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## Proceed with Caution: The Implications of the OMB Peer Review Guidelines on Precautionary Legislation

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# PROCEED WITH CAUTION: THE IMPLICATIONS OF THE OMB PEER REVIEW GUIDELINES ON PRECAUTIONARY LEGISLATION

## INTRODUCTION

Imagine this situation: A nervous young father is eager to help his flu-ridden daughter feel better. To alleviate her pain, as any parent would do, he opens the medicine cabinet for some aspirin, checks the warning and dosage label, and administers the medication to his child. She later develops Reye's syndrome—a rare but debilitating disease that can be fatal. Unbeknownst to this parent, studies had revealed a higher incidence of Reye's syndrome in children who had been given aspirin to ease pain caused by certain viral infections. No warning label existed because the aspirin industry was fighting government efforts to include a warning label despite four studies linking Reye's syndrome to aspirin use.<sup>1</sup> The industry successfully persuaded the government to undertake further studies, but in December 1985, the Federal Drug Administration (FDA) finally issued a proposal mandating labels cautioning potential users about the risks of Reye's.<sup>2</sup> Since 1986, labels have been included on all aspirin bottles warning that administering aspirin to children with colds, flu, or chicken pox, could lead to an increased chance of developing Reye's syndrome.<sup>3</sup> Had the government been authorized to act in a timelier manner, perhaps more instances of this illness could have been avoided.<sup>4</sup>

Citizens expect their government to promulgate rules and regulations that are based on accurate information.<sup>5</sup> Agencies are generally considered

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1. See Joseph Gastwirth, *The Need for Careful Evaluation of Epidemiological Evidence in Product Liability Cases: A Reexamination of Wells v. Ortho and Key Pharmaceuticals*, 2 LAW PROB. & RISK 151, 156 (2003).

2. Proposed Labeling for Oral Aspirin-Containing Drug Products, 50 Fed. Reg. 51,400 (Dec. 17, 1985).

3. Labeling for Oral and Rectal Over-the-Counter Aspirin and Aspirin-Containing Drug Products, 51 Fed. Reg. 8180 (Mar. 7, 1986). For a detailed factual account of the history surrounding the efforts to include warning labels, see *American Home Products Corp. v. Johnson & Johnson*, 672 F. Supp. 135, 137–41 (S.D.N.Y. 1987).

4. See Letter from Joseph L. Gastwirth, Professor of Statistics, George Washington University, to Jack B. Weinstein, Senior District Judge, United States District Court for the Eastern District of New York (Mar. 13, 2001) (concluding that some 100 cases of Reye's syndrome might have been prevented had the FDA issued warnings in 1982).

5. Donald T. Hornstein, *Accounting for Science: The Independence of Public Research in the New, Subterranean Administrative Law*, LAW & CONTEMP. PROBS., Autumn 2003, at 246 ("Science is an enormously important public resource in a free society, and there are, accordingly, enormous benefits in maintaining public confidence in its underlying integrity as a process.").

to have expertise in their particular field of regulation, and are trusted to use this expertise to make policy decisions in the best interest of society. Agencies rely on scientific studies to guide them in making these policy choices, but this guidance is rarely conclusive as even the most advanced scientific research will leave some questions unanswered.<sup>6</sup>

For instance, when experiments are conducted to determine the toxicity of particular chemicals, the data cannot establish a “safe” level of exposure.<sup>7</sup> Instead, it is the agency officials who must consider competing policy concerns in quantifying the risk at an appropriate level.<sup>8</sup> Moreover, it is very difficult, if not unethical, to conduct research with respect to many of the greatest public health and environmental concerns.<sup>9</sup> As a result, agencies are often forced to make decisions based on scientific research riddled with uncertainty.<sup>10</sup>

Concrete assurances that the benefits of a given regulation will outweigh its risks seem the best way to ensure the administration of true “justice.”<sup>11</sup> However, this goal is difficult to reconcile with the field of science where research is hampered with uncertainty.<sup>12</sup> Such uncertainty should not bar all regulations, but most would agree that some restraints

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6. See Wendy E. Wagner, *The “Bad Science” Fiction: Reclaiming the Debate over the Role of Science in Public Health and Environmental Regulation*, LAW & CONTEMP. PROBS., Autumn 2003, at 64 (“Science teases policymakers with the prospect of providing definitive guidance for regulatory decisionmaking. But in reality, the information that most scientific research provides to health and environmental regulation is incomplete and inconclusive . . .”).

7. See Wendy Wagner, *The Science Charade in Toxic Risk Regulation*, 95 COLUM. L. REV. 1613, 1622 (1995) (explaining that while scientific experiments can establish the effects of certain substances on controlled subjects in controlled circumstances, the quantitative risk to humans can not be conclusively resolved through science, leaving those gaps to be filled by policy choices).

