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# OMB AND THE POLITICIZATION OF RISK ASSESSMENT

BY

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*In January 2007, the Office of Management and Budget (OMB) withdrew its proposed draft Risk Assessment Bulletin (Bulletin), containing guidelines for the conduct of all risk assessments by government agencies, after being advised by a committee of the National Research Council of the National Academy of Sciences that the guidelines were too flawed to be repairable. OMB's failures can be attributed to its lack of scientific expertise, but OMB also saw the guidelines as an opportunity to politicize the risk assessment process in the federal government. This Article explores the potential for politicization of science in safety, health, and environmental regulation, and how the Bush Administration sought to take advantage of this potential in the proposed guidelines. It also considers what role OMB should play in the development of risk assessment guidelines, concluding that OMB should play an agenda setting and coordination role to improve agency science as necessary, but the actual job of writing scientific guidelines should be left to the agencies themselves.*

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## I. INTRODUCTION

In 2004, sixty of the nation's most eminent scientists signed a declaration objecting to the politicization of science in the Bush Administration.<sup>1</sup> The administration's efforts to politicize science are documented in recent books and reports.<sup>2</sup> According to one author, "[t]he degree of lying, deception, and manipulation of information reported across so many federal agencies would seem to have required in the administration of George W. Bush a combination of callousness, mendacity, and hubris that is rare even in the messy history of American politics."<sup>3</sup>

In January 2006, the Office of Management and Budget (OMB) proposed a draft Risk Assessment Bulletin (Bulletin) containing guidelines for the conduct of all risk assessments by government agencies.<sup>4</sup> The Bulletin covered any scientific or technical document that assessed possible risks to human health, safety, or the environment.<sup>5</sup> OMB sought comments on the proposed Bulletin from the public and from regulatory agencies,<sup>6</sup> and it asked the National Research Council (NRC) of the National Academy of Sciences (NAS) to conduct an independent "scientific and technical review of the proposed [B]ulletin."<sup>7</sup> The NRC empanelled a committee of experts on

<sup>1</sup> Union of Concerned Scientists, *Restoring Scientific Integrity in Policy Making*, [http://www.ucsusa.org/scientific\\_integrity/interference/scientists-signon-statement.html](http://www.ucsusa.org/scientific_integrity/interference/scientists-signon-statement.html) (last visited Nov. 18, 2007).

<sup>2</sup> See, e.g., SETH SHULMAN, *UNDERMINING SCIENCE: SUPPRESSION AND DISTORTION IN THE BUSH ADMINISTRATION* (2006); CHRIS MOONEY, *THE REPUBLICAN WAR ON SCIENCE* (2005); UNION OF CONCERNED SCIENTISTS, *SCIENTIFIC INTEGRITY IN POLICYMAKING: AN INVESTIGATION INTO THE BUSH ADMINISTRATION'S MISUSE OF SCIENCE* (2004), available at <http://www.americanprogress.org/kf/ucsintegrity.pdf>; MINORITY STAFF OF H. COMM. ON GOV'T REFORM, SPECIAL INVESTIGATIONS DIV., 108TH CONG., *POLITICS AND SCIENCE IN THE BUSH ADMINISTRATION*, at i (2003), available at [http://oversight.house.gov/features/politics\\_and\\_science/pdfs/pdf\\_politics\\_and\\_science\\_rep.pdf](http://oversight.house.gov/features/politics_and_science/pdfs/pdf_politics_and_science_rep.pdf).

<sup>3</sup> SHULMAN, *supra* note 2, at xv.

<sup>4</sup> OFFICE OF MGMT. & BUDGET, *PROPOSED RISK ASSESSMENT BULLETIN*, available at [http://www.whitehouse.gov/omb/inforeg/proposed\\_risk\\_assessment\\_bulletin\\_010906.pdf](http://www.whitehouse.gov/omb/inforeg/proposed_risk_assessment_bulletin_010906.pdf) [hereinafter PROPOSED BULLETIN].

<sup>5</sup> See *id.* at 1.

<sup>6</sup> Proposed Risk Assessment Bulletin, 71 Fed. Reg. 2,600, 2,600 (Jan. 17, 2006) (requesting comments).

<sup>7</sup> COMM. TO REVIEW THE OMB RISK ASSESSMENT BULLETIN, NAT'L RESEARCH COUNCIL, *SCIENTIFIC REVIEW OF THE PROPOSED RISK ASSESSMENT BULLETIN FROM THE OFFICE OF MANAGEMENT AND BUDGET 1* (2007), available at <http://books.nap.edu/catalog/11811.html#toc> [hereinafter NRC Report].

risk assessment to undertake the review,<sup>8</sup> and the committee sought review of its draft report from additional experts.<sup>9</sup>

The committee began its work anticipating that “its role would be to recommend modifications [to the Bulletin], if necessary. [However,] [a]fter digging deeply into the bulletin and after extensive discussion, the committee reluctantly came to its conclusion that the bulletin could not be rescued.”<sup>10</sup> The report indicates the scope of the problems found by the committee.<sup>11</sup> The appendix lists each OMB requirement in the proposed Bulletin line by line.<sup>12</sup> The committee has an objection or problem with nearly every line.<sup>13</sup> In January 2007, the NRC panel advised OMB that it should withdraw the proposed Bulletin,<sup>14</sup> which OMB did.<sup>15</sup> In September 2007, OMB issued a memorandum on “Updated Principles for Risk Analysis,” which restates and updates an earlier OMB memorandum on risk assessment.<sup>16</sup> The memorandum, however, leaves open the issue for the next administration of what role OMB should play regarding agency risk assessment.<sup>17</sup>

OMB’s lack of scientific expertise played a role in the failure of the Bulletin, but there is also abundant evidence that OMB saw the Bulletin as an opportunity to politicize risk assessment. It is therefore worthwhile to analyze OMB’s initial effort and to consider what role OMB should play in superintending the risk assessment process in the federal government. This Article proposes that OMB should restrict its role to performing an agenda-setting and coordination role.

The argument for this conclusion proceeds in five steps. Section II explains how the relationship of science, law, and policy in regulation opens the door for politicization of science. Section III offers a description of

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<sup>8</sup> A list of committee members and their biographies can be found on the National Academies Press website, available at [http://books.nap.edu/openbook.php?record\\_id=11811&page=113](http://books.nap.edu/openbook.php?record_id=11811&page=113). NRC REPORT, *supra* note 7, at 113–20.

<sup>9</sup> NRC REPORT, *supra* note 7, at 1.

<sup>10</sup> *Id.* at 7.

<sup>11</sup> *Id.* at 107–10.

<sup>12</sup> *Id.* at 130.

<sup>13</sup> *Id.* at 35–69.

<sup>14</sup> Press Release, The Nat’l Academies., Report Recommends Withdrawal of OMB Risk Assessment Bulletin (Jan. 11, 2007), available at <http://www8.nationalacademies.org/onpinews/newsitem.aspx?RecordID=11811>; see also Kara Sissell, *Science Panel Tells OMB to Withdraw Risk Guidelines*, CHEM. WK. 43, Jan. 24, 2007.

<sup>15</sup> Ralph Lindeman, *OMB Regulatory Policy Chief Anticipates New Draft of Risk Assessment Guidance*, Daily Rep. for Executives (BNA) A-24, A-24 (May 10, 2007), available at <http://pubs.bna.com/ip/bna/der.nsf/eh/a0b4m6p7d7>; Cornelia Dean, *Risk-Assessment Plan Is Withdrawn*, N.Y. TIMES, Jan. 12, 2007, available at <http://nytimes.com/2007/01/12/washington/12risk.html>.

<sup>16</sup> Memorandum from Susan E. Dudley, Adm’r, Office of Info. & Regulatory Affairs, Office of Mgmt. & Budget, & Sharon L. Hayes, Assoc. Dir. & Deputy Dir. for Sci., Office of Sci. & Tech. Policy, to the Heads of Executive Departments & Agencies, Updated Principles for Risk Analysis 1–2 (Sept. 19, 2007) available at <http://www.whitehouse.gov/omb/memoranda/fy2007/m07-24.pdf> [hereinafter Memorandum, Updated Principles for Risk Analysis].

<sup>17</sup> *Id.* at 2.

OMB's draft Risk Assessment Bulletin. Section IV considers whether the many problems with the Bulletin identified by the NRC committee can be explained by OMB's lack of scientific expertise. This section argues that OMB's lack of expertise is a reason for the failure of the draft Bulletin, but OMB also saw the Guidelines as an opportunity to politicize the risk assessment process in the government. Section V explains how the NRC committee's evaluation of the Bulletin reveals OMB's political motives in proposing the Bulletin. Section VI discusses an appropriate role for OMB in superintending science. It explains why OMB should restrict its role to performing an agenda setting and coordination role.

