (I.3., p. 23). Within the discussion of the Bulletin, this is further defined as applying to, "*documents that <u>could</u> be used for risk assessment*

purposes, such as an exposure or hazard assessment that might not constitute a complete risk assessment as defined by the National Research Council" (p. 8) (underline added for emphasis).

To demonstrate the unusually broad scope of this Bulletin, the discussion specifically identifies examples of assessment that are not normally considered to be risk assessment but that are intended to fall within the purview of this Bulletin:

- margin of exposure estimates,
- hazard determinations,
- EPA Integrated Risk Information System used by regulators to set clean up and emission limits
- assessment that support EPA National Ambient Air Quality Standards to set limits on air emissions
- FDA tolerance value that set an upper limit on the tolerable levels of toxics allowed in food products
- ATSDR toxicological profiles that provide scientific hazard information to the general public and state and federal regulators
- HHS/NTP substance profiles that provide toxicological information to regulators and the public
- NIOSH current intelligence bulletins and criteria documents that provide updated scientific information to regulators and the public
- risk assessments performed as part of economically significant rulemakings

It is of significant concern that this Bulletin forces itself upon any piece of information that could conceivably be used for an assessment even though it is not in fact a risk assessment (see standard definitions above). This is so extensive and inclusive that it is difficult to imagine how such a broad definition that is forced across all federal agencies would not result in forcing many federal information assembling activities to a screeching halt. Many risk assessment scholars believe that this may be the intent of the Bulletin, and not just collateral damage. Either result is unacceptable and profoundly inconsistent with the protective nature of environmental and safety legislation.

The Bulletin protects industry assessments from scrutiny

Maybe because of the astoundingly broad reach of the Bulletin, the sectors that are exempted from coverage are worth some scrutiny. The Bulletin specifically does not apply to registration, approval, or licensing, and does not apply to product labels (II.2., p. 23). These are specific agency responsibilities that heavily rely on data and risk assessments provided by the product registrant, i.e. the product manufacturer, producer, or supplier. For example, the registration of pesticides and agricultural pesticides relies almost exclusively on toxicity and exposure data sponsored by the registrant, usually unpublished, and not accessible to the public. This Bulletin protects from scrutiny the risk information that is most likely to be biased, weak, incomplete, and unreliable.

Numerous examples of biased industry science have been reported in the scientific literature: 1) U.S. Environmental Protection Agency (EPA) scientists compared the results from registrant-submitted mutagenicity studies to the EPA Office of Pesticide Programs with those from the published literature, and found a selection bias where registrant-submitted studies on atrazine mutagenicity all reported no mutagenic activity, whereas over a dozen studies in the published literature reported mutagenic activity.[5] 2) An analysis of studies submitted to EPA on the effects of atrazine on frog reproductive development reported that financial sponsorship was a strong predictor of study outcome (p=0.009); funding sources varied for studies reporting adverse effects (including government and industry funding) whereas all of the studies that failed to detect adverse effects were funded by the manufacturer of atrazine.[6] 3) An analysis of 115 published studies on low-dose effects of the plastics-component Bisphenol A found that over 90% of government-funded studies reported significant low-dose effects, whereas none of the industry-funded studies did, and that, "Some industry-funded studies have ignored the results of positive controls, and many studies

[5] Dearfield KL, Stack HF, Quest JA, Whiting RJ, Waters MD. 1993. A survey of EPA/OPP and open literature data on selected pesticide chemicals tested for mutagenicity. I. Introduction and first ten chemicals. Mutat Res 297(3):197-233.

[6] Hayes T. 2004. There is no denying this: defusing the confusion about atrazine. BioSci 54(12):1138-1149.

reporting no significant effects used a strain of rat that is inappropriate for the study of estrogenic responses".[7] 4) Studies of documents from the tobacco industry archives have revealed evidence of concerted industry efforts to obscure the contribution of secondhand smoke and other environmental toxics to disease through the development of their own version of "good epidemiological practices" and "sound science".[8] As Professor Wendy Wagner reported in her recent article, a close examination of instances of scientific misdeeds showed little evidence that the ostensible target of the guidance – federal agency studies – have shown a pattern of bias.[9] In other words, as others have already asked, what problem does this bulletin fix?

The broad sweep taken by this Bulletin in its definition of risk assessment and specific inclusion of exposure and other assessments makes it unlikely that it was by accident that the Bulletin forces itself on data that supports regulatory action, but carves out a specific exception for industry data.

