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Dear Ms. Beck:

OMB Watch and Public Citizen write to submit joint comments on the Proposed Risk Assessment Bulletin.

We are deeply concerned by the bulletin's one-size-fits-all straightjacket on agency efforts to identify and evaluate the hazards from which we expect the government to protect us. While we generally favor precautionary approaches that shift the burden of proof onto corporate special interests to demonstrate that the public is not being exposed to unnecessary risk, we must nonetheless expect agencies to do the best job they can to protect the public given the current legal regime which tends to promote risk-based policymaking over safety-first approaches. Given the importance of risk assessment in regulatory policy, we must oppose initiatives like the Proposed Risk Assessment Bulletin, which would so burden risk assessment and other risk-related assessment activities that agencies would wind up paralyzed, unable to establish a case for protecting the public.

Our comments make three basic points:

1. The Proposed Risk Assessment Bulletin is a strategically incoherent document, in which incoherencies operate as covert mechanisms for distorting risk assessment and supplanting agency discretion with OMB's.
2. The Proposed Risk Assessment Bulletin will put the public at risk, as agencies are unduly burdened and standards are shifted to favor corporate special interests in the regulatory process.
3. The Proposed Risk Assessment Bulletin is an unacceptable arrogation of power to the White House, and there is no basis in law or policy for this power grab.

I. OMB'S PROPOSED RISK ASSESSMENT BULLETIN IS STRATEGICALLY INCOHERENT.

OMB's Proposed Risk Assessment Bulletin is a volatile text. There is much in the Proposed Risk Assessment Bulletin that fails to comport with what is generally known and assumed about risk assessment, that cannot harmonize with existing statutory and executive branch mandates, and that even falls apart internally in the text of the bulletin itself. A significant sign of the bulletin's volatility is that these observations have already been raised, in one form or other, by legions of commenters — an unexpectedly large number for so technical and abstruse a topic as the procedures for conducting quantitative risk assessments.

The bulletin's volatilities are not simply flaws to be corrected but actually are fundamental elements of the text. Recent pathbreaking scholarship in legal academia has discovered that legal and policy texts do their work of altering relationships and directing action not only through their overt commands but also through their incoherencies: their internal faults and gaps, logical fissures, and unexplained dissonances with prior legal and policy texts.¹ Incoherence is, in this manner, a working part of the OMB bulletin. The Proposed Risk Assessment Bulletin is a *strategically* incoherent policy document, using incoherencies as an organizing principle and as a covert mechanism for manipulating agency conduct of risk assessments and the White House's role in that process.

There are three important kinds of incoherence in the Proposed Risk Assessment Bulletin:

1. *Definitional incoherence.* Key definitions in the text fail to define any clear boundaries for the subject of the bulletin. The incoherence of these definitions is not the product of sloppy draftsmanship but, instead, is carefully crafted to achieve OMB's political goals.
2. *Substantive incoherence.* At a slightly further remove from the words themselves, the bulletin is premised on an understanding of the relationship

¹ See, e.g., JANET E. HALLEY, DON'T: A READER'S GUIDE TO THE MILITARY ANTI-GAY POLICY (1998) (explicating textual and political volatilities of the U.S. military's "Don't Ask, Don't Tell" policy); Janet E. Halley, *Romer v. Hardwick*, 68 U. COLO. L. REV. 429 (1997) (reading the unexplained trouble points in the relationship between *Romer v. Evans*, 517 U.S. 620 (1996), and *Bowers v. Hardwick*, 478 U.S. 186 (1986), not as gaps to be filled but as new features of the legal world created by the *Romer* decision). Halley's work is the apotheosis in legal scholarship of two otherwise unrelated trends in literary studies and philosophy: the discovery in literature that ambiguity can be *read* as a formal element of a literary text, just like such familiar formal features as rhyme, plot, character, and metaphor, see WALTER J. EMPSON, SEVEN TYPES OF AMBIGUITY (1930), and the development of ordinary language philosophy, with the attendant discovery that speech acts are notable not just for the meaning of their content but also *as actions*, such as when a minister declares a couple husband and wife, see J.L. AUSTIN, HOW TO DO THINGS WITH WORDS (2d ed., J.O. Urmson & Marina Sbisa eds. 1975). Whereas most legal scholars and commentators regard incoherencies in legal and policy texts as flaws to be corrected (with their own commentary offered as advice to a future court or policymaker), Halley's insight is to read incoherence as a feature of the text that is notable not just as an error but also as an active part of the legal or policy document.

between risk assessment, risk management, and risk communication that fails to correspond with the widely accepted view of that relationship. Through this gap between what is presumed in the bulletin and what is otherwise generally believed, OMB actually seeks to effect a change in the very nature of the enterprise of risk assessment and other risk-related assessment activities.