8. *Id.* at 1622 n.28 (defining “policy” to include “the reasoned weighing of various economic and social outcomes . . . [and] the conscious or subconscious biases, guesses, and intuition of decisionmakers.”).

9. *Id.* at 1621 (identifying the ethical limitations of toxic testing that force scientists to extrapolate from animal studies rather than conduct experiments on human subjects).

10. See Wagner, *supra* note 7, at 1619–22 (describing the limits of science in the context of risk assessment and explaining that where science is unable to provide a conclusive answer, policy considerations must fill in these gaps).

11. See David Kriebel et al., *The Precautionary Principle in Environmental Science*, 109 ENVTL. HEALTH PERSP. 873, 875 (2001) (“Although there are some situations in which risks clearly exceed benefits no matter whose values are being considered, there is usually a large gray area in which science alone cannot (and should not) be used to decide policy.”).

12. See Holly Doremus, *Listing Decisions Under the Endangered Species Act: Why Better Science Isn’t Always Better Policy*, 75 WASH. U. L.Q. 1029, 1063–64 (1997) (“Because no theory is ever proven to an absolute certainty, no bright line separates hunches from established scientific knowledge . . . Reliance on science must, by necessity, include reliance on some hunches.”). See also *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 590 (1993) (“[A]rguably, there are no certainties in science.”).

upon regulation are still necessary.<sup>13</sup> Given that scientific uncertainty is a reality, the government must be equipped to promulgate protective regulations notwithstanding unanswered questions regarding the degree of harm the regulated entity may present.<sup>14</sup>

Congress has addressed this concern by passing several statutes authorizing agencies to promulgate regulations even where the science fails to provide a conclusive answer.<sup>15</sup> For example, the Environmental Protection Agency (EPA) is authorized by statute to regulate hazardous air pollutants to protect public health by an “ample margin of safety,”<sup>16</sup> and contaminants in drinking water if it is shown that they “*may* have an adverse effect on the health of persons.”<sup>17</sup> These and other similarly worded statutes are said to exemplify a precautionary approach to regulation by embodying what is commonly referred to as the precautionary principle.<sup>18</sup>

Concerned that such precautionary statutes led too many agencies to disseminate inaccurate information and promulgate regulations on the basis of insufficient science, lawmakers sought to establish more stringent guidelines that would improve agency science.<sup>19</sup> The push for “sound science” can be traced back to the tort and regulatory reform movements of the Reagan Administration.<sup>20</sup> One of the most tangible results of this

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13. Hornstein, *supra* note 5, at 246.

14. *See, e.g.*, *Motor Vehicle Mfrs. Ass’n v. State Farm Mut. Auto. Ins. Co.* 463 U.S. 29, 52 (1983) (“It is not infrequent that the available data does not settle a regulatory issue and the agency must then exercise its judgment in moving from the facts and probabilities on the record to a policy conclusion.”).

15. *See infra* text accompanying notes 48–53.

16. Clean Air Act (CAA) § 112(d)(4), 42 U.S.C. § 7412(d)(4) (2000).

17. Safe Drinking Water Act, 42 U.S.C. § 300g-1(b)(1)(A)(i)-(iii) (2000) (emphasis added).

18. The precautionary principle is discussed more fully *infra* notes 43–54. In general, this approach favors government action despite scientific uncertainty, if the risks of inaction could harm human health or the environment. *See* SIDNEY SHAPIRO & ROBERT GLICKSMAN, *RISK REGULATION AT RISK: RESTORING A PRAGMATIC APPROACH* 15 (2003) (describing risk regulation as a congressional tool designed to “permit the government to act on the basis of anticipated harm”).

19. One example of congressional attempts to improve agency science came in the form of the Data Access Amendment, also known as the Shelby Amendment. *See infra* text accompanying note 64. In justifying his namesake legislation, Senator Richard Shelby stated: “Public confidence in the accuracy and reliability of information being used to drive public policy ultimately is in the best interest of scientific research. Increasing access to such data promotes the transparency and accountability that is essential to building public trust in government actions and decision-making.” Richard Shelby, *Accountability and Transparency: Public Access to Federally Funded Research Data*, 37 HARV. J. ON LEGIS. 371, 379 (2000).