## II. THE EXPLOITATION OF SCIENTIFIC UNCERTAINTY

One of the primary ways the Bush Administration has politicized science has been to change scientific results or to repress them. The most well-known example involves Phillip Cooney, former chief of staff of the White House Council on Environmental Quality until 2005, who edited government climate reports to overemphasize the uncertainty of a human role in global climate change and deemphasize the scientific evidence of such a role.<sup>18</sup> Administration officials at other agencies, however, have also asked or demanded that scientists change risk assessments because the results did not support policy outcomes preferred by the Administration.<sup>19</sup> In other instances, administration officials have refused to permit agency scientists to publish scientific papers or make presentations at scientific meetings in order to suppress inconvenient scientific information.<sup>20</sup>

The Administration has also engaged in science denial. Its obsessive refusal to acknowledge or act on the overwhelming scientific evidence of global climate change is the most obvious example of this type of politicization,<sup>21</sup> but it is not the only type of such activity in the Bush Administration. The Food and Drug Administration (FDA), for example, refused to approve the emergency contraceptive Plan B, despite the fact that

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<sup>18</sup> Andrew C. Revkin & Matthew L. Wald, *Material Shows Weakening of Climate Change Reports*, N.Y. TIMES, Mar. 20, 2007, at A16. Before joining the administration, Cooney was the "climate team leader" for the American Petroleum Institute, the oil industry's principal lobby in Washington. *Id.*

<sup>19</sup> See Press Release, Union of Concerned Scientists, FDA Scientists Pressured to Exclude, Alter Findings; Scientists Fear Retaliation for Voicing Safety Concerns (July 20, 2006), available at [http://www.ucsusa.org/news/press\\_release/fda-scientists-pressured.html](http://www.ucsusa.org/news/press_release/fda-scientists-pressured.html). A survey of Food and Drug Administration (FDA) scientists by the Union of Concerned Sciences found that nearly one-fifth of the 997 scientists who responded to the study said that they "have been asked, for non-scientific reasons, to inappropriately exclude or alter technical information or their conclusions in a FDA scientific document." *Id.* A joint survey conducted by the Union of Concerned Scientists and the Public Employees for Environmental Responsibility found that close to one-fifth of the respondents at the U.S. Fish and Wildlife Service reported that they had been instructed inappropriately to "exclude or alter technical information from a scientific document." SHULMAN, *supra* note 2, at 83.

<sup>20</sup> See TAREK MAASSARANI, GOV'T ACCOUNTABILITY PROJECT, REDACTING THE SCIENCE OF CLIMATE CHANGE: AN INVESTIGATION AND SYNTHESIS REPORT 64-74 (2007).

<sup>21</sup> SHULMAN, *supra* note 2, at 16-30.

two scientific advisory committees had overwhelmingly found that the drug was safe and effective. In light of the advisory committee recommendations, FDA's weak efforts to justify the outcome strongly suggest the Administration was supporting the reproductive agenda of its religious supporters.<sup>22</sup>

OMB's efforts to politicize risk assessment involve a more subtle form of politicization—the exploitation of scientific uncertainty. This section explains this form of politicization.

### *A. The Interaction of Law, Science, and Policy*

Congress passed most of the legislation used in this country to regulate the risks that technologies pose for people and the environment in the 1960s and 1970s.<sup>23</sup> A common feature of this legislation is the authorization to act on the basis of anticipated harm.<sup>24</sup> Specifically, Congress specified “risk triggers” that establish the evidentiary burden that an agency has to meet in order to regulate.<sup>25</sup> Under a “risk-based threshold,” for example, an agency must prove that the public or the environment is exposed to a substance or hazard at a potentially dangerous level.<sup>26</sup> A regulatory agency will marshal scientific evidence to determine whether a regulatory trigger has been met.

Whether an agency has sufficient scientific evidence to satisfy a statutory risk trigger is a legal issue and not a scientific one. It is a legal issue because Congress intended agencies to make regulatory decisions on the basis of imperfect scientific knowledge.<sup>27</sup> Congress adopted this policy so that agencies could act in anticipation of harm to individuals and the environment. This means agencies are not required to conform to scientific standards of certainty. As Judge Skelly Wright once explained, “[a]gencies are not limited to scientific fact, to 95% certainties.”<sup>28</sup> A determination that there is sufficient evidence to satisfy a risk trigger is therefore legally valid even if the scientific community does not universally agree about the degree of risk that exists.<sup>29</sup>

Although an agency does not have to wait for universal scientific agreement in order to act, it still must have sufficient scientific evidence to satisfy a statutory trigger. An agency, for example, could not regulate a chemical to protect individuals from cancer if there is no reasonable

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<sup>22</sup> *Id.* at 48–53.

<sup>23</sup> See SIDNEY A. SHAPIRO & ROBERT L. GLICKSMAN, *RISK REGULATION AT RISK: RESTORING A PRAGMATIC APPROACH* 3–4 (2003) (describing the risk regulation statutes). Most of the regulatory agencies in charge of regulating these risks were created during this same time period. SIDNEY A. SHAPIRO & JOSEPH P. TOMAIN, *REGULATORY LAW AND POLICY: CASES AND MATERIALS* 17–18 (3d ed. 2003).

<sup>24</sup> SHAPIRO & GLICKSMAN, *supra* note 23, at 6.

<sup>25</sup> *Id.* at 31–34.

<sup>26</sup> *Id.* at 33.

<sup>27</sup> *Id.* at 31; SHELLA JASANOFF, *THE FIFTH BRANCH: SCIENCE ADVISORS AS POLICYMAKERS* 50 (1990).

<sup>28</sup> *Ethyl Corp. v. EPA*, 541 F.2d 1, 28 (D.C. Cir. 1976).

<sup>29</sup> JASANOFF, *supra* note 27, at 50.

scientific support in the rulemaking record that the chemical presents a “risk” of cancer. A decision to regulate without sufficient evidence would be arbitrary and capricious under the Administrative Procedure Act (APA).<sup>30</sup>

The Supreme Court’s recent decision in *Massachusetts v. Environmental Protection Agency (Massachusetts v. EPA)*<sup>31</sup> illustrates this interaction of law, policy, and science. The state of Massachusetts and other parties sued the Environmental Protection Agency (EPA) after it rejected a petition from the parties to regulate greenhouse emissions from new motor vehicles under section 202 of the Clean Air Act (CAA).<sup>32</sup> The Court held that EPA’s rejection of the petition was “arbitrary and capricious.”<sup>33</sup> EPA defended its rejection of the petition in part on the ground that NAS said a causal link between greenhouse gases and global warming could not be “unequivocally” established.<sup>34</sup> The Court concluded that the absence of scientific certainty was “irrelevant” because the question under the statute was whether the scientific evidence was sufficient to make an endangerment finding.<sup>35</sup> Section 202 mandates that the EPA “Administrator shall by regulation prescribe . . . standards applicable to the emission of any air pollutant from any class . . . of new motor vehicles . . . which may reasonably be anticipated to endanger the public health or welfare.”<sup>36</sup> Since Congress ordered EPA to act on less than definitive scientific evidence, the Court held the CAA required EPA to regulate unless “scientific uncertainty is so profound that it precludes EPA from making a reasoned judgment as to whether greenhouse gases contribute to global warming.”<sup>37</sup>

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<sup>30</sup> 5 U.S.C. § 706(2)(A) (2000). Under some statutes, Congress has required that agencies have “substantial evidence” for their factual conclusion. WILLIAM A. FUNK, SIDNEY A. SHAPIRO & RUSSELL L. WEAVER, *ADMINISTRATIVE PROCEDURE AND PRACTICE* 161 (3d ed. 2006). Appellate courts tend to treat the “arbitrary and capricious” standard and the “substantial evidence” standard as functionally identical. *Id.* at 162.

<sup>31</sup> 127 S.Ct. 1438 (2007).

<sup>32</sup> *Id.* at 1449 (referencing CAA, 42 U.S.C. § 7521 (2000)).

<sup>33</sup> *Id.* at 1463.

<sup>34</sup> *Id.* at 1451.

<sup>35</sup> *Id.* at 1463.