3. *Policy incoherence.* The Proposed Risk Assessment Bulletin does not exist in isolation; agencies must comply with it as well as other existing policies and laws. The bulletin does not cohere in this larger universe of mandates, even though agencies will be expected to comply with all of these mandates simultaneously.

A. The core definitions in the Proposed Risk Assessment Bulletin are incoherent.

The definitions that form the very core of the Proposed Risk Assessment Bulletin are incoherent. The Proposed Risk Assessment Bulletin notionally starts with the universe of agency information, drills down to the set of information that can be called risk assessment, and then carves out a subset of risk assessments that are *influential* risk assessments subject to further prescriptions. This elaborate taxonomy is actually a sham, resulting in an unmanageably vast set and an incoherently defined subset. The inherently meaningless definitions at the core of the bulletin are meaningful in one way: they open the door to a powerful new role for OMB as the arbiter of the case-by-case application of the bulletin for whatever agency informational assessments it decides to govern.

1. *The definition of “risk assessment” covers an unmanageably vast range of agency information.*

As was noted by several presenters at the May NAS session, the bulletin uses a definition of “risk assessment” that sweeps in a much broader universe of agency information than has ever been contemplated by any standard, widely accepted definition. The OMB bulletin uses the following definition:

- (1) A scientific or technical document
- (2) That
 - (a) assembles and
 - (b) synthesizes scientific information
- (3) To determine
 - (a) whether a potential hazard exists and/or

- (b) the extent of possible risk to human health, safety, or the environment.²

On its face, the definition is already so broad as to be meaningless. Moreover, OMB adds that the definition of “risk assessment” will cover many risk-related assessment activities that stop short of full risk assessments, such as hazard identification programs like IRIS and the Report on Carcinogens.³

In fact, the definition of risk assessment is so broad that it would sweep in large number of activities that would never normally be considered risk assessments. The National Weather Service, for example, issues heat advisories and hurricane advisories, which are (1) meteorological pronouncements (2) that draw from empirical observation, computer modeling, and the professional scientific judgment of expert meteorologists (3) to determine (3a) whether a severe weather event, such as a hurricane or intense heat, is likely or imminent and (3b) the extent of that risk for persons exposed to or in the path of the weather event. Likewise, the U.S. Department of Agriculture issues food preparation notifications to the general public, which are (1) health notifications (2) that draw from bacteriology, virology, epidemiology, food and nutrition science, and centuries of empirical observations to suggest safe food handling, preparation, and cooking practices, based on (3) determinations of (3a) whether a hazard exists from handling, preparing, and cooking meats and other foods and (3b) the extent of the risks to human health from unsanitary practices and wrong cooking temperatures. Even the most pro-bulletin corporate special interest would have to concede that weather advisories and food preparation tips are not risk assessments in need of the laborious requirements of the Proposed Risk Assessment Bulletin.

2. *The subset of “influential risk assessment” is likewise incoherent.*

The subject of the bulletin is no clearer once we drill down from “risk assessments” to the subset of “influential risk assessments” subject to even more burdens from the Proposed Risk Assessment Bulletin. OMB defines this subset as consisting of risk assessments (and other risk-related assessment activities falling under the bulletin’s expansive definition) that

- (1) An agency reasonably can determine
- (2) will have or do have
- (3) a clear and substantial impact
- (4) on important public policies or private decisions.⁴

² Proposed Risk Assessment Bulletin at 8 (outline numbering added for illustrative purposes).

³ *See id.* at 9 (“Documents that address some but not all aspects of risk assessment are covered by this Bulletin. Specific examples of such risk assessments include: margin of exposure estimates, hazard determinations, EPA Integrated Risk Information System (IRIS) values, risk assessments which support EPA National Ambient Air Quality Standards, FDA tolerance values, ATSDR toxicological profiles, HHS/NTP substance profiles, [and] NIOSH current intelligence bulletins and criteria documents . . .”).