20. *See generally* Thomas O. McGarity, *Our Science is Sound Science and their Science is Junk Science: Science-Based Strategies for Avoiding Accountability and Responsibility for Risk-Producing Products and Activities*, 52 U. KAN. L. REV. 897, 900 (2004) (presenting thesis on how regulatory and tort reform movements were an effort to avoid regulatory responsibility). Another product of this “sound science” movement took the form of a Supreme Court decision. In 1993, the Supreme Court

movement was the creation of the Information Quality Act (IQA).<sup>21</sup> Passed as an obscure rider to a voluminous appropriations bill, the IQA has the potential to make significant impacts in the regulatory world.<sup>22</sup>

The Office of Management and Budget (OMB) has promulgated a series of guidelines to direct agencies regarding implementation of the IQA.<sup>23</sup> The recently promulgated guidelines mandating peer review of “important scientific information” have been among the more controversial manifestations of the IQA.<sup>24</sup> The preamble to the regulations espouses the benefits of using peer review as a tool to evaluate scientific data.<sup>25</sup> Some agencies already had established peer review policies in place, but the guidelines provide a uniform standard to assess the quality of agency science.<sup>26</sup> While this new standardized system of review has

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raised the standards plaintiffs would have to meet before admitting scientific evidence into the court room in the landmark case of *Daubert v. Merrill Dow Pharm.*, 509 U.S. 579 (1993).

21. Treasury and General Government Appropriations Act for Fiscal Year 2001, Pub. L. No. 106-554, § 515(a), 114 Stat. 2763, 2763A-153-54 (2001) [hereinafter IQA]. For an interesting discussion of the motives which generated the “sound science” reform movements in the context of both administrative and tort law, see McGarity, *supra* note 20, at 900–14. A more complete picture of the events leading up to the passage of the IQA can be found in CHRIS MOONEY, *REPUBLICAN WAR ON SCIENCE* (2005). See also *infra* text accompanying notes 65–83.

22. The IQA was quietly passed as a rider to a voluminous appropriations bill and requires the Office of Management and Budget (OMB) to promulgate guidelines that will ensure and maximize the “quality, objectivity, utility, and integrity of information . . . disseminated by Federal agencies.” § 515(a), 114 Stat. 2763, 2763A-153-54. See Hornstein, *supra* note 5, at 232–33 (questioning the origins of this legislation); James T. O’Reilly, *The 411 on 515: How OIRA’s Expanded Information Roles in 2002 Will Impact Rulemaking and Agency Publicity Actions*, 54 ADMIN. L. REV. 835 (providing a favorable analysis of the IQA).

23. The OMB originally published interim guidelines interpreting the IQA on September 28, 2001. OMB Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies, 66 Fed. Reg. 49,718 (Sept. 28, 2001) [hereinafter Initial IQA Guidelines]. Following a series of corrections and updates to the guidelines, the OMB implemented the final guidelines on February 22, 2002. OMB Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies, Republication, 67 Fed. Reg. 8452 (Feb. 22, 2002) [hereinafter IQA Implementing Guidelines]. The peer review guidelines constituted the next significant rule-making under the IQA. OMB Proposed Bulletin on Peer Review and Information Quality, 68 Fed. Reg. 54,024 (Sept. 15, 2003) [hereinafter Proposed Bulletin]. For a general overview of the various iterations of the IQA guidelines, see Sarah Grimmer, Note, *Public Controversy Over Peer Review*, 57 ADMIN. L. REV. 275 (2005). The OMB has also published all documents related to the IQA on its website at <http://www.whitehouse.gov/omb/inforeg/infopoltech.html>.

24. Final Information Quality Bulletin for Peer Review, 70 Fed. Reg. 2664 (Jan. 14, 2005) [hereinafter Final Bulletin]. Some scholars question whether the IQA provides sufficient authority for the OMB to issue peer review guidelines. See Sidney A. Shapiro, *OMB’s Dubious Peer Review Procedures*, 34 ENVTL. L. REP. (ENVTL. L. INST.) 10,064 (2004).

25. Final Bulletin, 70 Fed. Reg. at 2665 (“Peer review is one of the important procedures used to ensure that the quality of published information meets the standards of the scientific and technical community.”).

26. *Id.* at 2666 (“This Bulletin establishes minimum standards for when peer review is required for scientific information and the types of peer review that should be considered by agencies in

garnered approval,<sup>27</sup> critics are concerned peer review will exploit the uncertainties which are inherently present in many scientific determinations, making it more difficult for agencies to move forward with regulations.<sup>28</sup>

This Note will evaluate how the peer review guidelines promulgated by the OMB interfere with the ability of agencies to implement rules and regulations in accordance with precautionary statutes. Part I of the Note will examine the evolution of the precautionary principle and the ways in which it has infiltrated the American legal system. Part II will trace the development of the peer review guidelines promulgated by the OMB, beginning with a general history of the IQA. Part III of this Note will examine the implications of requiring agencies to incur an additional layer of review when implementing statutes authorizing a precautionary approach, including a brief examination of current problems agencies have faced as a result of being subjected to IQA challenges. Part IV of this Note will propose amending the IQA requirements so that precautionary statutes will not be subjected to the same peer review requirements. This can be implemented in one of two ways. First, the IQA could be amended so that statutes with a precautionary element are not required to abide by the peer review regulations. Alternatively, the OMB regulations could be amended to expand the exemption to explicitly cover regulations which are authorized by precautionary legislation.