<sup>36</sup> 42 U.S.C. § 7521(a)(1) (2000). This quotation was edited to omit a portion of the statute that raised an issue of statutory interpretation. The unedited version of the statute reads:

The [EPA] Administrator shall by regulation prescribe (and from time to time revise) in accordance with the provisions of this section, standards applicable to the emission of any air pollutant from any class or classes of new motor vehicles or new motor vehicle engines, *which in his judgment* cause, or contribute to, air pollution which may reasonably be anticipated to endanger public health or welfare.

*Id.* (emphasis added). The D.C. Circuit held that the “in his judgment” language authorized the agency to refuse to regulate for policy reasons not associated with the status of the scientific evidence concerning whether a pollutant would endanger people or the environment. *Massachusetts v. EPA*, 127 S.Ct. at 1451. The Court rejected this interpretation, holding that EPA could “avoid taking further action only if it determines that greenhouse gases do not contribute to climate change or if it provides some reasonable explanation as to why it cannot or will not exercise its discretion to determine whether they do.” *Id.* at 1462.

<sup>37</sup> *Id.* at 1463. On remand, the Court held that “EPA must ground its reasons for action or inaction in the statute,” and explicitly declined to state whether EPA had to make an endangerment finding according to the terms of the statute or, if such a finding were made,

The mandate of agencies to act on the basis of anticipated harm makes scientific uncertainty an unavoidable aspect of regulatory science. An NRC report explained this problem in the context of assessing risks to human health:

[D]ata may be incomplete, and there is often great uncertainty in estimates of the types, probability, and magnitude of health effects associated with a chemical agent . . . and of the extent of current and possible future human exposures. These problems have no immediate solution, given the many gaps in our understanding of the causal mechanisms of carcinogenesis and other health effects and in our ability to ascertain the nature or extent of the effects associated with specific exposures.<sup>38</sup>

Risk analysts employ assumptions to overcome these and similar problems. The NRC describes these assumptions as “inference options” because they involve choices about alternative models and assumptions that are needed to complete risk assessments in the face of scientific uncertainty or knowledge.<sup>39</sup> Agencies can develop inference options on a case-by-case basis or they can establish standardized models or assumptions, which are known as “default” rules or assumptions.<sup>40</sup>

Default rules are “based [in part] on general scientific knowledge of the phenomena in question” or inferences considered by risk assessment professionals as an appropriate way to bridge uncertainties.<sup>41</sup> For example, agencies use the results of experiments involving animals to predict human reactions to a chemical or substance because there is sufficient scientific evidence that animal data are generally predictive of human effects.<sup>42</sup>

Default assumptions are not purely scientific, because they also reflect public policy.<sup>43</sup> For example, agencies usually assume in the absence of evidence to the contrary that a carcinogen has no threshold concentration below which the substance poses no risk of causing cancer.<sup>44</sup> An assumption like this one is commonly referred to as a “conservative” default rule

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whether policy considerations could inform an action taken by EPA. *Id.*

<sup>38</sup> NAT'L ACAD. OF SCIENCES, RISK ASSESSMENT IN THE FEDERAL GOVERNMENT: MANAGING THE PROCESS 11 (1983) [hereinafter RED BOOK].

<sup>39</sup> *Id.* at 4.

<sup>40</sup> SHAPIRO & GLICKSMAN, *supra* note 23, at 94–95.

<sup>41</sup> Proposed Guidelines for Carcinogenic Risk Assessment, 61 Fed. Reg. 17,960, 17,964 (Apr. 23, 1996).

<sup>42</sup> RED BOOK, *supra* note 38, at 22.

<sup>43</sup> Proposed Guidelines for Carcinogenic Risk Assessment, 61 Fed. Reg. at 17,964.

[D]efault assumptions are necessarily made in risk assessments in which data gaps exist in general knowledge or in available data for a particular agent. These default assumptions are inferences based on general scientific knowledge of the phenomena in question and are also matters of policy concerning the appropriate way to bridge uncertainties that concern potential risk to human health (or, more generally, to environmental systems) from the agent under assessment.

*Id.*

<sup>44</sup> SHAPIRO & GLICKSMAN, *supra* note 23, at 94–95. Related assumptions are used in devising conversion factors for translating the results of animal testing to humans. *Id.* at 95.



because it is highly protective of the public; that is, it resolves questions of uncertainty about the extent of a risk by assuming the worst case potential of the risk. A conservative risk assumption serves the protective mandate that Congress chose for risk regulation statutes because it minimizes the danger to the public if the agency underestimates a risk.<sup>45</sup>

### *B. Uncertainty and Politicization*

Congress expects regulatory agencies to protect people and the environment despite scientific uncertainty. The existence of this uncertainty, however, opens the door for two types of subtle politicization. Since the conduct of risk assessment requires the use of assumptions and default rules, administrators can politicize the assessment process by adopting scientifically inappropriate default rules. Opponents of regulation have also exploited scientific uncertainty by mischaracterizing uncertainty as a lack of "sound science." They then use this "sound science" claim to impose additional procedures on agencies to vet agency science. These procedures slow down or ossify the regulatory process without bringing additional clarity or benefit to the process.

#### *1. Scientifically Inappropriate Default Rules*

Administrative agencies employ default rules to overcome scientific uncertainty.<sup>46</sup> As discussed, the rules reflect policy judgments associated with the agency's mission, but they are also based on general scientific knowledge or inferences considered appropriate by risk assessment professionals to bridge evidentiary gaps.<sup>47</sup> Politicization occurs when an agency adopts default assumptions that are inconsistent with general scientific knowledge or with inferences used by risk professionals to complete risk assessments.<sup>48</sup> In other words, the risk assessment process is politicized when default rules are sufficiently inconsistent with specific or general scientific understanding that there is no acceptable scientific basis for the rules.

As will be developed in this Article, some of the OMB's proposed default rules fall into this category. OMB has proposed methods for risk assessment that lacked a scientific pedigree and promoted an anti-regulatory viewpoint.<sup>49</sup>

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<sup>45</sup> John S. Applegate, *A Beginning and Not an End in Itself: The Role of Risk Assessment in Environmental Decision-Making*, 63 U. CIN. L. REV. 1643, 1656 (1995). The assumption accomplishes this goal by assuming that it is worse to fail to regulate based on a false negative (an erroneous determination that a risk was not serious enough to warrant regulation) than a false positive (an erroneous determination that a risk was serious enough to warrant regulation). SHAPIRO & GLICKSMAN, *supra* note 23, at 95. Although this assumption is warranted by the protective nature of regulatory mandates, it is strongly opposed by corporate trade associations. See, e.g., *infra* note 131 and accompanying text.

<sup>46</sup> See SHAPIRO & GLICKSMAN, *supra* note 23, at 94–95.

<sup>47</sup> See *supra* Part II.A.

<sup>48</sup> See SHULMAN, *supra* note 2, at xiv–xv, 4; see also MOONEY, *supra* note 2, at 7–9.

<sup>49</sup> See *infra* Part V.B.

## 2. Ossification

Regulatory opponents also seek to exploit scientific uncertainty by arguing that regulatory action is not based on “sound science.”<sup>50</sup> Their real objection, however, is with the policy choice made by Congress not to wait for more definitive information about the extent of a risk before a regulatory agency acts to reduce that risk.<sup>51</sup> As Stanton Glantz and Elisa Ong, two health researchers, explain: “the ‘sound science’ movement . . . is not simply an effort from within the profession to improve the quality of scientific discourse. This movement reflects sophisticated public relations campaigns controlled by industry executives and lawyers to manipulate the standards of proof for the corporate interests of their clients.”<sup>52</sup> The tobacco industry invented the “sound science” strategy as part of its long effort to stave off government regulation,<sup>53</sup> and it has become a staple of anti-regulatory reformers.<sup>54</sup> It has also been “readily adopted as a rallying cry by top officials in the Bush Administration.”<sup>55</sup>

This form of politicization intentionally blurs the distinction between incomplete and poor quality information.<sup>56</sup> A risk assessment may be extremely competent, but it also may not yield definitive information about the extent of the risk being studied. Regulation may be justified nevertheless because, as discussed earlier, Congress requires regulatory agencies to “act on the basis of anticipated harm.”<sup>57</sup>

The Bush Administration has used the sound science campaign as a justification to impose internal roadblocks to regulation in the form of additional procedures to ensure the accuracy of the science that the government is using. In 2002, OMB issued government-wide information quality guidelines,<sup>58</sup> and it promulgated peer review guidelines in 2004.<sup>59</sup> As will be developed in this Article, the proposed Bulletin is another example of this tactic.<sup>60</sup>

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<sup>50</sup> See generally Elisa K. Ong & Stanton A. Glantz, *Constructing “Sound Science” and “Good Epidemiology”: Tobacco, Lawyers, and Public Relations Firms*, 91 AM. J. PUB. HEALTH 1749 (2001).