⁴ *Id.* at 9 (outline numbering added for illustrative purposes).

The narrative of the Proposed Risk Assessment Bulletin reveals that there are important caveats lurking between the lines of these elements. In the world according to OMB, a covered risk assessment or risk-related assessment activity should be considered “influential” and governed by additional strictures because it might influence the behaviors of distant third parties, such as consumers or even foreign governments.⁵ The definition is more like the following:

- (1) An agency reasonably can determine
- (2) will have or does have
 <<could have>>
 <<could be first domino in a chain of events to have>>
- (3) a clear and substantial impact
 <<actual or hypothetical>>
 <<direct or indirect>>
 <<proximate or remote>>
- (4) on important public policies or private decisions.

The relationship between “influential risk assessments” and any actual *influence* they have is so distended that it is difficult to understand just why this subset is called “influential” at all.

Later in the bulletin, the term *influential risk assessment* undergoes another twisting of meaning. In the course of justifying forcing influential risk assessments to find and examine all previously conducted risk assessments (apparently even stale or junk), OMB makes this startling statement:

By definition, influential risk assessments have a significant impact.⁶

In light of the way the term is actually defined, this declaration is an impressive feat of prescriptive tautology. The sentence makes sense only if a reader ignores the official definition of the term and reads the sentence with the ordinary meaning of the words in mind: an *influential* risk assessment, in the absence of any other definition, would probably be a risk assessment that exerts some *influence* and thus has some impact, possibly even a significant impact. “By definition,” however, the relationship of the category of influential risk assessments and their observable impacts is much less clear.

⁵ See *id.* (“A risk assessment can have a significant economic impact even if it is not part of a rulemaking. For instance, the economic viability of a technology can be influenced by the government’s characterization of the risks associated with the use of the technology. Alternatively, the federal government’s assessment of risk can directly or indirectly influence the regulatory actions of state and local agencies or international bodies.”).

⁶ *Id.* at 17.

The dynamic that OMB uses to achieve this definitional legerdemain is worth observing. OMB starts by defining the term “influential risk assessment” on page 9, then moves on page 17 to ignore the previous definition and exploit the meanings latent in the words themselves, in order to assert blithely what the definitions in the bulletin would not otherwise support. It could be schematized as follows:

- (1) Start with a term
- (2) Apply a definition from a specific context or create a new, unfamiliar definition
- (3) Switch to or exploit meaning of term different from (2), such as quotidian sense or a separate, distinct context
- (4) Pretend the shift or exploitation has not happened
- (5) Make other shifts between meanings, or exploit multiple meanings simultaneously, at will

It is a familiar habit of OMB during the tenure of John Graham: witness OMB’s strategically incoherent use of the term *uncertainty*⁷ or, in this bulletin, its manipulation of the term *expected risk*.

3. *These definitions are strategically incoherent.*

These incoherencies are worth charting not simply as an academic exercise in clever readings but, more importantly, as a necessary component of any full reading of the bulletin and its intended consequences. These incoherencies are not scrivener’s errors; they are *functional parts of the bulletin itself*. They are both an organizing principle and prescriptions that alter relationships just as much as any overt command.

One important consequence of the definitional incoherencies at the heart of the bulletin is that they create a rhetorical trap for any members of the concerned public commenting on the bulletin. By confusingly blurring the distinctions between risk assessment and other risk-related assessment activities, and then yoking them together under the bulletin’s own arbitrary definition of “risk assessment,” the bulletin forces commenters into the position of supporting the illusion of coherence in the bulletin any time they use the term “risk assessment.” It is, in fact, difficult for any commenter to construct a meaningful sentence about the subject of the bulletin without portraying it as more coherent than it actually is.

More palpable and longer lasting effects will take place behind the scenes, as the definitional incoherencies service OMB’s desire to arrogate yet more power to itself. OMB grants itself the responsibility for “overseeing agency implementation of” the bulletin.⁸ Because of the

⁷ See J. Robert Shull, OMB Watch, Comments on OIRA’s 2005 Annual Draft Report on the Costs and Benefits of Regulation, *available at* <<http://www.ombwatch.org/regs/Comments/Draft2005CostBenRep.pdf>>, at 48-50 (identifying discursive sleight-of-hand in OMB’s use of *uncertainty*).

