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Dr. Nancy Beck
Office of Information and Regulatory Affairs
Office of Management and Budget
725 17th Street, N.W.
New Executive Office Building, Room 10201
Washington, D.C. 20503

Re: Proposed Risk Assessment Bulletin

Dear Dr. Beck:

These comments are submitted by the Center for Progressive Reform (CPR or the Center), an organization of academics specializing in the legal, economic, and scientific issues that surround federal regulation. The comments concern the Office of Management and Budget's (OMB) Proposed Risk Assessment Bulletin (Proposed Bulletin), released on January 9, 2006. CPR notes that these comments are filed comments in accordance with OMB's June 15, 2006 deadline. However, the National Academy of Sciences (NAS) has appointed a panel to review the proposal and its report is unlikely to be issued before the end of the calendar year. Accordingly, CPR requests an opportunity to supplement these comments at that time, and urges OMB to allow members of the public a formal opportunity to do the same.

CPR's mission is to advance the public's understanding of the issues addressed by the country's public health, safety, and environmental laws. The Center is committed

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to developing and sharing knowledge and information, with the ultimate aim of preserving the fundamental value of the life and health of human beings and the natural environment. One component of the Center's mission is to circulate academic papers, studies, and other analyses that promote public policy based on the multiple social values that motivated the enactment of our nation's health, safety and environmental laws. The Center seeks to inform the public about scholarship that envisions government as an arena where members of society choose and preserve their collective values. We reject the idea that government's only function is to increase the economic efficiency of private markets. The Center believes that government authority and resources should be used to preserve collective values and to hold accountable those who ignore or trivialize them.

Overall Recommendation

CPR urges OMB to withdraw the Proposed Bulletin and abandon efforts to revise it. This recommendation is based on our conviction, informed by our many years of experience with risk assessment throughout the government, that any effort to issue uniform, one-size-fits-all guidelines for such a complex and disparate universe of issues will only cause confusion and delay in the protection of public and worker health and natural resources, as well as the safety of Americans at home and abroad.

OMB is not the appropriate institution to define what risk assessment must entail, nor does it have the expertise needed to supervise how scientists and science policymakers formulate such analyses government-wide. OMB is comprised primarily of economists and budget analysts known solely for their work on issues involving the federal budget, e-government, and cost-benefit analysis, despite the addition of a handful of scientists to the staff of the Office of Information and Regulatory Affairs (OIRA) during John Graham's tenure. Subjecting risk assessments to OMB review will undermine the credibility of risk assessments and further politicize regulatory science.

OMB does not appear to have spent adequate time consulting with federal agencies and departments regarding the impact that the Proposed Bulletin could have on the hundreds of types of risk assessments they conduct, nor did OMB conduct a cost/benefit analysis to determine whether the benefits of adhering to the Proposed Bulletin will outweigh the additional resources agencies and departments

will consume as they try require to comply with these overly simplistic, often ambiguous ground rules. Perhaps anticipating a critical reaction, OMB seeks to reassure agencies by explaining its goals in qualified terms throughout the 22-page statement that accompanies these instructions. This permissive language is unlikely to solve the problems raised by the Proposed Bulletin for three reasons.

First, the terminology and explanatory language used in both documents is ambiguous and confusing at several key points. See, for example, the confusion OMB creates by asserting that “central” and “expected” risk estimates are the same thing, discussed further below in the section entitled “Obscurity, Not Transparency.” This problem fatally undermines the one commendable goal of the document: to increase transparency in the performance of risk assessments. OMB asserts that the Proposed Bulletin is merely a restatement of the “best practices” identified in previous reports by the National Academy of Sciences (NAS) and others. However, as explained further below in the sections entitled “Worst Practices” and “Departures from NAS and Presidential Commission Best Practices,” the Proposed Bulletin does not track previous reports and instead contradicts several of their major recommendations.

Second, the Proposed Bulletin displays a thirst for information of all types, from the full range of possible causes of a risk to the availability and cost of remedies that would eliminate or reduce the risk. While scientists and science policymakers would always rather have this information than not, much of it is unattainable as a practical matter in most situations. OMB not only appears to ignore the burden these demands will impose, it does not acknowledge that agencies should and must act despite the uncertainty that is a core and inevitable characteristic of risk assessment.

Third, both of these shortcomings are compounded exponentially by the fact that OMB issued the Proposed Bulletin pursuant to the Information Quality Act (IQA), thus subjecting the question of whether agencies have fulfilled its requirements to potential judicial review. As OMB is well aware, the Fourth Circuit Court of Appeals recently held that the IQA does not provide for judicial review,¹ but the Chamber of Commerce has announced it will seek an amendment to the Act in order to make the

¹ *Salt Institute v. Thompson*, 440 F. 3d 156 (4th Cir. 2006).

Proposed Bulletin “enforceable” by business groups.² Of course, if judicial review becomes available, any group or individual aggrieved by an agency risk assessment, including but not limited to such stakeholders as highway construction contractors, airlines, manufacturers affected by Food and Drug Administration (FDA) safety alerts or pesticide tolerances, or companies that disagree with terrorism preparedness programs, could drag agencies and departments into court in challenges aimed at forcing them to revise their risk assessments to conform to OMB’s norms.

Substantive Flaws

The Proposed Bulletin has eight substantive flaws:

Corpuscularization: The tobacco industry resisted public health controls for years by launching full-scale attacks on any aspect of a scientific study that it perceived as adverse, using these minor complaints as the basis for a wholesale attack on the research supporting further controls on its products. Appropriately described as “corpuscularization” by Professor Thomas McGarity, the Proposed Bulletin is designed to strengthen this tactic on behalf of other harm-generating industries.

Paralysis by Analysis and Ossification. The Proposed Bulletin contains numerous new and unnecessary hurdles for agencies to surmount before they complete a risk assessment, including the instruction that they discover all the “causes” that contribute to a risk (Proposed Bulletin at 13). As explained in Appendix A to these comments – “The FDA Safety Alert Example” – the Proposed Bulletin could prevent the public from receiving information vital to avert major public health problems in a timely manner.

One-Size-Fits-All. The Proposed Bulletin would apply to a wide range of risk assessments dealing with a multitude of threats. But it is modeled on a specific form of risk analysis that was developed to assess the threat of chemically-caused cancer. The most glaring example of why this one-size-fits-all approach is inappropriate is the requirement that agencies provide

² U.S. Chamber: OMB Risk Assessment Bulletin Must Be Judicially Reviewable, May 18, 2006, available at <http://www.uschamber.com/press/releases/2006/May/06-84.htm>

quantitative risk estimates whenever possible, regardless of the complexity of the risk assessment or how they plan to use it.

Obscurity, Not Transparency. The demand that agencies calculate a single “central” estimate of risk frustrates transparency in risk assessment, instead pushing it back toward the stage of development where it produced answers without showing the way analysts did their work.

Conflation of Assessment and Management. The Proposed Bulletin requires agencies to identify and quantify the downsides of “risk reduction alternatives” – or, in other words, the remedies available to solve a problem – before they have even completed an assessment of the size and dimensions of a problem. This conflation creates the significant danger that the anticipated costs of the remedy will bias an honest assessment of the risk.

Injustice. The nation’s protective public health, safety and environmental laws are committed to preventing harm to the most vulnerable populations: children, workers, the elderly, people suffering from respiratory illness, and minority communities exposed to an insupportable pollution loads.³ Indeed, the requirement that agencies consider vulnerable populations is mandated by statute in many cases. The Proposed Bulletin shifts and dilutes this focus, demanding that agencies include estimates of the risk posed to entire populations so that costs and benefits can be calculated as a prerequisite to pollution or workplace controls. If such “aggregate” risks are low, vulnerable individuals would be left unprotected.