The Bulletin forces itself upon scientific and policy issues

The Bulletin forces economic analyses to precede risk assessments. The Bulletin states that the scope and content of each risk assessment "shall" consider the "benefits and costs of acquiring additional information before undertaking the assessment" (III.2). At one level, it is a good idea to ensure that there is real value to the additional information. But the requirement of a full assessment is unfair and unreasonable. It forces each risk assessment to undertake a full evaluation of the costs and benefits of conducting the assessment prior to initiating any and all assessments across all federal agencies

[7] vom Saal FS, Hughes C. 2005. An extensive new literature concerning low-dose effects of bisphenol A shows the need for a new risk assessment. Environ Health Perspect 113(8):926-933.

[8] Ong EK, Glantz SA. 2001. Constructing "sound science" and "good epidemiology": tobacco, lawyers, and public relations firms. Am J Public Health 91(11):1749-1757.

[9] Wendy E. Wagner, The "Bad Science" Fiction: Reclaiming the Debate over the Role of Science in Public Health and Environmental Regulation, 66(fall) Law & Contemp. Problems 63 (2003)

and under all conditions. The need to gather information and data should not be *a priori* contingent on an economic calculation. Moreover, it is unclear if the cost benefit analysis needs to comply with this Bulletin? If it does, this obvious tautology appears to lead to an unending pre-assessment analysis. If not, it seems rather ironic and disingenuous that an economic analysis that does not have to meet any standards of quality can be used to prevent a quality assessment from being initiated.

The Bulletin forces an unconventional scientific definition that dismisses early molecular events as non-adverse. The Bulletin states that, "where human health effects are a concern, determinations of which effects are adverse shall be specifically identified and justified…" (V.7., p. 25). This is an inappropriate attempt to force a scientific issue and a subsequent policy decision into a direction that suits OMB. The Bulletin goes so far as to define an adverse effect as typically implying "some functional impairment or pathological lesion that affects the performance of the whole organism or reduces an organism's ability to withstand or respond to additional environmental challenges" (p. 20). From the earliest periods of environmental law to the present, courts (e.g., Lead Industries) have recognized that effects that are precursors of frank illness are legitimate and indeed important markers to effectuate the protective goals of environmental legislation. NRDC agrees with OMB that delineating an adverse effect from a pre-adverse or non-adverse effect is becoming increasingly relevant as the scientific frontier of knowledge advances into molecular epidemiology, genotoxicology, and other sophisticated scientific arenas. It is clear now that each interaction between our bodies and the outside environment will induce thousands of cellular and molecular responses, and that a multi-disciplinary scientific discourse will be required to identify transient or homeostatic responses from those that are likely to induce permanent alterations such as cancer or neurological impairments. However, this cuts in the <u>opposite</u> direction from the directive, suggesting that earlier precursors rather than later ones will be increasingly important. Moreover – and especially in this period of rapid scientific advance – it is not the role of the White House, OMB, or even of

risk assessment to force the scientific discourse in a direction that *a priori* dismisses early molecular events as non-adverse.

Perchlorate is an example of OMB favoring the answer it wants over a rigorous risk assessment. Although OMB has been touting perchlorate as an example of a poorly-conducted EPA assessment that benefited from the more rigorous risk assessment performed by the National Academies,[10] nothing could be farther from the truth. In fact, whereas the National Academies does not perform risk assessment (only hazard assessment) and did not include any risk assessors on its scientific committee, the EPA assessment was a true risk assessment; it was quantitative, it included both exposure and hazard components, it considered each and every toxicological study ever done on perchlorate, it reviewed both published and unpublished studies, and it was a rigorous multi-agency intensive effort that spanned over a decade. However, the effort was delayed significantly by interference from the main polluters, the Department of Defense and its military contractors.[11] In 1998 the DOD and PSG contracted for more scientific studies on perchlorate toxicology,[12] but when EPA reported that the data supported a limit of no more than 1 ppb in water based on abnormal brain development in the offspring of perchlorate-exposed mother rodents,[13] PSG submitted a Data Quality Act petition against its own studies

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[10] Graham, J. Public presentation to the National Academies, May 22, 2006, and presentation to the Society for Risk Analysis, May 23, 2006. Washington, DC

[11] for a detailed review of the perchlorate assessment, see: Sass, J. (2004) US Department of Defense and White House working together to avoid cleanup and liability for perchlorate pollution. Int J Occup Env Health, 10: 330-334.

[12] Developmental Neurotoxicity Study, Argus Research Laboratories, 1998. Repeat morphometry with Argus 2001 Effects Study. Repeat DNT performed by US Navy, Bekkedal et al, 2000.