<sup>51</sup> Thomas O. McGarity & Sidney A. Shapiro, *OSHA’s Critics and Regulatory Reform*, 31 WAKE FOREST L. REV. 587, 612–13 (1996) (explaining that the “sound science” campaign objects not to the quality of data collected, but to regulations based on incomplete scientific information and conservative default rules).

<sup>52</sup> Ong & Glantz, *supra* note 50, at 1754; see also SHULMAN, *supra* note 2, at 14.

<sup>53</sup> SHULMAN, *supra* note 2, at 13–14; MOONEY, *supra* note 2, at 66–69.

<sup>54</sup> See MOONEY, *supra* note 2, at ch. 6 (linking “sound science” and opposition to government regulation).

<sup>55</sup> SHULMAN, *supra* note 2, at 14.

<sup>56</sup> Sidney A. Shapiro, *The Information Quality Act and Environmental Protection: The Perils of Reform by Appropriations Rider*, 28 WM. & MARY ENVTL. L. & POL’Y REV. 339, 350 (2004).

<sup>57</sup> SHAPIRO & GLICKSMAN, *supra* note 23, at 6. See also *supra* note 24 and accompanying text.

<sup>58</sup> Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies, 67 Fed. Reg. 8452, 8452–53 (Feb. 22, 2002).

<sup>59</sup> Final Information Quality Bulletin for Peer Review, 70 Fed. Reg. 2664, 2664–65 (Jan. 14, 2005).

<sup>60</sup> See *infra* Part V.

The requirement of additional procedures to vet regulatory science are a form of the sound science campaign because they slow down government action based on the false assumption that additional vetting of science is necessary. As Wendy Wagner has found:

After more than thirty years of vigorous public health and safety regulation, it seems almost inevitable that an agency would have relied upon a scientific study that ultimately proved unreliable. Yet, despite the thousands of public health and safety regulations promulgated annually, there are surprisingly few examples of EPA using unreliable science . . . . [If one subtracts the studies where industry or independent contractors fabricated data in order to support their application for a pesticide or drug license, then] the examples of regulatory bad science are winnowed down to a few, virtually all of which are contested.<sup>61</sup>

The requirement of procedures where the potential for error or mistake is reasonably low has the effect of stalling or delaying regulation without an offsetting benefit. This achieves the objective of the “sound science” campaign to avoid regulation by claiming agencies operate on the basis of bad science.

### III. OMB'S RISK ASSESSMENT BULLETIN

OMB's proposed Bulletin was the latest step by OMB in its efforts to superintend regulatory science across the government.<sup>62</sup> OMB issued government-wide information quality guidelines in 2002<sup>63</sup> and peer review guidelines in 2004.<sup>64</sup> These guidelines and the proposed Bulletin constitute a sustained effort by the Bush Administration to influence and supervise how regulatory agencies generate and evaluate scientific information. All three guidelines were issued under the authority of the Information Quality Act (IQA).<sup>65</sup> According to OMB, it proposed the Bulletin as part of an “ongoing effort to improve the quality, objectivity, utility, and integrity of information disseminated by the federal government to the public.”<sup>66</sup> This quoted language refers to the mandate of the IQA.

OMB established three tiers of requirements for agency risk assessments.<sup>67</sup> The first tier applied to all risk assessments in the government.<sup>68</sup> OMB defined “risk assessment” as any “scientific and/or technical document that assembles and synthesizes scientific information to

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<sup>61</sup> Wendy E. Wagner, *The “Bad Science” Fiction: Reclaiming the Debate Over the Role of Science in Public Health and Environmental Regulation*, 66 LAW & CONTEMP. PROBS. 63, 72-73 (2003) (footnotes omitted).

<sup>62</sup> PROPOSED BULLETIN, *supra* note 4, at 1.

<sup>63</sup> Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility and Integrity of Information Disseminated by Federal Agencies, 67 Fed. Reg. at 8452-53.

<sup>64</sup> Final Information Quality Bulletin for Peer Review, 70 Fed. Reg. at 2664-65.

<sup>65</sup> Information Quality Act, Pub. L. No. 106-554 § 515(a), 114 Stat. 2763A-153 (2000).

<sup>66</sup> PROPOSED BULLETIN, *supra* note 4, at 1.

<sup>67</sup> *See id.* at 11, 15-16.

<sup>68</sup> *Id.* at 11.

determine whether a potential hazard exists and/or the extent of possible risk to human health, safety, or the environment.<sup>69</sup> The first tier requirements included an obligation to provide a qualitative characterization of risk and, whenever possible, a quantitative estimate.<sup>70</sup> OMB also mandated that risk assessments should be “scientifically objective, neither minimizing nor exaggerating the nature and magnitude of the risks.”<sup>71</sup> In addition, risk assessments should be based on the “best available data” and “on the weight of the available scientific evidence.”<sup>72</sup> OMB stressed the “risk assessment report should also have a high degree of transparency with respect to data, assumptions, and methods that have been considered.”<sup>73</sup> Risk assessors were expected to explain “the basis of each critical assumption” and its effect on the risk assessment.<sup>74</sup>

The second tier of requirements applied to risk assessments used in regulatory analysis.<sup>75</sup> These included an obligation to develop “a range of plausible risk estimates, including central estimates,” as part of a quantitative risk assessment.<sup>76</sup> According to OMB, “the central estimate should neither understate nor overstate the risk, but rather, should provide the risk manager and the public with the expected risk.”<sup>77</sup>

The third tier of requirements applied to “influential risk assessments,” which encompass any risk assessment an “agency reasonably can determine will have or does have a clear and substantial impact on important public policies or private sector decisions.”<sup>78</sup> In addition to meeting the first two tiers of requirements, OMB imposed a number of additional requirements in this tier.<sup>79</sup> These included requirements to present the range of plausible risk estimates, including a central estimate, use statistical techniques to characterize the degree of uncertainty associated with risk estimates, and “evaluate and discuss alternative theories, data, studies and assessments that suggest different or contrary results than are contained in the risk assessment.”<sup>80</sup> Agencies were also required to prepare a response-to-comment document indicating the agency’s response to all significant comments it receives on a proposed risk assessment.<sup>81</sup>

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<sup>69</sup> *Id.* at 8.

<sup>70</sup> *Id.* at 13.

<sup>71</sup> *Id.* at 14.

<sup>72</sup> *Id.*

<sup>73</sup> *Id.*

<sup>74</sup> *Id.* at 15.

<sup>75</sup> *Id.* at 15–16.

<sup>76</sup> *Id.* at 16.

<sup>77</sup> *Id.* For a further discussion of central estimates, see *infra* Part V.B.2.

<sup>78</sup> PROPOSED BULLETIN, *supra* note 4, at 9.

<sup>79</sup> *Id.* at 16–21.

<sup>80</sup> *Id.* at 17–19.

<sup>81</sup> *Id.* at 20–21.

## IV. OMB'S LACK OF SCIENTIFIC EXPERTISE

The mission of OMB is to "assist the President in overseeing the preparation of the federal budget and to supervise its administration in Executive Branch agencies."<sup>82</sup> The Office of Information and Regulatory Affairs (OIRA) is the office within OMB responsible for the proposed Bulletin.<sup>83</sup> OIRA was created in 1980 to manage the Paperwork Reduction Act.<sup>84</sup> Since 1981, when President Reagan established the first comprehensive regulatory impact analysis requirements,<sup>85</sup> OIRA has also been the office in OMB that has reviewed proposed and final regulatory impact statements. The primary content of impact statements is a cost-benefit assessment of a proposed regulation.<sup>86</sup> Considering the responsibilities of OMB and OIRA, it is not surprising most of OMB's staff have professional degrees in such fields as economics, law, business, and accounting, and public administration and policy.<sup>87</sup>

OMB has hired some scientists and engineers in recent years,<sup>88</sup> but OIRA does not appear to have a significant scientific staff. OMB did say that it consulted with the Office of Science and Technology Policy (OSTP),<sup>89</sup> but it is not clear whether the White House science office also lacked scientific expertise concerning risk assessment, OMB ignored the advice it received from the office, or the office recognized but was unconcerned about the flaws in the proposed Bulletin.

The many defects in the proposed Bulletin might be attributed to OMB hubris in attempting to write state-of-the art risk assessment guidelines without significant scientific expertise. There are good reasons, however, for believing this is not the entire explanation for OMB's spectacular failure.