Violations of Statutory Mandates. Using central risk estimate and the quantification of remedial costs as part of a public health risk assessment would be illegal under specific statutory mandates that demand precautionary regulation.

Adoption of Worst Practices. In the crucial area of communicating risk to the public, the Proposed Bulletin adopts approaches that directly conflict with the recommendations developed by NAS and the 1998 Presidential Commission on Risk Assessment (Commission). Far from

³ John Wargo, *Our Children’s Toxic Legacy: How Science and Law Fail to Protect Us from Pesticides* (Yale Univ. Press, 2d ed. 1998).

being “best practices” in risk assessment, these approaches will confuse and mislead the public about what we know – and what we do not know – regarding risk.

Summary of Arguments

Fundamental Misfit

Policymakers are rightly focused on efforts to assess the threats posed to public and worker health, safety, and natural resources from exposure to toxic chemicals through inhalation, ingestion, or dermal exposure. They are also right to focus on the risks posed by other potentially harmful anthropogenic activities, such as filling in wetlands, destroying endangered species habitat, or dredging harbors. Incidents like Hurricanes Katrina, Rita, and Andrew have underscored the importance of government evaluation of possible natural disasters and the measures government should take to blunt their impact. The tragedies that began on September 11, 2001, have opened up broad, new vistas for preventive action based on projected threats to public health and safety.

Evaluations of all these problems increasingly depend on “risk assessments,” which have become the coin of the regulatory realm for agencies seeking to take protective action and courts reviewing regulatory action. “Risk assessment” is a term of art used to describe the analysis of risk by multi-disciplinary groups of experts. The Proposed Bulletin embraces the broadest possible meaning of these words, stating that the term means any “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.” (Proposed Bulletin at 23) Not content to leave it there, however, the Proposed Bulletin further expands this definition to include “documents that could 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.” (Proposed Bulletin at 8)

Risk assessments may grapple with activities ranging from terrorist attacks on critical infrastructure (e.g., the power grid) or the food supply. Or they may assess the threats to the environment and public health caused by air and water emissions from chemical manufacturing plants.

Risk assessments evaluate the safety of highway design features before approving the award of construction funding and play a role in determining the schedule and allocation formulas for infrastructure repair. Such assessments are used to evaluate microbial contaminants in meat and poultry. They are a tool used by the Departments of Defense and Energy to establish priorities and develop plans for cleaning up nuclear weapon production and weapons testing sites. They are also used to assess hazardous waste sites created by private parties and government institutions.

In their simplest form, scientists undertake a subset of risk assessment called “hazard assessment” in an attempt to establish a “reference dose” (RfD) for a single chemical. A reference dose estimates the amount of a chemical that people can be exposed to on a daily level without a risk of adverse health effects over their expected lifetime. Exposures *above* the RfD over a lifetime may pose a health risk and should be avoided, with risk generally rising in proportion to increased exposure.

Much of the language in the Proposed Bulletin suggests that this last category was the one that preoccupied OMB as it wrote the Proposed Bulletin, largely because the Environmental Protection Agency (EPA) conducts such assessments as a foundation for programs that control toxic chemical risks, and the chemical manufacturing sector has been among the most vociferous in urging OMB to step into the ongoing debate over how best to project such hazards. Indeed, former OIRA Director John Graham has used EPA’s star-crossed efforts to develop an RfD for perchlorate as his poster child in advertising the ostensible public health benefits of the Proposed Bulletin, arguing that if EPA could learn to do assessments better by following OMB’s lead, it would not suffer “late hits” that would delay protective regulation. Yet even if OMB’s guidance will contribute in a positive way to the process, which CPR believes it will not, RfDs represent only a small, albeit high-profile portion of the risk assessments that OMB seeks to control, leading directly to a Proposed Bulletin that is a misfit with much of the remaining universe.

Defeating Precaution and Exacerbating Injustice

Recognizing the importance of risk assessments in demonstrating the need for preventive and protective regulation, a fierce tug of war has arisen between those who would employ “conservative”

judgments about the elements of a risk and those who believe that less conservative assumptions are justified to reduce the economic impact of the resulting controls. Two distinctly different issues are at stake in this debate.⁴

The first involves scientists' efforts to cope with the *uncertainties* that afflict risk assessments. Responses to uncertainty address the reality that we do not know the true value for an input (e.g., cancer potency) to the risk assessment equation. A response may be more or less "conservative," representing a choice *among two alternative errors*. A conservative approach chooses one error: erring on the side of caution. A non-conservative approach chooses the opposite error.

So, for example, because much of the information we have on toxic chemical effects is derived from animal testing, and we cannot be sure whether animal testing accurately predicts the impact of human exposures, risk assessment panels typically add "safety factors" that reduce the levels of tolerable exposures in order to ensure that regulation is protective enough. Safety factors are often used by regulators carrying out national laws that emphasize the prevention of harm. Virtually all of our public health, safety, and environmental laws are written with this goal as their centerpiece.

The second, equally important issue involves efforts to deal with *variability* among exposed populations. Responses to variability address the fact that we know that there is a range of true values for an input to the risk assessment equation. The true values are not in question; they simply vary. So, for example, people may be exposed to hazards at different levels, depending on the amount of fish they consume, time they spend outdoors, or nature of the paint on the wall in their primary dwelling. A response to variability, then, is not a choice among errors. Rather, it is a choice among known values – and in the case of inter-individual variability regarding exposure, it is a choice to set regulatory protections that address the different levels of risk. Or, in other words, choosing to tolerate a lower level of exposure has the effect of choosing to protect more vulnerable people, including – for example – African American children living in the inner city, Native American subsistence fishermen in the Great

⁴ For further information, see Catherine O'Neill, *Variable Justice: Environmental Standards, Contaminated Fish, and "Acceptable" Risk to Native Peoples*, 19 STAN. ENV'T L. J 3 (2000).

Lakes region, or the elderly obtaining water from a well potentially contaminated by cryptosporidium from combined sewage overflows.

The Proposed Bulletin minimizes both of these issues by instructing agencies to conduct misleading numerical calculations designed to obscure the important choices involving precautionary treatment of uncertainty and protecting the most vulnerable among an exposed population. Two different iterations of this problem are OMB's garbled instructions for calculating "central" risk and its demand that agencies consider "population risk" in addition to the risk posed to vulnerable populations.

Voodoo Science, Take One: Calculating "Central" Estimates of Risk

Not all risk assessments need results that can be distilled down to a number. For many regulatory decisions, decisional criteria focus on whether a hazard exists, not on the degree of hazard (e.g., decisions about contamination remediation in brownfield revitalizations). In fact, as strongly recommended by NAS and the Presidential Commission, point estimates of risk should be avoided unless they are required by statute or regulation (see section "Departures from NAS and Presidential Commission Best Practices," beginning on page 24, below). Nevertheless, OMB's love affair with numbers, predictable given its budgetary background but inappropriate in many of the contexts where it seeks to impose this preference, is on full display in the Proposed Bulletin, to the detriment of sound science and science policy.