[13] Perchlorate Environmental Contamination: Toxicological Review and Risk Characterization (2002 External Review Draft). U.S. Environmental Protection Agency, Office of Research and Development, National Center for Environmental Assessment, Washington, DC, NCEA-1-0503, 2002.

claiming the data was of too poor quality to be useful.[14] With DOD and the polluters digging in their heels, the EPA risk assessment was sent to the National Academies, where a hazard assessment was performed of the available toxicity data. EPA relied on the National Academies hazard assessment to set a preliminary remediation goal of 24.5 ppb for cleanup. From this example, the most obvious lesson learned is that OMB is not the appropriate arbiter of risk assessment.

The Bulletin forces agencies to devote equal time to flat-earthers and other scientists-for-hire. In numerous places the Bulletin forces agencies to respond to any and all submissions, comments, hypotheses, analyses, and alternate analyses, as if each were of equal scientific value. The Bulletin specifically states that an agency risk assessment must be "scientifically objective" by "giving weight to both positive and negative studies in light of each study's technical quality", and in an "unbiased manner" (IV.4., p. 24). In fact, all studies are not equal and should not be given equal weight.

The regulated industries are known to seed the scientific literature with "anti-data" that reports on the absence of harm from its products or processes. This is the negative data that the Bulletin specifically forces the agencies to contend with. In one of the most egregious examples of White House data manipulation, this past June (June 08, 2005) a top White House environmental official and former oil industry lobbyist, Phillip A. Cooney, was shown to have repeatedly manipulated government reports to downplay the threat of global warming. Documents obtained by the Government Accountability Project revealed that between 2002 and 2003, Cooney, the chief of staff for the White House Council on Environmental Quality, edited drafts of climate change reports to weaken their conclusions that human activity contributes to global warming.

Forcing regulators to give equal weight to negative data is not likely an accidental or unintended effect of this Bulletin. Manufacturing uncertainty to

[14] Girard, M. Letter from the Chairman, Perchlorate Study Group submitted to U.S. EPA Information Quality Guidelines staff. Aerojet, Sacramento, CA. December 3, 2003

force agency inaction is often exactly what industry and OMB may seek to accomplish with such proposals. The tobacco industry introduced the technique of manufactured doubt as a means to deny health impacts and delay regulation of its products: "*Doubt is our product since it is the best means of competing with the 'body of fact' that exists in the mind of the general public. It is also a means of establishing controversy*." (1969 internal tobacco industry memo, stamped "confidential") Studies of documents from the tobacco industry archives have revealed evidence of concerted industry efforts to obscure the contribution of secondhand smoke and other environmental toxics to disease through the development of their own version of "good epidemiological practices" and "sound science", thereby infusing the scientific literature with "anti-data" intended to obfuscate scientific consensus (Ong and Glantz 2001). The OMB Bulletin stands in a long tradition of infusing uncertainty, subjecting evidence of harm to repeated challenges *ad infinitum*, and derailing or delaying regulatory actions.

OMB has not presented a compelling empirical justification for forcing a one-size-must-fit-all approach for all agencies. OMB insists on empirical evidence in the rulemaking process. But the Bulletin lacks any empirical evidence about the nature and extent of the problems with risk assessment practices in each of the agencies. The Bulletin only contains general pronouncements that the risk assessment process can be improved to be better understood, transparent, and more objective. Without knowing the specificity of the problems that the agencies and interested stakeholders are confronting, it becomes difficult to craft an appropriate solution or solutions.

Instead of presenting empirical evidence of the problems, OMB leaped to a solution, but again it failed to provide any evidence demonstrating the efficacy of its proposed one-size-fits-all solution for all agencies.

By rushing to judgment, OMB's Bulletin would effectively force the government to engage in a vast, unwieldy experiment. What is appropriate and necessary for the Food and Drug Administration in calculating and conducting risk assessments may not be appropriate for the Environmental Protection

Agency, for example, because different agencies have important differences in their statutory and regulatory mandates and procedural strictures. Likewise, the level of scientific rigor that a full risk assessment may undergo is likely to be far to stringent for a screening level assessment, a simple exposure assessment, a limited site-specific assessment, or a non-quantitative risk assessment such as the EPA IRIS program, the CDC NHANES biomonitoring data, or the NIEHS Report on Carcinogens. The Bulletin strips federal experts of the ability to exercise expert judgment in developing assessments that are site-specific, timely, and responsive.