⁸ Proposed Risk Assessment Bulletin at 26 § IX.

incoherence of the core definitions of the bulletin and the threat of complete paralysis should the bulletin's strictures actually be applied to all potentially covered agency activities, there will be a great need for OMB's "overseeing" work. The inevitable consultation in case-by-case decisions of the Proposed Bulletin's applicability will give meaning to the Proposed Bulletin that its definitions fail to provide, but the public will not have access to those backdoor decisions. As a result, the agencies' discretion over risk assessment will be supplanted by OMB's.

B. The Proposed Risk Assessment Bulletin is premised on a distortion of the relationships between risk assessment, risk management, and risk communication.

The Proposed Risk Assessment Bulletin distorts the relationship between risk assessment, risk management, and risk communication. As these activities have assumed increasing importance for regulatory policy, the relationships between them have come to be marked by both convergence and separation:

- On the one hand, risk assessment is a purposive activity. Both in the shadow of the law⁹ and in accordance with extralegal mandates,¹⁰ agencies perform risk assessment in order to establish a sound basis for their risk management decisions. Risk assessments and risk-related assessment activities also can be performed for purely informational purposes, such as establishing values for the IRIS database. In other words, risk assessments are performed *for* use in risk management and risk communication. In that sense, the relationship between risk assessment, risk management, and risk communication is *convergent* on shared purposes.
- On the other hand, the activities themselves are treated as distinct and separate functions. In order to be most useful for risk management or communication purposes, risk assessment is an expert evaluation based on scientific evidence and informed judgment that is conducted in a protected sphere, separate from the politicized context of the final risk management decision. In this sense, the relationship between risk assessment, risk management, and risk communication is marked by *separation*.

In short, risk assessment, risk management, and risk communication have shared *purposes* while the *activities* themselves are distinct and separate.

⁹ Quantitative risk assessment is mandatory or quasi-mandatory in many specific contexts, as agencies seek to avoid sanction for being arbitrary and capricious in regulatory decisions, attempt to implement specific statutory commands, observe presumptive mandates in light of the Benzene Case, or comply with formal agency policy or longstanding agency practice from which agencies deviate at some peril.

¹⁰ See, e.g., Exec. Order No. 12,866 § 6.

The Proposed Risk Assessment Bulletin flips the balance of convergence and separation. In the bulletin, OMB blurs what should be kept distinct while separating risk assessment from its shared purposes.

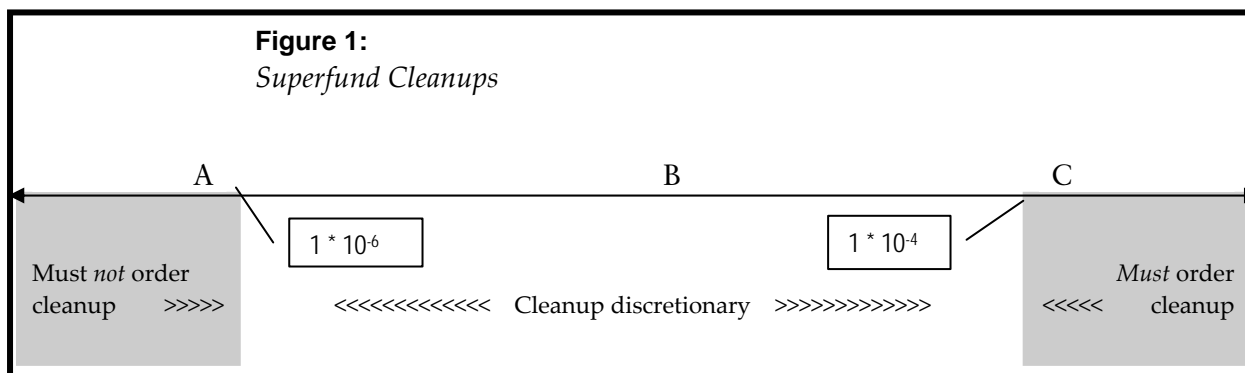
One of the most appalling ways that the distinct activities have been blurred is the Proposed Bulletin's insistence that risk assessors perform risk/risk comparisons. The Proposed Bulletin would require risk assessors to include an executive summary that provides "information that places the risk in context/perspective with other risks familiar to the target audience."¹¹ In other words, risk assessors would be forced to engage in a risk communication — or, more appropriately, risk *propaganda*. This requirement of the bulletin furthers the long-term agenda of former OIRA administrator John Graham who, at the Harvard Center for Risk Analysis, misled the public repeatedly by mischaracterizing protective policy with twisted risk/risk tradeoffs.¹² For example, Graham compared the lifetime fatality risk of dioxin to the risk of dying in a car crash and concluded that the risks of dioxin are minimal. In so doing, he engaged in serious mischaracterization of the risks: ignoring that risks are cumulative, that some risks are amenable to regulatory remedy in ways that others are not, and that some risks (those we consciously take on) are morally incomparable to others (those that we have no choice to face). The Proposed Risk Assessment Bulletin would not merely require risk assessors to do the work of risk communicators; it would require them to do that work *poorly*.