OMB describes the methodology for calculating a central estimate as an essentially mathematical process that develops a "weighted average of the results from alternative models." (Proposed Bulletin at 18) This statement recognizes that models vary in their reliability and must be evaluated taking those inevitable flaws into account. However, the notion that the way to conduct such evaluations is to undertake calculations using arbitrarily weighted versions of model results, regardless of the comparability of the set of models, is nonsensical from a scientific perspective. As the NAS has observed:

If, for example, there were model uncertainty about where on the Gulf Coast a hurricane would hit, it would be sensible to elicit subjective judgment about the probability that the model predicting that the storm would hit in New Orleans was correct, versus the probability that an alternative model – say, one that predicted that the storm would hit in Tampa – was correct. It

would also be sensible to assess the expected losses of lives and property if relief workers were irrevocably deployed in one location and the storm hit the other (“expected” losses in the sense of probability times magnitude). It would be foolish, however, to deploy workers irrevocably in Alabama on the grounds that it was the “expected value” of halfway between New Orleans and Tampa under the model uncertainty – and yet this is just the kind of reasoning invited by indiscriminate use of averages and percentiles from distributions dominated by model uncertainty.

NAS Science and Judgment Report at 173.

Voodoo Science Take Two: Addressing “Expected” Risk

While the Proposed Bulletin acknowledges the need to consider risk to the “maximally exposed individual,” it undermines this long-standing focus in several instances involving variability among exposed populations. For example, the Proposed Bulletin requires that each quantitative characterization of risk “include a range of plausible risk estimates, including central estimates. . . . The central risk estimate should *neither understate nor overstate* the risk, but rather, should provide the risk manager and the public with the *expected* risk.” (emphasis added, Proposed Bulletin at 16) This language suggests that OMB uses the phrase “expected risk” to mean the likely impact of exposure on the population taken as a whole, as opposed to the effect exposure has on the most vulnerable subpopulations.

This focus on expected risk is troubling from both an environmental justice and a public health perspective. For example, fish consumption rates are a parameter where variability is great and distribution of risk among the population is skewed, with some individuals (e.g., members of the fishing tribes, members of various Asian-American and Pacific Islander groups) consuming fish at large rates and some individuals consuming no fish at all. Therefore, the mean or average for the entire U.S. population will often be “zero” or close to it because so many individuals are not exposed that they cancel out the relatively fewer number of individuals with large positive values. Therefore, the choice of a mean or average value has the effect of “averaging away” individual characteristics that are very far away from those shared by the bulk of the population. This fatally flawed approach could be analogized to taking the mean of a population that includes men and women to determine the expected risk for prostate cancers.

Risk Estimates, Risk Ranges, and Action Levels

CPR supports OMB's advice that agencies include risk ranges in their final risk assessments because ranges give a clear sense of the degree of uncertainty involved in a risk assessment. We hasten to add, however, that because there should be a clear demarcation between assessments and the actual management of a risk, it is vital that OMB recognize the need for "action levels" that guide action. The recent arrival of George Gray as the EPA Assistant Administrator for Research and Development has prompted a renewed debate regarding the role of risk ranges in the accomplishment of EPA's overall mission. CPR urges OMB to resist the impulse to use relatively wide risk ranges as an excuse for inaction.

Worst Practices

The NAS has issued a series of reports on the risk assessment process, beginning with the 1983 volume *Risk Assessment in the Federal Government: Managing the Process* (frequently called the *Red Book*). See also National Research Council, *Understanding Risk: Informing Decisions in a Democratic Society*, Washington DC: National Academy Press (1996) and National Research Council, *Science and Judgment in Risk Assessment*, Washington, D.C.: National Academy Press (1994) (*NAS Science and Judgment Report*). In 1997, a Commission on Risk Assessment and Risk Management, appointed by the President and Congress, released *Risk Assessment and Risk Management in Regulatory Decision-Making*. Presidential/Congressional Commission on Risk Assessment and Risk Management, Vols. 1 & 2, *Risk Assessment and Risk Management in Regulatory Decision-Making* (1997) (*Presidential Commission Report*). In each instance, these panels of experts stressed the complexity inherent in risk assessment as both a theoretical and practical matter, and they urged government practitioners to tailor threshold assumptions, methodologies, and policy determinations to the problem at hand. While all of these reports have improved the effectiveness of how we practice risk assessment, they have led to more sophisticated, and complex, risk assessment methodologies and practices, as opposed to reducing risk assessment to a small set of simple, uniform rules.

John Graham and other OMB spokespeople have repeatedly asserted that the Proposed Bulletin merely summarizes the “best practices” identified in those previous reports. Once again, however, OMB overlooks many of the fundamental recommendations made by NAS and Presidential Commission reports, developing worst – as opposed to best – practices that would apply government-wide. Most of these worst practices concern the critical issue of properly characterizing risk to the public. They include:

1. **Insistence on Quantitative Analysis.** The Proposed Bulletin urges agencies to quantify risk when a qualitative assessment is the only feasible and accurate way to characterize the assessment’s conclusions.
2. **Misleading Use of Central Risk Estimates.** The Proposed Bulletin recommends that central risk estimates be used in characterizing risk to the public in a manner that would mislead people into thinking they were not a risk when they very well might be.
3. **Mischaracterizations of Scientific Uncertainty.** The Proposed Bulletin lends a deceptive aura of certainty to public characterizations of findings that are based on irresolvable uncertainties.

Assessments, Not “Data”

Risk assessments must consider not only complex scenarios in which threats may arise. They must also try to address the synergistic and cumulative effects of various exposures and threats. In all arenas, data gaps undermine efforts to predict such harms with precision. As any participant in the process or user of the product knows, the work of risk assessment panels is invariably plagued by substantial scientific uncertainty and one of a panel’s main tasks is to apply judgment to incomplete facts in order to come up with an estimate of threats. Given these challenges, it is crucial that risk assessments remain transparent so that all of their underlying data, assumptions, and conclusions are available to policymakers and the public.

In contrast to this widely acknowledged reality, OMB appears to view risk assessment as primarily involving information that is either “correct” or “incorrect.” Industry representative Jim Tozzi,

who is widely credited as the primary advocate for the Information Quality Act, has described such assessments as pieces of “data” that should be modified at the direction of OMB if they are not in accordance with facts. The Proposed Bulletin’s requirement that risk assessments, taken as a whole, must be “reproducible” confirms this mischaracterization of risk assessments as akin to laboratory experiments where answers are either “right” or “wrong.” (Proposed Bulletin at 16)

It is possible that OMB, Mr. Tozzi, and other supporters of the Proposed Bulletin advance this view in order to strengthen OMB’s argument that the IQA requires it to issue such guidance. Whatever their reasoning, these fundamental misperceptions of how the risk assessment process is regarded by scientists suggests that OMB must study the matter at greater length to make the best use of this important analytical methodology.

Politicizing Science

As one would expect, opponents of protective regulation have long emphasized that precautionary laws have a real downside: they impose compliance costs. However, they have been unable to obtain relief through the legislative process, because even the Republican-dominated Congress recognizes the critical importance that most Americans attribute to environmental, health, and safety protection. With the front door closed, these groups have resorted to back-door methods of changing the way that we measure risk and of interposing expensive and time-consuming analysis between identification of a potential problem and an appropriate regulatory response. Thus, they advocate more testing, ostensibly in order to reduce scientific uncertainty but with the more important effect of making it difficult for agencies to issue protective regulation.

Clashes between these disparate points of view have created the impression that risk assessment, like every other form of regulatory analysis, is subject to political pressure that undermines its credibility. At its worst, risk assessment is perceived as a mysterious process, masquerading as pure science, with its most troubling assumptions and policy judgments obscured by deceptively precise numbers that purport to characterize the nature and scope of risk. To restore credibility to the risk assessment process, it is vital that such deliberations be viewed as objective and independent. OMB’s Proposed Bulletin will

accomplish the opposite, deepening the perception that the process is a weapon to further congeal the regulatory process.