OMB has not presented any legal basis giving it the authority to effectively amend eviscerate existing statutory mandates. Although NRDC agrees that improvements should be made in agency risk assessment practices, we are troubled that OMB did not present any legal basis for engaging in this reform endeavor, which will effectively eviscerate existing statutory mandates by requiring the calculation of "central" risk estimates and the quantification of remedial costs as part of a risk assessment for health-based statutes. Whatever authorities OMB may have, it is only through a tortured interpretation of existing law that OMB could derive implicit authority to effectively amend virtually all of the nation's public health, safety, and environmental laws that are premised on the precautionary principle.

The Clean Air Act is such a statute. Section 109 of the Clean Air Act instructs EPA to use a health-based standard for setting ambient air quality standards. In setting the levels, the U.S. Supreme Court has consistently held that the statute and its legislative history make clear that economic considerations should play no part. Consequently, it would be unlawful for OMB to require the agency to quantify costs of proposed standards as part of its risk assessment. Because Congress never implicitly or expressly empowered OMB to amend these statutes by executive fiat, we therefore urge OMB to withdraw its Proposed Bulletin.

Judicial review

A special section, XI, on judicial review states that the Bulletin, "is not intended to, and does not create any right or benefit, substantive or procedural, enforceable at law or in equity, against the Unites States, its agencies or other entities, its officers or employees, or any other person" (XI. p. 26). A press release issued by the U.S. Chamber of Commerce last week (May 18, 2006) stated, "*If the Bulletin is not judicially reviewable, then agencies can ignore it," said William Kovacs, vice president of the Chamber's environment, technology & regulatory affairs division. "What measures will OMB undertake to ensure that the agencies follow the instructions set out in the Bulletin? Unfortunately, the Bulletin lacks clarity on this important matter*."[15] The Chamber of Commerce is correct that OMB has been disconcertingly vague on this critical issue. Is it any wonder that Corporate America wants to increase the force of this Bulletin? It is very likely to bring regulatory actions to a stand-still, especially if outside parties like the Chamber of Commerce can bring a legal challenge against the agencies every time they step out of the straightjacket that this Bulletin places around them.

CONCLUSION

As it is now proposed, this Bulletin contains several significant weaknesses that are likely to be used by industry and the regulated community to challenge regulatory actions *ad infinitum*. The Bulletin imposes costly and time-consuming burdens on federal agencies to respond to challenges by outside parties. It is unnecessarily broad in its application and gives little or no deference to the judgments of the agencies which have the actual scientific expertise to conduct and evaluate risk analyses. It is unfairly burdensome to regulators while giving industry assessments a free pass. And, it pre-ordains a built-in bias against issuance of health protection on key scientific and policy issues. Most concerning

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[15] U.S. Chamber of Commerce Press Statement. U.S. Chamber: OMB Risk Assessment Bulletin Must Be Judicially Reviewable. May 18, 2006. http://www.uschamber.info/ct/u12v2W91xzO9/

is that despite these biases towards industry interests, the Bulletin is mandatory as opposed to providing guidance or recommendations. If it is truly the goal of OMB to "provide clear, minimum standards for the scientific quality of federal agency risk assessments"[16], then it should clearly state that it is guidance only and not prescriptive, that it is not judicially reviewable, and that it is not applicable to all assessments in all situations.

REQUEST FOR RESPONSE FROM OMB

1. OMB's Risk Assessment Bulletin appears to require agencies to conduct cost-benefit analysis and comparative risk assessment to be done in conjunction with risk assessments. What legal authority, if any, authorizes OMB to require agencies to conduct cost-benefit and comparative risk assessment when doing so may contravene the underlying statute?

2. Given that OMB often demands evidence in the rulemaking process, what are the problems with the current implementation of agency risk assessments that lead OMB to conclude its Risk Assessment Bulletin was necessary? What problem is OMB trying to fix, and how will this broad and forceful Bulletin fix that problem without creating new ones?

3. The proposed risk assessment guidance directs agencies to perform substantial analysis to estimate benefits, which can be used as part of cost-benefit analysis. However, there is no corresponding guidance that requires equivalent detailed analytical rigor when estimating costs. Does OMB intend that cost estimation must requires at least as much attention to uncertainty and variability for costs as it does for benefits? If so, why is this not stated in the Bulletin?

[16] Office of Management and Budget. Press release. OMB requests peer review of proposed risk assessment bulletin. January 9, 2006.

4. Please provide the public with an estimate of the additional costs each agency will incur annually to produce risk assessments under the Risk Assessment Bulletin and an estimate of the corresponding benefits in terms of improved risk analysis.

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