Some of the other requirements of the bulletin make sense only in light of the bulletin's mismanagement of the roles of risk assessment and risk management, and its decision to divorce risk assessment from the risk management contexts in which it is performed. The most significant of these problems is that risk assessors would be forced to supplant point estimates for mushy ranges. Risk assessors are called upon to bring scientific expertise and professional judgment to bear in the face of uncertainty in order to aid risk managers in the policy (and political) decisions that they must make. In the aftermath of the Benzene Case, many agencies make key decisions based on the decision points of 1 in one million (usually treated as a remote or acceptable risk) and 1 in 10 thousand (usually treated as unquestionably actionable risk). Without risk assessors bridging the gap between the known and unknown by applying their professional judgment to assess, on the weight of the evidence, how to characterize risks between those decision points, risk managers will be left with the responsibility of finishing the incomplete work of assessment.

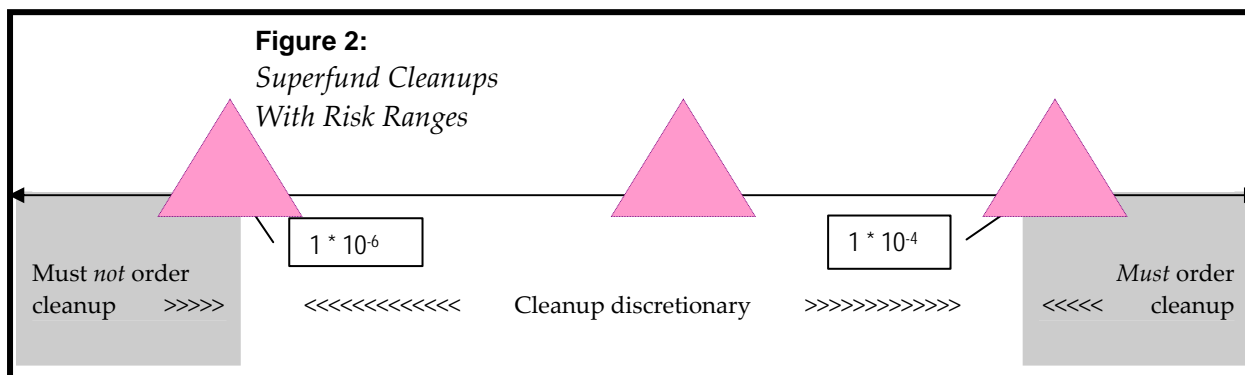
The clearest example of the problems that will result is Superfund cleanups. At the familiar decision points of one in 1 million and one in 10 thousand, EPA policy toggles on and off its officials' discretion over whether or not to order a cleanup: sites that present a risk to the individual reasonably maximally exposed of 1 in 1 million or smaller cannot be subject to a cleanup order, whereas sites that present a risk of 1 in 10 thousand or greater *must* have a cleanup order, and sites between those risk points are left to the agency's discretion.

¹¹ Proposed Risk Assessment Bulletin at 24 § IV(6)(d).

¹² See Laura I. MacCleery, Public Citizen, *Safeguards at Risk: John Graham and Corporate America's Backdoor to the Bush White House* (Mar. 2001), available at <<http://www.citizen.org/documents/grahamrpt.pdf>>, at 17-18.