OMB's first assertion of its authority under the IQA was a similar guidance on the use of peer review throughout the government. That proposal was so controversial that it was condemned by mainstream scientific organizations like the American Association for the Advancement of Science (AAAS), and OMB was compelled to sharply curtail its scope.⁵ It is likely that the Proposed Bulletin on risk assessment will prove no less controversial.

ADDITIONAL ANALYSIS

Corpuscularization

The IQA says that information “disseminated” by the government must be “correct” and of high “quality, objectivity, utility and integrity.”⁶ The concept for such a mandate originated with EPA's report on second-hand smoke. Philip Morris Inc. was fighting a rear-guard battle against further controls of tobacco and was heavily invested in picking apart every aspect of the report. The company hired Jim Tozzi, a Reagan-era OIRA veteran, to persuade his former colleagues to accomplish this charmingly over-simplistic mandate administratively. After all, who could oppose the idea that government should establish a process for outside parties to challenge its dissemination of incorrect information?

As it turned out, seasoned bureaucrats could easily harbor misgivings about this new approach to obstruction and Tozzi's arguments fell on deaf ears during the Clinton Administration. Frustrated by OMB's indifference, Tozzi went to Capitol Hill where he achieved relief via an obscure, midnight rider on 2001 “must pass” appropriations legislation. From these modest origins, the IQA has spawned guidance from every federal agency and department explaining how officials will consider requests for correction of a wide variety of information.⁷

⁵ For more information, see CPR Comments on the OMB guidance at http://www.progressivereform.org/issue_science.cfm.

⁶ Section 515 of the FY 2001 Appropriations Act, P.L.106-554, 114 Stat. 2763A-153-154 (December 21, 2000)

⁷ For a fuller account of this history, see Thomas O. McGarity et. al, *Truth and Science Betrayed: The Case Against the Information Quality Act* (March 2005), available at <http://www.progressivereform.org/articles/iqa.pdf>; Sidney A. Shapiro, et al., *Ossifying Ossification: Why the Information Quality Act Should Not Provide for Judicial Review* (February 2006), available at http://www.progressivereform.org/articles/CPR_IQA_601.pdf.

Of course, “truth” is an elusive concept when the science, technology, and economics underlying such decisions become ever more complex and when scientific uncertainty is the dominant fact. As the tobacco industry well understood, challenging any debatable assertion, no matter how minor, contained in every piece of unfavorable research is the best way to muddy the waters enough to confound regulators, stalling decisions until the tide of research turns completely and washes away these last outposts of resistance.

This “corpuscularization” of science, to use the term coined by Professor Thomas McGarity, is the foundation of the “sound science” movement spearheaded by regulated industries that is in full swing not just in the U.S., but internationally.⁸ Its central tactic is the flyspecking of scientific studies to find individual “errors” of three distinct kinds: (1) clear misstatements of fact; (2) decisions affecting the conduct of research that could have been made differently; and (3) science policy judgments that are unpopular with special interests. As just one example, all of these tactics have been employed in the increasingly desperate and embarrassing campaign by regulated industries to deny the scientific consensus that global warming is an alarming trend that must be addressed and reversed.

The problem with the first kind of objection is that corpuscularists demand the exclusion of a research study whether a factual error is major or minor, preventing the scientists on a risk assessment team from using their expertise in a “weight of evidence” evaluation that takes mistakes into account in evaluating individual pieces of research. When scientists conduct such evaluations, they understand that studies often have characteristics that affect their relevance to the risk assessment at issue. Rather than discard studies on the grounds that they are not perfect, interdisciplinary panels take these constraints into consideration as they weigh the evidence as a whole.

This problem is exacerbated by OMB’s insistence that “documents that could be used” for risk assessments are included in the ambit of its new guidance. This broad definition suggests that the large body of scientific literature developed over the past 30 to 40 years could be discounted one-by-one due to

⁸ For further discussion, see Thomas O. McGarity, *Our Science Is Sound Science and Their Science Is Junk Science: Science-based Strategies for Avoiding Accountability and Responsibility for Risk-producing Products and Activities*, 52 KAN. L. REV. 897 (2004).

the absence of, among other calculations, central estimates of risk and proper characterizations of uncertainty. None of the instructions contained in the Proposed Bulletin were applicable at the time these studies were conducted, and original data needed for these calculations may well not be available.

The second category of objections offers regulated industries ample opportunities to assail judgments scientists make judgments all the time in order to proceed with their work. For example, scientists may decide to use 25, not 40, rats in a bioassay. Or they may decide to control for smoking as a confounding factor in studying a population to detect connections between pollution and disease, but they may decide not to go to the extra expense of examining the differences between their subjects' diets or stress levels. By challenging such judgments as mistakes that should discredit a study, corpuscularists put everyone on a treadmill of charges and countercharges with no easy escape.

The tactic of challenging science policy judgments such as the use of “safety factors” to compensate for uncertainties in animal testing may be legitimate in deciding what to do in response to a study. Corpuscularists go further, however, and urge decisionmakers to ignore studies solely because they disagree with these science policy judgments. So, for example, a risk assessment that depends on animal testing to derive a Reference Dose (RfD) for people might add a safety factor of ten -- that is, reduce the acceptable dose to one-tenth of what the animals could tolerate – in order to ensure that people are adequately protected. Corpuscularists would urge decisionmakers to ignore the risk assessment because the addition of this safety factor is a factual error, as opposed to a policy position that they find objectionable.

Ossification

The Proposed Bulletin's potential to ossify rulemaking has three components: (1) it conflicts with existing agency policies; (2) it requires agencies to obtain considerable additional information; and (3) it subjects risk assessments to constant challenges by regulated industries and others who are dissatisfied with any aspect of agency decisionmaking.

Conflicts with Long-Established Agency Approaches

The NAS panel conducting a peer review of the Proposed Bulletin held a daylong public hearing in Washington to gather knowledgeable stakeholders' views of its provisions. Representatives from agency after agency testified that the Proposed Bulletin conflicts with well-established procedures that they have developed over the years to conduct risk assessments. The agency representatives also said that figuring out how to conform existing practices to the Proposed Bulletin would consume substantial resources.

Additional, Elusive Information

The Proposed Bulletin identifies several items of information that agencies should develop in the course of risk assessments, all of which are probably desirable, but many of which are either unavailable or very costly to obtain. For example, the Proposed Bulletin urges agencies to identify all potential causes of the adverse health effect under study and consider whether those other causes could play a role in harming human health or the environment. If one kind of air pollutant causes lung cancer, but other environmental exposures, genetic traits, or workplace hazards also result in the disease, EPA would never emerge from a risk assessment that included all these factors. Even without the strictures of the Proposed Bulletin, EPA's reassessment of dioxin, a chemical substance known to be an extremely potent human carcinogen, took over a decade – and this is apparently OMB's model for regulatory expedition.

As explained further in Appendix A, "The FDA Safety Alert Example," this requirement could also undermine federal efforts to issue warnings to the public in emergency circumstances, especially if decision are subject to challenge under the IQA.