OMB had some familiarity with risk assessment because it is a component of regulatory impact analyses that OIRA analysts regularly

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<sup>82</sup> OMB, *OMB's Mission*, <http://www.whitehouse.gov/omb/organization/role.html> (last visited Nov. 18, 2007).

<sup>83</sup> See Office of Management and Budget Proposed Risk Assessment Bulletin Notice, 71 Fed. Reg. 2600, 2600 (proposed Jan. 17, 2006) (directing requests for information to OIRA).

<sup>84</sup> See Paperwork Reduction Act, 44 U.S.C. §§ 3503, 3505 (2000) (giving OIRA authority to control the extent to which federal agencies can impose paperwork requirements on the public).

<sup>85</sup> See Regulatory Flexibility Act, 5 U.S.C. § 601 (1982) (requiring each agency to prepare and consider a Regulatory Impact Analysis with every major rule).

<sup>86</sup> See 5 U.S.C. § 601 (Supp. V 1994) (amending 5 U.S.C. § 601 (1988)) (instructing each agency to assess both costs and benefits of intended regulation and to choose "approaches that maximize net benefits" as required by the regulatory philosophy).

<sup>87</sup> See OMB, *The Staff of the Office of Management and Budget*, <http://www.whitehouse.gov/omb/recruitment/staff.html> (last visited Nov. 18, 2007) ("Over seventy percent of the staff are professionals, most with graduate degrees in economics, business and accounting, public administration and policy, law, engineering, and other disciplines.")

<sup>88</sup> See PETER L. STRAUSS, TODD D. RAKOFF & CYNTHIA R. FARINA, GELLHORN AND BYSE'S ADMINISTRATIVE LAW: CASES AND COMMENTS 650 (rev. 10th ed. 2003) (reporting an announcement by John Graham that OIRA was "adding some engineers and scientists to its 40-odd professionals").

<sup>89</sup> PROPOSED BULLETIN, *supra* note 4, at 2.

review.<sup>90</sup> Furthermore, John Graham, OIRA's director when the Guidelines were issued, had been the head of the Center for Risk Analysis at the Harvard School of Public Health prior to joining OIRA.<sup>91</sup> These connections should have been sufficient to indicate to OMB that its lawyers and economists, and even its scientists, lacked the detailed, cutting-edge scientific knowledge to write guidelines for risk assessment for the entire federal government.

More significantly, if it had been OMB's intention to conform health risk assessment processes to state of the art risk assessment practices, it could have simply adopted the consensus recommendations spelled out in a series of NRC reports on risk assessment.<sup>92</sup> Instead, the NRC committee found that OMB mostly ignored or misconstrued this impartial consensus advice.<sup>93</sup>

OMB should have known it lacked the capacity to write guidelines for risk assessment. Its decision to proceed anyway suggests that it had other motives besides adopting scientifically appropriate guidelines. As the next section develops, OMB hoped to use the occasion of promulgating the Bulletin to politicize agency risk assessment.

#### V. OMB'S POLITICAL MOTIVES

The NRC committee's evaluation of the Bulletin reveals a number of requirements that indicate OMB's political motives. One such motive was to ossify the rulemaking process by requiring additional procedures to verify scientific evidence. Another motive was to bend the risk assessment process away from the protective stance that Congress has required. This evidence of politicization is mitigated somewhat by the fact that OMB sought peer review by the NRC. This action, however, does not establish OMB's innocent intentions.

##### A. Ossification

Two aspects of the Bulletin demonstrate OMB's intent to ossify the rulemaking process. OMB made no effort to assess if the Bulletin was actually necessary or appropriate, and it exempted industry generated risk assessments although this exemption is inconsistent with improving the risk assessment process.

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<sup>90</sup> See SHAPIRO & GLICKSMAN, *supra* note 23, at 94–97.

<sup>91</sup> Frederick S. Pardee Rand Graduate School News, *OMB Regulatory Affairs Head and Former Harvard Professor John Graham Announced as New PRGS Dean*, [http://www.prqs.edu/news/new\\_dean.1005.html](http://www.prqs.edu/news/new_dean.1005.html) (last visited Nov. 18, 2007). Graham, however, is a social scientist. He has a B.A. in economics and politics from Wake Forest University, an M.A. in public affairs from Duke University, and a Ph.D. in urban and public affairs from Carnegie Mellon University. *Id.*

<sup>92</sup> See, e.g., RED BOOK, *supra* note 38; COMM. ON RISK ASSESSMENT OF HAZARDOUS AIR POLLUTANTS, NAT'L RESEARCH COUNCIL, SCIENCE AND JUDGMENT IN RISK ASSESSMENT 173 (student ed. 1994) [hereinafter SCIENCE AND JUDGMENT]; COMM. ON RISK CHARACTERIZATION, NAT'L RESEARCH COUNCIL, UNDERSTANDING RISK 155–66 (1996).

<sup>93</sup> NRC REPORT, *supra* note 7, at ch. 2.

### *1. No Assessment of Potential Problems*

As noted earlier, OMB issued the proposed Bulletin under the legal authority of the Information Quality Act.<sup>94</sup> The IQA was “a two paragraph appropriations rider . . . slipped into a 2001 appropriations bill without legislative hearings, committee review, or debate.”<sup>95</sup> The legislation was written by an industry lobbyist who is active in the industry’s “sound science” campaign.<sup>96</sup> Responding to the rider, OMB has required agencies to comply with elaborate procedural requirements before they can disseminate scientific and technical information.<sup>97</sup> These requirements are roadblocks to government action because they require procedures to vet scientific information even though there is no serious evidence that they are addressing a real problem of bad science.<sup>98</sup> The proposed Bulletin, had it been adopted, would have added even more procedures without evidence that they were necessary.

The NRC committee’s overriding criticism was that OMB had failed to obtain the information necessary to assess the need for and benefit of any risk assessment guidelines.<sup>99</sup> OMB had implied that agencies did not meet the guidelines that it sought to establish, but the committee found it failed to establish “a baseline of each agency’s risk assessment proficiency, including the extent to which generally satisfactory or high-quality risk assessments are produced or how some agencies fall short of the specified standards.”<sup>100</sup> Moreover, OMB did not consider whether agencies that performed poorly on risk assessments did so because they did not know what good practices were or they lacked the ability, resources, or incentives to meet such standards.<sup>101</sup> Finally, the committee found that OMB had not identified the costs that would be encountered by implementing the Bulletin.<sup>102</sup>

OMB’s lack of concern about ossification is related to the IQA. The Act makes the improvement of information an absolute commitment; nothing in the Act suggests that OMB is to weigh costs and benefits. Moreover, there is

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<sup>94</sup> See *supra* note 65 and accompanying text.

<sup>95</sup> Sidney A. Shapiro, *OMB’s Dubious Peer Review Procedures*, 34 *Envtl. L. Rep. (Envtl. Law Inst.)* 10064, 10064 (2004) [hereinafter Shapiro, *OMB’s Dubious Procedures*].

<sup>96</sup> Sidney A. Shapiro, *The Case Against the IQA*, *ENVTL. FORUM*, July/Aug. 2005, at 27–28 [hereinafter Shapiro, *The Case Against the IQA*]; see also Sidney A. Shapiro, *The Information Quality Act and Environmental Protection: The Perils of Reform by Appropriations Rider*, 28 *WM. & MARY ENVTL. L. & POL’Y REV.* 339, 349–51 (2004) [hereinafter Shapiro, *The Perils of Reform*].

<sup>97</sup> Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies; Republication, 67 *Fed. Reg.* 8452, 8453 (Feb. 22, 2002); Memorandum from Joshua B. Bolton, Dir., Office of Mgmt. and Budget, to Heads of Departments and Agencies (Dec. 16, 2004), available at <http://www.whitehouse.gov/omb/memoranda/fy2005/m05-03.pdf>.

<sup>98</sup> See Shapiro, *OMB’s Dubious Procedures*, *supra* note 95; Shapiro, *The Case Against the IQA*, *supra* note 96, at 26; Shapiro, *The Perils of Reform*, *supra* note 96.

<sup>99</sup> NRC REPORT, *supra* note 7, at 5–8.

<sup>100</sup> *Id.* at 6.

<sup>101</sup> *Id.*

<sup>102</sup> *Id.*

no obligation under the IQA that OMB produce proof that existing information is inadequate before it adds additional procedures or process. These features are not surprising in light of the sound science assumptions that underlie the Act. Moreover, while it is always possible to seek better quality information, the perfection of information becomes the enemy of protecting people and the environment. Indeed, it is inconsistent with the protective legislation that risk regulation agencies administer because an open-ended commitment to perfecting the quality of information makes it more difficult for agencies to act in a preventative manner.