In Figure 1, the standard scenario, the choice for Superfund officials is clear: a site presenting an assessed risk of value A cannot result in a cleanup order; a site with risk C must result in a cleanup order; and a site with risk B is left up to the officials’ discretion. Under OMB’s Proposed Risk Assessment Bulletin, with point estimates replaced by mushy ranges, the situation would look like Figure 2 — and would be much less clear for administrators. With the work of *assessment* left unfinished, the Superfund administrator would be left with only one clear result: a site with risk B would be left to the administrator’s discretion. Sites with risk ranges at A and C, however, would be much less clear, because the ranges straddle the key decision points. A decision to order a cleanup in case A or not to order a cleanup in case C could immediately be subject to litigation and a protracted legal battle.



Seeing the Proposed Risk Assessment Bulletin in this light — divorcing risk assessment from the risk management purposes for which it is conducted — is the key to making sense of the many new requirements for risk assessments. The bulletin would lard risk assessments with all manner of information that would be irrelevant or extraneous to the risk manager’s needs. For example, the bulletin requires risk ranges, central estimates and efforts to downplay worst-case scenarios, and population-wide risk estimates, even though many risk management decisions require point estimates of risks to individuals in worst-case scenarios. These approaches are utterly inapposite for many specific risk assessment contexts, such as the following:

Comprehensive Environmental Response, Compensation and Liability Act	Reasonable maximum exposure to the individual most exposed
Federal Insecticide, Fungicide, and Rodenticide Act	Not maximum but still above average
Resource Conservation and Recovery Act	Highly exposed individuals
Clean Air Act § 112	Individual most exposed to emissions
Clean Water Act	Assess state proposed standards based on risk to individuals in 90th percentile of fish and water consumption

These are not documents produced in a void, or produced for their own sake as a species of agency activity that can be considered in isolation; they are produced for a specific risk management or other informational purpose. The Proposed Risk Assessment Bulletin treats all risk assessments and risk-related assessment activities as a generic activity that can be systematized with a one-size-fits-all policy. Even worse, it appears intended to take the assessment out of risk assessment, to replace scientific expertise and professional judgment with mechanistic probabilistic exercises. If we must live in a world in which quantitative risk assessment rather than precautionary imperatives guides decision making, then those risk assessments should not be so gutted of all potential utility for regulators.

C. OMB's bulletin would create new, potentially paralyzing uncertainties for regulatory policy.

The final incoherence worth observing is intertextual: how the Proposed Risk Assessment Bulletin relates with other existing policies and laws with which agencies must comply. For example, as other commenters have already observed, the Proposed Risk Assessment Bulletin conflicts with the public interest edicts of the executive orders for child safety and environmental justice.¹³ The bulletin does not clarify whether OMB intends it to trump those executive orders or expects agencies to attempt to observe them all at the same time.

More importantly, agencies perform risk assessments according to specific statutory mandates and judicial interpretations such as the Benzene Case, and the proposed bulletin's one-size-fits-all requirements would likely conflict with the agencies' legal obligations. In fact, a

¹³ See generally Exec. Order Nos. 12,898, Federal Actions to Address Env'tl. Justice in Minority Pops. & Low-Income Pops. (Feb. 1, 1994) & 13,045, Protection of Children from Env'tl. Health Risks & Safety Risks (Apr. 23, 1997).

preliminary analysis conducted by Reps. Gordon, Dingell, Waxman and Oberstar found that “the analytical approach mandated in [the bulletin] represents a significant departure from approaches contained in the many statutes governing health, safety, and the environment, and from statutory direction to federal agencies to protect human health, safety, and the environment.”¹⁴ The representatives determined that the bulletin conflicts with statutory mandates including separation of cost-benefit analysis and risk analysis, and noted that Congress has traditionally guided agencies individually in their risk assessment practices.¹⁵

The Proposed Risk Assessment Bulletin does not exist in isolation; agencies must comply with it as well as other existing policies and laws. The bulletin does not cohere in this larger universe of mandates, even though agencies will be expected to comply with all of these mandates simultaneously. In the name of forcing more transparency and accuracy about scientific uncertainties, OMB will plunge regulatory policy into a new uncertainty of an altogether different sort: an instability of the legal soundness of important decisions to protect the public.

II. THE PROPOSED RISK ASSESSMENT BULLETIN WILL PUT THE PUBLIC AT RISK.

What is most coherent about the Proposed Risk Assessment Bulletin is most troubling: the serious consequences it would have for federal agencies’ ability to protect the public. Harris surveys have repeatedly found that the public demands the federal government play an important role in protecting public health and safety. By burdening the agencies’ ability to identify and characterize the hazards we face, the bulletin would detract agencies from fulfilling that expectation and serving the public interest.