IQA Review

The campaign to deconstruct science in order to slow or to gain the upper hand in regulatory decisionmaking has continued at a rapidly quickening pace in all arenas – from rulemaking to judicial proceedings to the scientific literature. To this point, the IQA has played only a supporting role. Government-wide, IQA "Requests for Correction" number in the hundreds, not thousands, and agencies have rejected most of them in short order. All that could change, however, if the IQA provides a route to

judicial review, especially for studies, reports, toxicological profiles, and risk assessments issued before or apart from rulemaking. Whether or not regulated industries win such appeals, opportunities to undermine the validity of research disliked by special interests and to delay decision-making could well be worth the litigation costs.

Recently, the U.S. Court of Appeals for the Fourth Circuit made short shrift of a bid to obtain judicial review of agency IQA decisions under existing language.⁹ Judge J. Michael Luttig wrote that the IQA does not create a cause of action for any particular person or group to challenge the correctness of information in court because Congress did not specify who would have standing in such circumstances. Of course, Congress could amend the statute and the Chamber of Commerce has pledged to pursue such relief.

Unlike a candid, frontal attack on environmental laws, which would have little or no chance of succeeding, this kind of side-door attack is a matter of real concern. However, if the matter is debated fully and the purpose and effect of the amendment is clearly disclosed, and if industry lobbying does not win out over the long-standing concerns of the House and Senate judiciary committees about acute docket overload in the federal courts, the IQA could be transformed from nuisance to major wrench in the works of health and safety regulation. In effect, it would then amount to a codification of corpuscularization, especially with respect to documents such as risk assessments covered by the Proposed Bulletin, which was supposedly written to implement the IQA.¹⁰ It would also mean, in effect, that the decision regarding the quality of the study or report out of the hands of the scientific experts and place it in the hand of the well-meaning but not scientifically trained judges.

One-Size-Fits-All

Even if one takes the stated purposes of the Proposed Bulletin at face value, it reflects the naïve belief that uniform, government-wide standards would improve a process that has almost as many iterations as it does results. The Proposed Bulletin requires agencies to include a “central or expected

⁹ The decision, *Salt Institute v. Thompson*, 440 F. 3d 156 (4th Cir. 2006), is available at <http://pacer.ca4.uscourts.gov/opinion.pdf/051097.P.pdf>.

¹⁰ For more information, see CPR Data Quality perspective at <http://www.progressivereform.org/perspectives/dataQuality.cfm>.

risk estimate” whenever a “quantitative characterization of risk” is made available, and mandates that quantitative estimates should be done “whenever possible.” (Proposed Bulletin at 23-24) Just how would one calculate this central estimate?

This Bulletin uses the terms ‘*central*’ and ‘*expected*’ estimates synonymously. When the model used by assessors is well established, the central or expected estimate may be computed using *standard statistical tools*. When model uncertainty is substantial, the central or expected estimate may be a *weighted average of results* from alternative models. *Formal probability assessments* supplied by qualified experts can help assessors obtain central or expected estimates of risk in the face of model uncertainty.

Proposed Bulletin at 23-24.

Suppose we must conduct a risk assessment of a single toxic substance (think: arsenic, dioxin, perchlorate, mercury, or vinyl chloride) and have available chemical structure analyses, animal and epidemiological studies, and fate and transport models. Each piece of research has its strengths and weaknesses, including the inevitable policy-laden, default assumptions about the shape of the dose response curve, the level of exposure of both animal and human populations, and the pharmacokinetics of what happens to the chemical once it enters the body.

The Proposed Bulletin appears to require that the numeric results of specific subgroups of models be averaged together. One example is the hotly contested area of dose response curve models that use either traditional, “no threshold” assumptions or assume that low doses of specific chemicals are “acceptable.” But the Proposed Bulletin does not stop there. Instead, it appears to require that the numeric results of the full range of “apples and oranges” models somehow be subject to number crunching, also yielding a single estimate of risk.

Given a balanced, suitably skillful risk assessment panel, a reference dose (RfD) for a single chemical can be calculated, although the calculation will require a series of scientific findings *and* science policy judgments that must remain fully transparent so that they can be debated fully. These difficulties are the reason why NAS panels routinely wring their hands over such numbers and either add

a series of safety factors to ensure safety, as done in the case of perchlorate, or pronounce the EPA RfD “justifiable,” as done in the mercury review.¹¹

Now suppose that we are doing a risk assessment that has considerably more dimensions: an evaluation of the risks posed by a substantial expansion of nuclear energy or an examination of the implications of a terrorist attack on the chemical industry. Anyone familiar with the practice of risk assessment in this broader context would recognize the foolishness of attempting to calculate a single “central” number that reflects the wide variety of models and other methodologies used by multi-disciplinary approaches. Reducing such disparate pieces of data to one number can only produce the “junk” science that sound science advocates assure us they are determined to eradicate. Even constructing a meaningful *qualitative* statement summarizing central risk poses substantial challenges.

Conflation of Assessment and Decisionmaking

As discussed, risk assessments come in all shapes and sizes. They can take weeks, months, years, or decades. The perceived magnitude and seriousness of the risk that is the focus of a study inevitably plays a crucial role in determining an assessment’s nature and scope, and OMB wisely advises risk assessors to be transparent about these decisions. But it is one thing to acknowledge that science policymakers cannot help but think about the importance of a problem and what they might be able to do about it when they design an assessment and quite another to say that they must identify and assess those solutions *before* the nature of the risk is established. And yet the Proposed Bulletin demands that they undertake exactly this task:

[R]isk assessments that will be used for regulatory analysis ... shall include ... an evaluation of alternative options, clearly establishing the baseline risk, as well as the risk reduction alternatives that will be evaluated [and] a *comparison of the baseline risk against the risk associated with the alternative mitigation measures being considered.*

Proposed Bulletin at 24 (emphasis added)

Distinctions between risk *assessment* and risk *management* have provoked many a lengthy and esoteric argument in the rarified circles that undertake this troublesome work. Across the political

¹¹ See, e.g., National Research Council, *Health Implications of Perchlorate Ingestion* (Washington, D.C.: National Academy Press, 2005); National Research Council, *Toxicological Effects of Methyl Mercury* (Washington, D.C.: National Academy Press, 2000). Both are available at <http://books.nap.edu/openbook/0309071402/html/index.html>.

spectrum, many believe that there is no clear line between the two, especially in the sense that policymaking, as opposed to “pure” science, infects both aspects of any problem. “Hard” science informs the design of experiments and generates and interprets the results, while “trans-science” permeates everything that happens to those results before they affect human affairs. Nevertheless, if risk assessors and decisionmakers are to be transparent about what they are doing – for themselves and for the public whom they are supposed to protect – they need to be clear when they are engaged in “hard” science and when they just make judgments, and about whether the basis for the judgment is scientific expertise or policy choices. The assessment-management distinction, while imperfect, helps to make that distinction, and the Proposed Bulletin sweeps it away. This is especially ironic, because the assessment-management distinction was a cornerstone of the Red Book, which OMB purports to follow.

Acknowledging this reality is not the same thing as accepting the very large stride that is necessary to get to the idea that risk assessors must worry about the difficulty of finding a remedy before they have assessed the risk. One especially pungent example is testimony by Colonel Dan Rogers, a lawyer by training and Department of Defense’s point person on perchlorate, before the NAS panel reviewing EPA’s RfD on perchlorate:

Thousands of men and women in the uniformed services of the United States of America eagerly await the results of your careful and considered and objective deliberations, for what you decide will have a greater impact on their lives than on any others. ... [T]here is no room for reliance on science *policy* precaution for its own sake ... Every layer of science *policy* precaution inhibits our ability to train ... *[putting] our combat forces and, ultimately, our nation at risk.* (italics added)

Colonel Daniel Rogers, U.S. Air Force, Presentation to the National Academy of Sciences Committee to Assess the Health Implications of Perchlorate Ingestion (Oct. 27, 2003)

Or, in other words, the Proposed Bulletin supports Colonel Rogers’ demands that the panel consider his dire warnings about diminution of national security at the same time that it grapples with how much perchlorate might pose a risk to public health. That is, he was insisting that the panel adjust its *scientific* analysis so that it would support the Army’s *policy* preferences.