## 2. Industry-Generated Risk Assessments

The NRC Committee also found fault with OMB's exemption of industry-generated risk assessments from the requirements in the Bulletin. This occurred because OMB exempted risk assessments performed in the context of agency adjudications.<sup>103</sup> Regulatory agencies commonly use adjudication to determine if the firm is eligible for a license or permit. In the environmental context, private companies that seek a license or permit from the government submit their own risk assessments in support of their applications.<sup>104</sup> The committee observed that OMB failed "to explain the basis for exempting risk assessments associated with licensing and approval processes."<sup>105</sup>

OMB did not completely exempt adjudications from the Bulletin. An adjudication was exempted unless an agency determined that compliance with the Bulletin was "practical" and the "risk assessment is scientifically or technically novel or likely to have precedent-setting influence on future adjudications and/or permit proceedings."<sup>106</sup> Nevertheless, OMB did not offer a justification for its asymmetrical treatment of risk assessments.<sup>107</sup>

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<sup>103</sup> PROPOSED BULLETIN, *supra* note 4, at 23. OMB qualified this exemption, however. *See infra* note 107.

<sup>104</sup> *See* Shapiro, *OMB's Dubious Procedures*, *supra* note 95, at 10071 (discussing industry generated risk assessments in the context of licensing and permit procedures).

<sup>105</sup> NRC REPORT, *supra* note 7, at 6.

<sup>106</sup> PROPOSED BULLETIN, *supra* note 4, at 23.

<sup>107</sup> The Administrative Law Section of the American Bar Association has defended OMB's position. Letter from Eleanor D. Kinney, Chair, Admin. Law & Regulatory Practice Section, Am. Bar Ass'n, to Dr. Nancy Beck, Office of Info. & Regulatory Affairs, (May 22, 2006), at 8 [hereinafter ABA Letter] available at [http://www.whitehouse.gov/omb/inforeg/comments\\_rab/aba.pdf](http://www.whitehouse.gov/omb/inforeg/comments_rab/aba.pdf). The ABA argued first that OMB lacked legal authority to establish risk assessment guidelines for adjudications, but this argument is not persuasive. There is nothing in the language of the IQA, however, that suggests it does not cover adjudication. *See* Consolidated Appropriations Act, 2001, Pub. L. No. 106-554, § 515(a), 114 Stat. 2763, 2763A-153-54 (2000). The ABA was on stronger ground arguing that there are significant practical problems with integrating peer review into formal adjudication because of *ex parte* contact restrictions. If an agency is engaged in formal adjudication, Section 554 of the Administrative Procedure Act prohibits an ALJ from "consult[ing] a person or party on a fact in issue, unless on notice and opportunity for all parties to participate." 5 U.S.C. § 554 (2000); *see* ABA Letter, *supra*, at 8. Such a restriction would make it very hard for an ALJ to conduct either peer review or a risk assessment. *Id.* The ABA conceded, however, that risk assessment guidelines could be accommodated in informal adjudications. *Id.*



Thus, while all government risk assessments were subject to the Bulletin, it covered industry risk assessments only if they were novel or precedent setting.

This aspect of the Bulletin suggests it was promoting the sound science campaign. The Bulletin would not have applied to the risk assessments corporations submit to the government in support of licenses or permits unless a risk assessment raised an unprecedented or novel issue.<sup>108</sup> This meant the Bulletin was unlikely to slow down most industry efforts to obtain a license or permit. By comparison, OMB required that the Bulletin apply to risk assessments used in rulemaking or in government reports regardless of whether the risk assessment presented an unprecedented or novel issue.

If OMB's goal was to ensure the quality of risk assessments, there appears to be no good reason to exempt industry-generated risk assessments except in the context of formal adjudications.<sup>109</sup> Indeed, the nature of private scientific research makes it particularly vulnerable to bias. Wendy Wagner and David Michaels explain:

Sponsors face strong incentives to design and report research in ways most favorable to their interests and to suppress adverse results provided they can do so without detection. In the past, more than a few products or pollutants have been left effectively unregulated because the manufacturer or polluter concealed evidence of the true harm or obscured adverse results. Privately sponsored science, if done without guarantees of research independence, thus violates one of the most fundamental norms of science; namely, that research be disinterested.<sup>110</sup>

### *B. The Bending of Risk Assessment*

OMB's enthusiastic embrace of the "sound science" premises of the IQA caused it to bypass any investigation of whether detailed risk assessment guidance was necessary or appropriate. OMB also proposed default rules that would have had the impact of bending the risk assessment process away from the preventative orientation that agencies are required by statute to use.<sup>111</sup> In each instance, the NRC committee found the proposed default rule lacked sufficient scientific support. OMB used an anomalous definition of "risk," proposed an unrealistic methodology to calculate "central risks," and required "risk communications" that were potentially misleading.<sup>112</sup> In addition, although OMB's professed intent was to promote the objectivity of

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<sup>108</sup> PROPOSED BULLETIN, *supra* note 4, at 23. OMB qualified this exemption, however. See *supra* note 106 and accompanying text.

<sup>109</sup> See *supra* note 107 (discussing significant problems with integrating peer review into formal adjudication because of *ex parte* contact restrictions).

<sup>110</sup> Wendy Wagner & David Michaels, *Equal Treatment for Regulatory Science: Extending the Controls Governing the Quality of Public Research to Private Research*, 30 AM. J.L. & MED. 119, 122 (2004).

<sup>111</sup> See *supra* notes 24–25 and accompanying text.

<sup>112</sup> NRC REPORT, *supra* note 7, at chs. 3–4.

the risk assessment process, it ignored the problem of unbalanced advisory committees.

### *1. Anomalous Definition of Adverse Effects*

The Bulletin told agencies not to consider “non-adverse” effects as constituting a risk to individuals in risk assessment.<sup>113</sup> Instead, it limited risk assessment to estimating actual adverse health effects in individuals.<sup>114</sup> OMB’s justification for this position was that the dictionary definition of risk refers to an “adverse” consequence or effect.<sup>115</sup>

The NRC Report found OMB’s distinction between “adverse” and “non-adverse” was inconsistent with good risk assessment practices.<sup>116</sup> The scientific literature demonstrates that non-adverse effects may sometimes be the appropriate end point for risk assessment.<sup>117</sup> For example, a non-adverse effect may correlate with an adverse effect, and the non-adverse endpoint is easier to measure than an adverse effect.<sup>118</sup> A non-adverse effect in other situations may be a precursor to a serious medical problem. In this circumstance, an agency might decide that focusing on the precursor serves the public health goal of controlling exposures before there is functional impairment of an individual’s health.<sup>119</sup> Although OMB told the committee that it had not intended to prevent risk assessments based on precursor data, the committee concluded the draft Bulletin had sent a “strong message” that non-adverse effects were not acceptable end points for toxicological risk assessment.<sup>120</sup>

OMB’s proposal would have weakened regulatory protections. By ordering risk assessors to ignore evidence that scientists understand is predictive of human health risks, OMB sought to adopt a default rule that was inconsistent with both scientific practice and agency mandates.

### *2. Central Estimate*

The proposed Bulletin provided that risk estimates used for regulatory purposes should include “whenever possible, a range of plausible estimates, including central or expected estimates, when a quantitative characterization of risk is made available.”<sup>121</sup> The requirement of a central estimate was mandatory for influential risk assessments.<sup>122</sup> According to

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<sup>113</sup> See PROPOSED BULLETIN, *supra* note 4, at 20.

<sup>114</sup> *Id.*

<sup>115</sup> *Id.* (explaining that “[s]ince the dictionary definition of ‘risk’ refers to the possibility of an adverse consequence or adverse effect, it may be necessary for risk assessment reports to distinguish effects which are adverse from those which are non-adverse”).

<sup>116</sup> See NRC REPORT, *supra* note 7, at 56.

<sup>117</sup> See *id.* at 54–55.

<sup>118</sup> See *id.* at 55–56.

<sup>119</sup> *Id.* at 56–58.

<sup>120</sup> *Id.* at 58.

<sup>121</sup> PROPOSED BULLETIN, *supra* note 4, at 24.

<sup>122</sup> *Id.* at 25.