A. The proposed bulletin would hinder agency response to risks facing the public.

The Center for Progressive Reform (CPR) notes in its comments that the proposed bulletin demands that agencies identify all potential sources of harm when conducting risk assessments. In many cases, this would be an incredibly time-consuming task that would delay agency actions to prevent harm to the public, as adverse effects could be attributed to myriad different sources.

The case of the Food and Drug Administration’s July 2005 safety alert¹⁶ warning consumers against drinking Orchid Island orange juice, which the agency linked to a number of salmonella infections, illustrates this danger. In issuing the safety alert, the agency acted on the best available information and with the urgency demanded by the threat at hand. It did not,

¹⁴ Reps. Bart Gordon, John Dingell, Henry Waxman, & James Oberstar, letter to Dr. Ralph Cicerone, President, National Academy of Sciences, May 5, 2006.

¹⁵ *See id.*

¹⁶ *See* Food and Drug Administration, “FDA Issues Nationwide Health Alert on Orchid Island Unpasteurized Orange Juice Products,” July 8, 2005.

however, consider all alternative sources of salmonella that could have explained the numerous cases of infection. Salmonella can come from many different sources, and identifying all potential sources of the bacteria would have significantly delayed the agency's safety alert, leaving the public unaware of the risk of infection from the orange juice.

Essentially, the proposed bulletin would deprive agencies of the discretion to determine the best approach to risk assessments given the particular circumstances involved, such as the urgency for agency action. But the subject matter in risk assessments also varies widely between agencies, and what is the best approach to risk assessments for one agency may not be the best approach for another. At the May NAS meeting, representatives from many agencies expressed concern that the proposed bulletin would force a one-size-fits-all approach despite fundamental differences between agencies. For instance, a USDA representative argued that it conducts diverse assessments that are not likely to fit into the strictures of the bulletin, and a NASA representative argued that the proposed bulletin would not fit the unique risk assessment approaches it has developed to serve its particular needs.

Adding to the potential for regulatory incapacitation, the bulletin assumes an overly expansive scope, subjecting a wide array of agency actions to its constrictive requirements. The bulletin does this by broadening the definition of risk assessment 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."¹⁷ Subjecting all documents that simply *could* be used for risk assessment purposes to the proposed bulletin's requirements would tie up agencies in pointlessly constrictive practices for the most mundane activities. Officials for the National Institute of Environmental Health Science (NIEHS), the Food and Drug Administration, and the National Institute for Occupational Safety and Health all expressed concern over the wide range in the proposed bulletin.¹⁸

Furthermore, the additional time and resources that agencies will need to comply with the bulletin will demand additional finances. If agencies are required to commit additional finances to comply with the bulletin, they likely will need to cut funding for existing agency activities, compromising their ability to protect the public. OMB provides no estimate of the financial costs that the bulletin will impose upon agencies, nor any cost-benefit analysis. In short, the bulletin is an unfunded mandate. If the Proposed Risk Assessment Bulletin is adopted in its current form, OMB must at a minimum increase the budgets for agencies subject to the bulletin, in order to provide the resources necessary to implement the new requirements.

The potential for the bulletin to hog tie regulatory efforts is all the more acute if it is subject to judicial review, which would allow industry groups to initiate length law suits when an agency does not comply with the bulletin. OMB has left vague the issue of whether the bulletin is judicially reviewable, but the Chamber of Commerce has already expressed its hopes for the bulletin, as indicated by its press release titled "OMB Risk Assessment Bulletin Must Be Judicially

¹⁷ Office of Management and Budget, Proposed Risk Assessment Bulletin, January 2006, at 8.

¹⁸ Pat Phibbs, "Definition of Risk Assessment Deemed Too Broad by Several Health Agency Officials," *BNA*, May 23, 2006.

Reviewable.”¹⁹ Of course, it is clear that the bulletin, both by itself and in conjunction with the unreviewable Data Quality Act, could not be judicially reviewed, but these gestures from the Chamber may be the preliminary steps of a long-term lobbying strategy to legislate this outcome.