Testimony such as Colonel Rogers’ and the requirement to determine costs of clean-up or regulation prior to completing an initial baseline risk substantially increases the potential for bias in the

interpretation of the scientific studies supporting the risk assessment. This actually defeats one of the primary goals of the Proposed Bulletin which is to improve the objectivity of the risk assessment process.

Injustice

Many pollutants affect specific people far more severely than they affect the population as a whole, due either to greater individual susceptibility (that is, some people respond to much lower doses) or higher than average exposures. Children are especially vulnerable to neurotoxins that interfere with the development of their brains. When pregnant women ingest or inhale toxic chemicals that can “cross” the placenta, their developing fetuses may suffer birth defects. Workers exposed to vinyl chloride or polychlorinated biphenyls when they handle these hazardous substances in large amounts daily may suffer sterility or develop cancer. Those who live in the vicinity of chemical plants may breathe substantially more airborne contaminants than their neighbors a few miles away. And people with suppressed immune systems are at heightened risk when exposed to bacterial contamination of the drinking water and food supply.

Typically, risk assessors focus on the threats posed by given exposures to the most vulnerable individuals in a population. They also consider what will happen to the “maximally exposed individual” – that is the people who experience the largest exposures. After all, if we do not prevent pollution to the point that we are able to protect these people, regulation is likely to prove ineffective. Moreover, protecting the most vulnerable offers a precautionary margin of safety for those who are not in sensitive subpopulations.

OMB does not forbid risk assessors from performing such analyses. However, it requires that “[w]hen estimates of individual risk are developed, estimates of population risk should also be developed. Estimates of population risk are necessary to compare the overall costs and benefits of regulatory alternatives.” (Proposed Bulletin at 16.) Since OMB believes that comparative risk assessment – that is, the comparison of the overall costs and benefits of regulatory alternative – is the best, even the only, way to make regulatory decisions, this approach in effect means that agencies will be distracted from their traditional focus on the most vulnerable. It is difficult to argue in the abstract that

more information is not better in any context. In this context, imposing this additional demand on risk assessors will not simply ossify affirmative action to protect public health, but will give OMB crucial tools to enforce its deregulatory goals, shifting an agency's focus, once again, from specific benefits to overall costs.

Violations of Statutory Mandates

Virtually all of the nation's public health, safety, and environmental laws are premised on the principle that we must do what we can to *prevent* risk, rather than taking the approach reflected in tort (or common) law of compensating people after they are injured. These precautionary mandates are exemplified by the Clean Air Act's (CAA) requirement that National Ambient Air Quality Standards (NAAQS) – the most important protections under the Act -- be set at levels that provide an “adequate margin of safety” for public health and the environment. In 1990, Congress restated this standard for air toxics. As recently as 2001, the Supreme Court issued a unanimous opinion stating that the CAA prohibits EPA from considering costs before it establishes a NAAQS.¹² Both the calculation of a “central” risk estimate and the quantification of remedial costs as part of a public health risk assessment create a climate where violations of these specific statutory mandates are possible, even likely.

Obscurity, Not Transparency

We live in a society preoccupied with numbers. Precise numerical quantification of projected future events – whether the costs of regulation, the number of human lives that might be saved by a regulatory intervention, or the amount of money people might be willing to accept in return for being exposed to risk – create an illusion of certainty when the underlying analysis that produced the number is in fact informed guesswork based on speculative information. Once a single number is presented, it takes on a life of its own, substituting for a detailed examination of those assumptions and predictions.

Assuming agencies can figure out how to satisfy OMB's requirement that they calculate a central or expected risk estimate, such numbers are likely to take on a life of their own, triggering the delusion of precision and obscuring, rather than enhancing, the transparency of how an assessment was performed.

¹² *Whitman v. American Trucking Associations, Inc.*, 531 U.S. 457 (2001).

It is crucial that transparency be restored to the scientific process.¹³ It is also important that the issues and information underlying regulatory decisions be simplified, rather than made complex, so that lay people affected by the outcome can understand how those outcomes were determined. But neither goal should be achieved at the expense of an honest and complete statement of the science and science policies that form the foundation for a risk assessment.

Departures from NAS and Presidential Commission “Best Practices”

The Proposed Bulletin is heavily focused on reforming how the results of agency risk assessments are characterized. Proper risk characterization is essential because it influences how risk managers use risk assessments to make regulatory decisions and how the public interprets the potential dangers caused by all of the elements of their environment. The *NAS Science and Judgment Report* provides a useful taxonomy of the four elements of the risk characterization process:

1. a determination of quantitative risk estimates;
2. a description of uncertainty in the risk estimates;
3. proper presentation of risk estimates; and
4. proper communication of the risk estimates.

The Proposed Bulletin purports to address each of these points, but overlooks the NAS report’s recommendations regarding how these analyses should be handled. These shortcomings will make risk estimates less transparent and more likely to be misinterpreted.

Determination of Quantitative Risk Estimates

OMB’s demand that agencies compute single numerical estimates of risk directly conflicts with recommendations by the Presidential/Congressional Commission on Risk Assessment and Risk Management:

Risks have generally been communicated to the public as single numerical estimates, which are easily misinterpreted and misused in the absence of qualitative information about the nature of the risk and about the weight of evidence that supports it.

Presidential Commission Report, Vol. 2 at 85.

¹³ For further explanation, see CPR Science perspective at <http://www.progressivereform.org/perspectives/science.cfm>.

As the Presidential Commission recognized, point estimates are dangerous because they create a false sense of precision. Risk assessment is an uncertain process, and the end result of that process – the risk estimate – embodies all of the uncertainties encountered in the process. To present a risk estimate alone in numeric form ignores the fact that the risk estimate embodies all of this uncertainty and creates a false impression that there is a bright line dividing what is and what is not an acceptable risk.

The Proposed Bulletin contradicts this “best practice” by requiring quantitative risk characterization “whenever possible,” as opposed to “whenever appropriate,” as recommended by the Presidential Commission. (Proposed Bulletin at 24) Even where quantitative risk characterization is appropriate, the Proposed Bulletin’s requirements create more problems than they solve. The Proposed Bulletin makes an effort to address the problem of misinterpreted quantitative risk estimates by requiring that all quantitative risk estimates be accompanied by qualitative risk characterization and “a range of plausible risk estimates.” (Proposed Bulletin at 24) However, this invitation to include risk ranges does not make the risk estimate any more reliable. A range creates the impression that all values within that range are equally plausible. In reality, there will always be some non-uniform distribution of plausibility across the range.