OMB, a “central estimate should neither understate nor overstate the risk, but rather, should provide the risk manager and the public with the expected risk.”<sup>123</sup>

A central estimate, however, is highly misleading in the context of many risk assessments. The problem arises because agencies are often confronted with risk studies that employ different models or assumptions to predict expected risk. According to the NRC report, “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.*”<sup>124</sup> An earlier NRC report explained:

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.<sup>125</sup>

The production of a central risk estimate, even in circumstances where it is statistically meaningful, is still problematic if it ignores variability in the susceptibility of individuals to exposure levels or to becoming ill after being exposed to the same level as other persons. The NRC report was concerned that such variability could be overlooked because of OMB’s emphasis on central estimates.<sup>126</sup> This was of concern to the committee because the goal in public health practice and prevention is often to protect the most vulnerable in the population, such as “children, the elderly, people with illnesses (such as respiratory or cardiac disease), the developing fetus, and workers.”<sup>127</sup> The NRC warned that “[u]sing the mean or central estimate would not accomplish that goal unless it reflected the mean response of the distribution of vulnerable or susceptible individuals.”<sup>128</sup>

An objection raised by the Center for Progressive Reform to the Bulletin illustrates the previous problem:

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<sup>123</sup> *Id.* at 16.

<sup>124</sup> NRC REPORT, *supra* note 7, at 41 (quoting I NAT’L RESEARCH COUNCIL, SPACECRAFT MAXIMUM ALLOWABLE CONCENTRATIONS FOR SELECTED AIRBORNE CONTAMINANTS, 173 (1994)).

<sup>125</sup> SCIENCE AND JUDGMENT, *supra* note 92. This quotation is cited in the Letter from Rena Steinzor, Center for Progressive Reform, to Dr. Nancy Beck, Office of Info. & Regulatory Affairs, at 9–10 (June 15, 2006) [hereinafter CPR Letter].

<sup>126</sup> NRC REPORT, *supra* note 7, at 41–42.

<sup>127</sup> *Id.* at 42.

<sup>128</sup> *Id.* at 42.

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.<sup>129</sup>

The concept of an “average risk” estimate weakens existing approaches to risk regulation in two ways. First, as discussed earlier, agencies currently use “conservative” default rules in risk assessment.<sup>130</sup> Regulated entities typically oppose these rules on the grounds that they lead to overregulation. The American Chemistry Council (ACC), for example, told OMB that “[r]isk assessments should not continue an unwarranted reliance on ‘conservative (worst-case) assumptions’ that distort the outcomes of the risk assessment, ‘yielding estimates that may overstate likely risks by several orders of magnitude.’”<sup>131</sup> Since OMB’s requirement of a central estimate would bend risk assessment toward the determination of what exposures are best documented, this process would become a counterweight to the use of conservative default rules.

Second, the use of central estimates undermines the commitment to protect sensitive populations from chemical and other health hazards.<sup>132</sup> This methodology would not protect such sensitive individuals because it would focus the agencies analysis on the risk to the “average” person.<sup>133</sup>

### 3. *Inappropriate Risk Communication*

The proposed Bulletin also required agencies to prepare an executive summary for all risk assessments that included, among other requirements, “information that places a risk in context/perspective with other risks familiar to the target audience.”<sup>134</sup> While the NRC committee conceded there are legitimate reasons for making such comparisons, it opposed OMB’s simplistic requirement on the grounds that the requirement was likely to be misleading in light of what is known about risk communication.<sup>135</sup> This type of simplistic comparison is a staple of regulatory critics who use such comparisons to suggest that regulation is unnecessary or is too stringent.<sup>136</sup>

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<sup>129</sup> CPR Letter, *supra* note 125, at 10.

<sup>130</sup> See *supra* note 45 and accompanying text.

<sup>131</sup> Letter from James W. Conrad, Jr., Assistant Gen. Counsel, and Richard A. Becker, Senior Toxicologist/Senior Director, American Chemistry Council, to Dr. Nancy Beck, Office of Info. & Regulatory Affairs, at 7 (June 15, 2006).

<sup>132</sup> See *supra* note 126 and accompanying text.

<sup>133</sup> NRC REPORT, *supra* note 7, at 42.

<sup>134</sup> PROPOSED BULLETIN, *supra* note 4, at 24.

<sup>135</sup> NRC REPORT, *supra* note 7, at 60.

<sup>136</sup> See, e.g., McGarity & Shapiro, *supra* note 51, at 592–94 (offering examples of simple

The communication of comparable risks can inform the public by giving readers an intuitive feeling for the size of a risk by comparing it to other similar risks that readers would understand. For example, how does the risk of dying in an airplane crash compare to being hit by lightning? The difficulty is that persons who studied risk communications found that readers need additional information in order to understand the comparison. For example:

Individual Americans face different risks from lightning. [The risks] are, on the average, much higher for golfers than nursing-home residents. A blanket statement would mislead readers who did not think about this variability and what their risk is relative to that of the average American.<sup>137</sup>

Moreover, the simple comparison of risks does not necessarily indicate that a risk from one source is more acceptable if it is lower than another source. People evaluate risks according to a number of properties besides the probability of being injured or killed. For example, whether a person's exposure to a risk is voluntary or non-voluntary is a significant consideration. Thus, it is inappropriate to make risk comparisons except for comparisons that have been developed in a scientifically sound and empirically evaluated way that addresses all the values and circumstances that might impact the acceptability of the risks.<sup>138</sup>

### *C. Consulting the NRC*

Defenders of OMB could counter that OMB's good intentions are indicated by the fact that it requested public and agency comment on the proposed Bulletin and that it contracted with the NRC to engage in a peer review of the Bulletin.<sup>139</sup> This suggests that OMB saw the Bulletin as merely the first step in drafting the guidelines, and that it intended to fix any glitches after receiving input from the NRC and the public.

While it is in OMB's favor that it asked the NRC to peer review the proposed Guidelines, this action does not remove the suspicion that the Bulletin was the product of weak science and strong politics. OMB's solicitation of public and scientific comment was both politically necessary and strategically useful. OMB could not have legitimately promulgated a guidance document for risk assessment without seeking such input. At the same time, OMB could have anticipated it would amend the proposal only to the minimum extent necessary in light of the comments received. In employing this strategy, OMB may have underestimated the number of flaws in the Bulletin.

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comparisons of risk intended to support deregulation); THOMAS O. MCGARITY, SIDNEY A. SHAPIRO & DAVID BOLLIER, *SOPHISTICATED SABOTAGE: THE INTELLECTUAL GAMES THAT INDUSTRIES PLAY TO SUBVERT RESPONSIBLE REGULATION 103-05* (2004) (discussing the use of simplistic risk comparisons to criticize some types of regulation).

<sup>137</sup> *Id.* at 60.

<sup>138</sup> *Id.* at 61.

<sup>139</sup> See PROPOSED BULLETIN, *supra* note 4, at 1.

OMB's actions regarding its peer review guidelines followed a previously-created battle plan. In 2003, OMB proposed guidelines for agency use of peer review.<sup>140</sup> The peer review guidelines were strongly supported by business trade associations and strongly opposed by environmental and public interest groups.<sup>141</sup> In addition, OMB's proposal was opposed by leading scientific organizations, numerous invited speakers at a workshop convened by the National Academy of Sciences,<sup>142</sup> and an editorial in *Science* magazine.<sup>143</sup> OMB modified the guidelines to respond to some of the concerns expressed by the scientific community, but it also retained many aspects of the guidelines that were opposed by scientists and progressive public interest groups. Professor David Michaels explains:

While other modifications make the peer review requirements somewhat less onerous for agencies . . . the fundamental issue raised by scientists at the initial NAS workshop remained: OMB failed to establish the need for a single government wide peer review policy. The final Bulletin provides little evidence with which to question the initial conclusion of many observers: that the new requirements are a poorly camouflaged attempt to introduce delays into already slow regulatory processes, and further hamper government activities aimed at protecting the public health and environment.<sup>144</sup>

#### VI. OMB'S APPROPRIATE ROLE

OMB's withdrawal of the proposed Bulletin raises the issue of what role, if any, OMB should play in supervising risk assessment within the government. In September 2007, OMB offered an interim answer in the form of a memorandum on risk assessment.<sup>145</sup> The memorandum restates a set of principles for risk assessment, management, communication, and priority setting that OMB originally issued in 1995.<sup>146</sup> It also updates those principles by discussing how they relate to the Information Quality Act, other OMB memoranda, and to reports on risk assessment issued by the National Academy of Sciences.<sup>147</sup> Susan Dudley, ORIA Administrator, has said that she expects agencies to adhere to the 1995 principles, as interpreted by the memorandum, and that the 1995 principles are no longer aspirational.<sup>148</sup> The principles themselves, however, are sufficiently general and non-specific

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<sup>140</sup> Proposed Bulletin on Peer Review and Information Quality, 68 Fed. Reg. 54,023 (Sept. 15, 2003).