The consequences of judicial reviewability of the bulletin are illustrated when considered in the context of FDA’s safety alert concerning Orchid Island orange juice contaminated with salmonella. In the Orchid Island case, the proposed bulletin would have given Orchid Island Juice Company an opportunity to delay FDA’s safety alert by alleging that the agency did not follow the bulletin’s guidelines and filing suit. Regardless of the merit of the manufacturer’s claim, by the time the allegations would be resolved, the tainted orange juice would likely have already reached consumers and seriously harmed them. Such a result would undermine the agency’s statutory mandate to safeguard the public health.

B. The proposed bulletin exempts risk assessments most in need of guidelines.

In contrast to the extensive requirements for agency risk assessment activities, the proposed bulletin gives a free pass to assessments used in characterizing risk on product labels if the label is required to be approved by a federal agency, even though those risk assessments most in need of guidelines to ensure quality and objectivity. In many cases, the risk assessments used by agencies in approving labeling for a product are conducted or sponsored by the manufacturer of the product. Manufacturers clearly have an incentive to downplay the harm associated with their product, and a number of studies reveal bias in manufacturer assessments.²⁰ This giveaway to manufacturers undermines the purpose and objectivity of the proposed bulletin.

C. The proposed bulletin would taint science with White House politics.

OMB, a White House policy office with little scientific or technical expertise, is simply not qualified to impose guidelines on agency risk assessments, especially compared to the agencies themselves, which possess the expertise needed to inform good practices in risk assessments. Given OMB’s lack of expertise and abundance of political motivation, it can be expected that the proposed bulletin will serve to conform the risk assessments to White House political whims. Allowing OMB, through the bulletin, to influence regulations by shaping the assessments informing regulatory decisions signals a dramatic expansion of OMB’s power, without statutory authorization, and poses the threat that White House political priorities will permeate the science underlying regulatory activities.

¹⁹ U.S. Chamber of Commerce, “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>>.

²⁰ Jennifer Sass, letter to Dr. Nancy Beck regarding NRDC comments on the OMB Proposed Risk Assessment Bulletin, June 15, 2006.

III. THERE IS NO BASIS FOR THE BULLETIN.

The Proposed Risk Assessment Bulletin is an unacceptable arrogation of power to the White House over matters entrusted by Congress to the agencies. Constitutional design and longstanding traditions of American governance ensure that no single office wields too much concentrated power. For example, power is diffused in the legislative branch by the bicameral structure and such important traditions as the separation of appropriations and authorization functions. Likewise, the judicial branch diffuses power by separating findings of fact and questions of law between juries and judges at the trial level and, on appeal, requiring appellate courts to defer to factual but not legal conclusions of the trial courts. So, too, with the executive branch: although the Framers opted not to create an executive council instead of a single president, they specifically provided that Congress would be empowered to delegate authorities directly to the departments of government.²¹ Unless Congress legislates to the contrary, the president lacks the “authority to dictate decisions entrusted by statute to executive officers.”²²

Moreover, there is simply no need for this one-size-fits-all straightjacket on the agencies. While in many ways the bulletin would conflict with existing agency risk assessment practices, in other ways it would be simply redundant, as agencies currently follow many of the bulletin’s guidelines. A number of agencies – including OSHA, EPA, DOD and CDC – mentioned at the NAS forum that the bulletin simply reiterates the practices to which they currently adhere in conducting risk assessments. This begs the question of what deficiency is the bulletin intended to address. And this question is all more critical given that proposed bulletin would *create* deficiencies, such as slowed agency response to risks facing the public. OMB, however, presents no evidence that current agency risk assessment practices require improvement – a glaring omission given that OMB demands evidence of the need for regulation in rulemaking processes.

²¹ See Robert V. Percival, *Presidential Management of the Administrative State: The Not-So-Unitary Executive*, 51 Duke L.J. 963, 967-69 (2001).

²² *Id.* at 966. See also Lisa Heinzerling, *Statutory Interpretation in the Era of OIRA* (Geo. Pub. L. Res. Paper No. 899025, April 2006), available at <http://papers.ssrn.com/sol3/papers.cfm?abstract_id=899025>; Kevin M. Stack, *The President’s Statutory Powers to Administer the Laws*, 106 Colum. L. Rev. 263 (2006).

CONCLUSION

Proffered in the name of good government, the Proposed Risk Assessment Bulletin represents a deep hostility to the federal role in protecting the public. We demand that OMB retract this bulletin and spend no further taxpayer dollars on developing or implementing such a dangerous policy.

Respectfully submitted,

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