The *NAS Science and Judgment Report* provides a striking example of why the Proposed Bulletin’s requirements regarding risk characterization conflict with best practices. The report describes a scenario in which a risk assessment of carcinogenicity is based on a bioassay of 1,000 mice. If 200 of those mice develop tumors at a certain dose, the risk to mice at that dose would be 0.2. In translating this risk to humans, scientists might disagree as to whether carcinogenicity in mice is at all relevant to humans (perhaps because of different metabolic processes). As explained in the text, if the scientists determine that the effect in mice has a 50% chance of being relevant to humans and a 50% chance of being totally irrelevant, the range of plausible risks to humans would be 0 to 0.2, with a central (or expected) value of 0.1. (*NAS Science and Judgment Report* at 172) Under the Proposed Bulletin, this figure is all that a risk assessment would have to report – the range and the central (or expected) estimate. This approach was definitively rejected by the NAS panel:

We contend that in such cases ... it would be a mistake simply to report the confidence limits and expected value ..., especially if one then used these summary statistics to make a regulatory decision. The risk communication problem in treating this dichotomous model uncertainty as though it were a continuous probability distribution is that it obscures important information about the scientific controversy that must be resolved. Risk managers and the public should be given the opportunity to understand the sources of the controversy, to appreciate why the subjective weights assigned to each model are at their given values, and to judge for themselves what action is appropriate when the two theories, *at least one of which must be incorrect*, predict such disparate outcomes.

NAS Science and Judgment Report at 175 (emphasis in original).

Description of Uncertainty in Risk Estimates

In order to properly communicate the results of a risk assessment to risk managers and the public, it is necessary to first develop a clear description of the uncertainty attached to any risk estimate. The uncertainty in a risk estimate is essentially the summation of all of the uncertainties inherent in each step of the risk assessment process. In general, all uncertainty in risk assessment can be divided into two categories: model uncertainty and parameter uncertainty. *See NA Science and Judgment Report* at 165.

The term “model uncertainty” is used to describe not only uncertainty resulting from uncertainty as to the correct choice between alternate plausible models, but also uncertainty resulting from the various assumptions built in to a given model. The term “parameter uncertainty” is used to describe uncertainties arising out of a number of sources, including measurement errors, use of surrogate data in the place of real-world measurements, and random sampling error. Note that parameter uncertainty is closely linked to, but separate from, the idea of variability. Variability in a parameter can cause uncertainty (e.g., a risk assessment might use standard emissions factors for a particular industrial process rather than taking measurements to determine real-world emissions).

The Proposed Bulletin seems to recognize this distinction – the uncertainty analysis required under Special Standard 4 focuses on model uncertainty only. But while the Proposed Bulletin recognizes the distinction, it does not deal with the distinction properly: it lacks any requirements for analysis of parameter uncertainty. As the NAS panel recognized, focusing on only part of an assessment’s total uncertainty is a major problem:

[A]n uncertainty analysis that carefully keeps separate the influence of fundamental model uncertainties versus other types of uncertainty can reveal which controversies over model choice are actually important to risk management and which are “tempests in

teapots.” If, as might often be the case, the effect of all parameter uncertainties (and variabilities) is as large as or larger than that contributed by the controversy over model choice, then resolving the controversy over model choice would not be a high priority. In other words, if the “signal” to be discerned by a final answer as to which model or inference option is correct is not larger than the “noise” caused by parameter uncertainty in either (all) model(s), then effort should be focused on data collection to reduce the parameter uncertainties, rather than on basic research to resolve the modeling controversies.

NAS Science and Judgment Report at 174-75.

Thus, all of the uncertainty analysis required under Special Standard 4 could very well be a huge waste of agency resources since it focuses entirely on model uncertainty without any reference to parameter uncertainty.

The question remains whether the Proposed Bulletin’s uncertainty analysis is useful in any other respect. For the most part, it is not. The Proposed Bulletin’s extensive requirements for quantitative uncertainty analysis just add more sources of bias and uncertainty to the overall risk assessment process. Special Standard 4(b) requires sensitivity analysis and Special Standard 4(c) requires quantitative uncertainty distributions. The results of both of these requirements are highly dependent on the statistical methods chosen by a risk assessor. Without guidelines setting forth default methods for conducting sensitivity analysis and developing quantitative uncertainty distributions, Special Standard 4 simply adds another potential source of bias to the risk assessment process.

The only useful part of Special Standard 4 is part (a), which requires qualitative discussion of model uncertainty. But again, Special Standard 4(a) is of limited usefulness because it requires qualitative discussion only of model uncertainty. As noted above, parameter uncertainty is a component of total risk assessment uncertainty that cannot be overlooked. By dwelling on model uncertainty without any analysis or discussion of parameter uncertainty, the Proposed Bulletin’s overall uncertainty analysis mandates increased costs to risk assessors without ensuring any concomitant benefit for the overall risk assessment process.

Qualitative discussions of uncertainty focus on the reasons for uncertainty, promoting better transparency in the risk assessment process. The quantitative uncertainty analysis required by the Proposed Bulletin, on the other hand, hides the reasons for risk uncertainty behind a patina of biased

charts and mathematical distributions. This problem brings us to the third element of the risk characterization process: proper presentation of risk estimates.

Proper Presentation of Risk Estimates

After developing a risk estimate and a description of the uncertainty inherent in that estimate, risk assessors must next determine the proper form for presenting that information to both risk managers and the public. The most important consideration in determining the proper form for presenting risk estimates is to be sure that a risk estimate contains adequate qualitative discussion. As noted by the NAS:

Certain expressions of probability are subjective, whether qualitative (e.g., that a threshold might exist) or quantitative (e.g., that there is a 90% probability that a threshold exists). Although quantitative probabilities could be useful in conveying the judgments of individual scientists to risk managers and to the public, the process of assessing probabilities is difficult. Because substantial disagreement and misunderstanding concerning the reliability of single numbers or even a range of numbers can occur, the basis for the numbers should be set forth clearly and in detail.

NAS Science and Judgment Report at 13.

In other words, quantitative risk estimates and uncertainty analyses are useless without adequate qualitative discussion of the principles underlying the numbers. The Proposed Bulletin contradicts this best practice by focusing on quantitative, as opposed to qualitative analysis. Absent such a distinction, the final step in the risk characterization process will lack the transparency the Proposed Bulletin is supposed to enhance.

Uncertainty Analysis

The discussion above describes how the Proposed Bulletin's requirements related to uncertainty analysis are not helpful as they relate to risk characterization and communication. Additionally, the uncertainty analysis requirements are flawed in and of themselves. As is the case for much of the Proposed Bulletin, the uncertainty analysis requirements contradict important findings and recommendations provided in the *NAS Science and Judgment Report*.

One significant problem is the Proposed Bulletin's requirement that risk assessors combine and average risk estimates derived from varying models (General Standard 7(e)). This "apples to oranges" comparison is something that the NAS panel warned against:

Simply put, although classical decision theory does encourage the use of expected values that take account of all sources of uncertainty, it is not in the decision-maker's or society's best interest *to treat fundamentally different predictions as quantities that can be "averaged" without considering the effects of each prediction on the decision that it leads to.*

NAS Science and Judgment Report at 173 (emphasis in original).

In this context, best practices would be a qualitative discussion of any quantitative characterization of risk, not simplistic and misleading summary statistics of the quantitative characterization.

Contextualization of Risk

The Proposed Bulletin requires that risks be put in the context of "other risks familiar to the target audience." (Proposed Bulletin at 24) As explained by the Presidential Commission, the most significant problem with this requirement is that contextualized risk has the effect of minimizing the audience's appreciation of the risk more often than it helps the audience better comprehend the risk.

There are proven dangers in comparing familiar and unfamiliar risks, natural and manufactured risks, and voluntary and involuntary risks, such comparisons can be perceived as minimizing a risk. It is sometimes difficult to find risks that are sufficiently similar to make a comparison meaningful. In general, comparisons of unlike risks should be avoided; they are often perceived as manipulative and confusing.