<sup>141</sup> David Michaels, *Politicizing Peer Review: A Perspective*, in *RESCUING SCIENCE FROM POLITICS: REGULATION AND THE DISTORTION OF SCIENTIFIC INFORMATION* 219, 233-35 (Wendy Wagner & Rena Steinzor eds., 2006).

<sup>142</sup> *Id.* at 233-34.

<sup>143</sup> Donald Kennedy, *Disclosure and Disinterest*, *SCI.*, Jan. 2, 2004, at 15.

<sup>144</sup> Michaels, *supra* note 141, at 236.

<sup>145</sup> Memorandum, Updated Principles for Risk Analysis, *supra* note 16, at 2.

<sup>146</sup> *Id.*

<sup>147</sup> *Id.* at 1.

<sup>148</sup> Ralph Linderman, Dudley Says New Risk Assessment Memo Aimed at Reinforcing Existing OMB Policies, *Daily Rep. for Executives (BNA)* A-41, A-41 (Sept. 28, 2007).

that they do not appear to mandate specific approaches to risk assessment of the type sought in the OMB's proposed Bulletin. Thus, while the memorandum may highlight aspects of risk assessment that OMB would discuss with an agency, the memorandum does not mandate any specific approach to risk assessment. Ultimately, the memorandum appears to be a place holder and the issue of OMB's approach to risk assessment will be decided in the next Administration.

OMB's role in overseeing risk assessment in the federal government presents a dilemma. On the one hand, the President has a constitutional obligation to ensure the laws are faithfully executed,<sup>149</sup> and OMB supervision of regulatory agencies is generally accepted as a legitimate exercise of that authority.<sup>150</sup> On the other hand, as we have seen, White House involvement has the potential to politicize regulatory science.<sup>151</sup> How can we reconcile the President's constitutional function to oversee the government with the potential that the White House will politicize science in performing this role?

The NRC Report suggested a way out of this dilemma for risk assessment. While the committee thought "there is room for improvement in risk assessment practices," it also recommended that "OMB should limit its efforts to stating goals and general principles of risk assessment."<sup>152</sup> The committee based its recommendations on the lack of expertise at OMB to improve risk assessment in the government: "The details should be left to the agencies or expert committees appointed by the agencies, wherein lies the depth of expertise to address the issues relevant to the specific types of risk assessments."<sup>153</sup> This approach, however, also minimizes the potential for politicization by the White House, since OMB would not be responsible for developing the details of risk assessment guidelines.

The conception of OMB's role as one of coordination and delegation is also consistent with the President's responsibility to manage the government. I have previously made this point in the context of presidential review of individual regulations:

White House oversight can potentially serve three functions: agenda-setting, coordination, and review of individual regulations. In the [Reagan administration and the first Bush Administration] rule review was emphasized, coordination was given some attention, and agenda-setting was almost ignored. A better approach would be to reverse these priorities. Presidential oversight should have as its first priority the establishment of a regulatory agenda, as its second priority the coordination of regulation, and as its last priority the review of individual regulations.<sup>154</sup>

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<sup>149</sup> U.S. CONST. art. II, § 3.

<sup>150</sup> See PETER L. STRAUSS, *ADMINISTRATIVE JUSTICE IN THE UNITED STATES* 101-09 (2d ed. 2002) (discussing the legitimacy of White House oversight of the regulatory process).

<sup>151</sup> See *id.* at 103.

<sup>152</sup> NRC REPORT, *supra* note 7, at 8.

<sup>153</sup> *Id.*

<sup>154</sup> Sidney A. Shapiro, *Political Oversight and the Deterioration of Regulatory Policy*, 46 ADMIN. L. REV. 1, 30-31 (1994).

My argument for these priorities was based on the fact that OMB is the only government agency in a position to carry out planning and coordinating functions.<sup>155</sup> Moreover, unless the White House is committed to using OMB to minimize regulation, the delegation of the details concerning individual regulations makes sense.

The same conclusions apply in the context of risk assessment. Unless the goal is politicization, it makes no sense for OMB (or even OSTP) to learn the details of the various risk assessment methodologies used across the government. It may make sense, however, for OMB to create an agenda for the improvement of risk assessment practices and to coordinate the fulfillment of that agenda. For example, the NRC committee recommended that agencies that assess similar risks should work together to improve their risk assessment capabilities and ensure consistency.<sup>156</sup>

A recent analysis of centralized oversight by OMB comes to similar conclusions. After an exhaustive analysis of the justifications for and practice of OMB rulemaking review, Nicholas Bagley and Richard Revesz conclude it is time to change centralized review from "its historical roots in checking agency behavior and securing it to a more broadly conceived mission of harmonizing the operation of our regulatory apparatus."<sup>157</sup> The authors recommend a harmonization of the different default guidelines used by different agencies to analyze cancer risks.<sup>158</sup>

Bagley and Revesz are not entirely clear how intrusive a role OMB would play in this effort. They note the accusations that OMB's supervision of science is biased and inappropriate, but decline to pursue such claims as beyond the scope of their article.<sup>159</sup> They justify their agnosticism on the ground that OMB is in the best position to coordinate agency science despite its potential flaws in terms of bias or politicization.<sup>160</sup> While I agree it is appropriate to expect OMB to fulfill this agenda-setting and coordination role, our experience to date with OMB supervision of science suggests that it should have a limited role in the creation of common default rules.

OMB's role in superintending regulatory science should be limited in the following ways. First, OMB should not assume that agency risk assessments are poorly done or that the solution is additional guidelines if there is such a problem. If OMB is genuinely interested in improving agency science, it should initiate a study of that science and the reasons for any poor science that is found.

Second, if OMB seeks to harmonize agency default rules for health risk assessments, it should require agencies with common risk assessment methodologies to meet and jointly agree on common default rules. The default rules should be written by risk assessment experts at their respective

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<sup>155</sup> *Id.* at 39.

<sup>156</sup> NRC REPORT, *supra* note 7, at 8.

<sup>157</sup> Nicholas Bagley & Richard Revesz, *Centralized Oversight of the Regulatory State*, 106 COLUM. L. REV. 1260, 1329 (2006).

<sup>158</sup> *Id.* at 1316–24.

<sup>159</sup> *Id.* at 1316.

<sup>160</sup> *Id.* at 1329.



agencies, and they should be subject to peer review by scientific advisory committees from which agencies routinely seek expert advice. OMB's role should be limited to convening inter-agency committees and to ensuring that agencies have non-arbitrary reasons for maintaining different default rules.

Third, since it is possible that agencies themselves will seek to politicize the risk assessment process,<sup>161</sup> OMB should require that the development of risk assessment guidelines be a transparent and public process. Moreover, given the importance of default rules in health risk assessments, the work product of the inter-agency task force should be made available for public comment and NRC review.

#### VII. CONCLUSION

The NRC Committee asked by OMB to review its proposed risk assessment guidelines gave OMB a grade of "F."<sup>162</sup> OMB's failures may be attributable to its lack of scientific expertise, but it is obvious that OMB also saw the Guidelines as an opportunity to politicize the risk assessment process in the government. Emboldened by the IQA, OMB did not bother to find out whether agency risk assessments were unsound, and if so, why. OMB's lack of curiosity indicates its lack of concern about delaying government action and its interest in adding to that ossification. Moreover, OMB's hubris that its few scientists and many economists and lawyers could write state-of-the-art science guidelines suggests that it had goals other than bettering agency science. Finally, OMB's adoption of simplistic or unrealistic methodologies might be explained by its lack of scientific expertise except that OMB's methodologies would have bended risk assessment away from the preventative orientation that the Bush Administration and industry oppose.

This debacle does not mean the federal government should not pursue efforts to improve and coordinate agency science. It does mean that the role of OMB in these efforts should be circumscribed. OMB should create an agenda to improve agency science only after it has studied the current state of agency science and the causes of any problems with it. OMB should play an agenda-setting and coordination role to improve agency science as necessary, but the actual job should be left to the agencies themselves. Unlike OMB, these agencies have the scientific expertise to do the job. It also reduces the likelihood that OMB can politicize the results. Finally, OMB must create a process that also reduces the possibility that agencies themselves will politicize the results.

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<sup>161</sup> Indeed, this is where most of the politicization of science has occurred during the current Bush Administration. *See supra* Part II.

<sup>162</sup> *See* NRC REPORT, *supra* note 7, at 6-7.