Presidential Commission, Risk Assessment and Risk Management in Regulatory Decision-Making Final Report Vol. 2 1997 at 42-43 (citation omitted).

Even if we accept, for the sake of argument, that contextualization of risk assessments is a legitimate practice, the standard for comparison should not be simply "familiar to the target audience." Best practices dictate that the standard should be "familiar to the target audience *and proper for comparison.*" For example, the risk of being seriously injured for lack of a seatbelt might be familiar to the target audience, but it is not proper for comparison because putting on a seatbelt is voluntary and many environmental risks are not. As the Presidential Commission pointed out, only risk comparisons that have been tested and found to properly convey what a risk assessment says should ever be used. By failing to include such a limitation on the use of risk comparisons in General Standard 6(d), the Proposed Bulletin creates a distinct hazard that the results of agency risk assessments will be widely misconstrued and regulatory agencies will lose support for important public health agendas.

Conclusion

CPR urges OMB to abandon efforts to strait-jacket risk assessment through the imposition of one-size-fits-all standards that incorporate substantial departures from sound scientific practice. OMB is the wrong institution, acting in the wrong way and at the wrong time, to “improve” a complex and delicately balanced process that is developing at a fast pace throughout the government.

For further information, please call Professor Rena Steinzor at (410) 706-0564.

Sincerely,

A handwritten signature in black ink that reads "Rena Steinzor". The signature is written in a cursive, flowing style.

Rena I. Steinzor,¹⁴
Board Member
Jacob A. France Research Professor
University of Maryland School of Law

¹⁴ Others contributing to these comments include Dr. Katherine Squibb, director of the Program in Toxicology at the University of Maryland Medical School; law Professors John Applegate, Catherine O’Neill, Sidney Shapiro, and Wendy Wagner; CPR policy analyst Matthew Shultz; and CPR law clerk David McMurray.

APPENDIX A

THE FDA SAFETY ALERT EXAMPLE

During a hearing held by the NAS panel that is reviewing the Proposed Bulletin, the FDA representative, Steve Galson, warned that the OMB's proposed risk assessment standards could complicate FDA's efforts to issue safety alerts regarding the adverse effects of drugs, medical devices, or foods. Section 705(b) of the Food, Drug, and Cosmetic Act¹⁵ gives the FDA authority to issue new safety information "in situations involving, in the opinion of the Secretary, *imminent danger to health or gross deception to the consumer.*" (emphasis added) FDA invokes this authority when it discovers, through reporting mechanisms such as reports from consumers and their doctors, that a product under FDA jurisdiction poses a grave danger to human health. Generally, FDA provides public notice through a public health advisory or drug information page.¹⁶

The Proposed Bulletin would cover FDA safety alerts because it broadly defines the term risk assessment to cover any assembly of scientific information used to determine a risk to public safety and because it says that risk assessments are used to "inform the public." (Proposed Bulletin at 1, 3) According to Galson's testimony, the Proposed Bulletin would cover 92 of 109 different safety alerts, including public health advisories, a drug information page, and doctor and patient information sheets.

FDA begins a safety alert assessment (or "post-marketing surveillance") by collecting information from the medical community, the industry, other federal agencies, the World Health Organization, consumers, and so on. In fact, FDA receives about 25,000 voluntary reports to its MedWatch system from concerned citizens every year, along with mandatory reports from manufacturers.¹⁷ Once this information is received, it is compiled with similar information and analyzed. An assessment is triggered when an excess number of safety events compared to the number of persons using a product are reported or when surveillance indicates that the regulated product may cause a serious illness, injury, or a life-threatening situation. At this point, FDA further investigates the

¹⁵ 21 U.S.C. §375b.

¹⁶ See 71 Fed. Reg. 25591, 25592 (May 1, 2006).

¹⁷ See MedWatch: Managing Risks at the FDA, www.fda.gov/fdac/special/testtubetopatient/medwatch.html.

situation and responds differently depending on, for example, the disease being treated, the drug, and the rate of drug use.

Although the FDA receives a significant amount of information on new drugs, the data is limited to short-term studies, making it impossible to predict the long-term effects of these substances. And while FDA sometimes reaches agreements with drug manufacturers to conduct long-term, post-market studies, it reported in 2005 that 70 percent of nearly 1,200 studies had not yet begun.¹⁸ Consequently, adverse events may not appear until the FDA-regulated product is provided to a general, non-research population and consumers and their doctors alert the FDA to those problems. Once FDA learns of such effects, it must react quickly to minimize the potential adverse effects.

In response to the criticism from lawmakers, advocacy groups, and the general populace during the Vioxx fiasco, FDA official Lester Crawford has said that FDA will make new efforts to release safety information to the public “even if it is not complete or if the release displeases drug companies.”¹⁹ However, OMB’s Proposed Bulletin will undermine any such efforts.

The Proposed Bulletin makes an exception for emergency situations. However, even if FDA believes that the need for the safety alert meets the emergency exception, industry may challenge that belief with a lawsuit. The result would be a convoluted process where FDA is forced to meet the Bulletin’s standards on threat of being mired in lawsuits. As Galson noted in his NAS testimony, the public does not want to wait for a complex risk assessment before they are notified about problems with FDA regulated products; “[t]he public health interest may be to tell the public about an adverse event before a dose-response relationship can be defined [through a formal risk assessment].”²⁰

The Proposed Bulletin identifies several items of information that agencies should develop in the course of risk assessments, all of which are obviously desirable, but many of which are either unavailable or very costly to obtain. For example, the Bulletin urges agencies to identify all potential causes of the adverse health effect under study and consider whether those other causes could play a role in harming

¹⁸ See 70 Fed. Reg. 8379, 8380 (February 18, 2005).

¹⁹ See Marc Kaufman, *FDA Plans New Board to Monitor Drug Safety*, Washington Post, February 16, 2005, at A01.

²⁰ John Wilkerson, *FDA Says OMB Risk Assessment Bulletin Hampers Drug Safety Alerts*, FDA WEEK, May 22, 2006.

human health or the environment. In the case of FDA safety alerts, the result of such lengthy studies is an FDA that is not proactive, but instead mired in bureaucracy while the populace suffers the consequences.

Two recent examples illustrate these problems:

1. FDA recently considered a safety alert for a product whose use is associated with the blinding eye fungus *Fusarium keratitis*. Cases of this fungal infection have been confirmed or are suspected in 33 states and have harmed 197 people.²¹ Because the FDA did not have to consider every possible alternative cause of the risk, it was able to react quickly to alert the public of the possible cause. On the other hand, *Fusarium keratitis* might have blinded thousands if the FDA had to contend with the OMB Proposed Bulletin before disseminating the safety warning.
2. *Salmonella* Typharium, a bacteria that is fatal for young children and the elderly, has been discovered in orange juice that is not pasteurized.²² The Proposed Bulletin would give an opportunity to a distributor to fight an alert on the grounds that the FDA did not consider whether the reported cases might have been caused by alternative sources (salmonella is common in poorly prepared food) and that its “central estimate” of risk shows that very few people are affected. By the time these questions are answered, this kind of safety alert would likely be ineffective because the crisis had ended.

²¹ See Press Release, Centers for Disease Control and Prevention, *Fusarium keratitis* Update (May 12, 2006), <http://www.cdc.gov/od/oc/media/fusariumKeratitis/r060512.htm>.

²² See FDA Statement, U.S. Food and Drug Administration, FDA Issues Nationwide Health Alert on Orchid Island Unpasteurized Orange Juice Products (July 8, 2005).