## I. EVOLUTION OF THE PRECAUTIONARY PRINCIPLE IN AMERICAN LAW

When presented with a federal directive to regulate a particular entity or activity, administrative agencies are often faced with the difficult task of determining the extent of that regulation.<sup>29</sup> In making these decisions,

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different circumstances.”).

27. See Grimmer, *supra* note 23 at 281 nn.39–43 (summarizing comments received by OMB praising the peer review guidelines).

28. See Lars Noah, *Scientific “Republicanism”: Expert Peer Review and the Quest for Regulatory Deliberation*, 49 EMORY L.J. 1033, 1046 (2000) (“[P]olicymakers often seem to conflate peer review with science itself, which in turn may lead them to exaggerate the possible utility of independent expert scrutiny of decisions based on science.”). Some scholars, however, have suggested that exposing such uncertainties will strengthen agency decisions by forcing policymakers to clearly identify the aspects of a regulation where policy considerations, rather than science, informed a decision. See James Salzman & J.B. Ruhl, *In Defense of Regulatory Peer Review*, 84 WASH. U. L. REV. 1, 47 (2006) (“[P]eer review is not expected to prove any research wrong, but rather to identify flaws and deficiencies in a particular research effort that may call into question whether the researcher’s conclusions are justified.”).

29. See Wagner, *supra* note 7, at 1618 (describing how vague statutory mandates often leave agencies with the task of translating these directives into quantifiable standards).

government officials will often look to scientific studies for guidance, and while important information can be obtained from such studies, policy questions are usually left unanswered.<sup>30</sup> For example, a scientific experiment may provide information on the carcinogenic properties of a particular food additive in rodents, but it is the agency that must determine how these results will be used in developing a regulation which will both protect the public against cancer as well as account for the public interest in keeping such an additive on the market.<sup>31</sup>

While policy decisions can and should be supported by science, no amount of scientific research can provide a conclusive answer where policy choices are required.<sup>32</sup> For instance, while scientific studies can identify effects of certain air pollutants on animals in controlled experiments, it fails to answer the question of whether a given regulation provides an “adequate margin of safety”<sup>33</sup> for the human population, or ensures that car emissions will not “endanger the public health or welfare.”<sup>34</sup> Scientists simply do not have the tools to answer all of these questions and agencies must assume the role of using this inconclusive evidence to formulate regulations.<sup>35</sup>

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30. See Wagner, *supra* note 6, at 64, and accompanying text. While this Note focuses on one aspect of how science is used in regulatory decisionmaking, scientific interpretations have also created problems in the evidentiary setting. See, e.g., *Daubert v. Merrill Dow*, 509 U.S. 579, 590 (landmark case establishing standards by which judges may allow certain scientific evidence); Alan Charles Raul & Julie Zampa Dwyer, “Regulatory Daubert”: A Proposal to Enhance Judicial Review of Agency Science by Incorporating Daubert Principles into Administrative Law, 66 LAW & CONTEMP. PROBS. 7 (Autumn 2003).

31. See Wagner, *supra* note 6, at 64 (describing how toxicology risk assessments combine scientific information obtained from toxicity tests on animals with “science-policy judgments” such as determining how such exposure will affect humans).

32. However, some scholars have argued that agencies have attempted to avoid making these difficult policy decisions by relying too heavily on science to answer questions it is unequipped to answer. See Wagner, *supra* note 7, at 1613 (arguing lawmakers have avoided accountability for regulatory decisions by exaggerating the contributions of science in regulatory decisions); Salzman & Ruhl, *supra* note 28, at 44–45 (explaining that while the Fish and Wildlife Service was entitled to categorize its decision to terminate irrigation practices as part of a species-friendly policy, when the agency explained its decision solely in terms of scientific evidence there was no “reasoned alternative” by which the agency decision could stand once the science was refuted).

33. CAA § 109(b)(1), 42 U.S.C. § 7409(b)(1) (2000). This provision of the CAA directs the EPA Administrator to establish ambient air quality standards at the level that is required to protect the public health by an “adequate margin of safety.” *Id.*

34. CAA § 211(c)(1), 42 U.S.C. § 7545(c)(1)(A) (2000). This section of the CAA authorizes the EPA Administrator to regulate the manufacture or sale of certain fuel products, if, in her judgment, such products “may reasonably be anticipated to endanger the public health or welfare.” *Id.* (emphasis added).

35. For a specific example of the questions which science can answer (dose-response outcomes in mice) and the questions which it can not (how this data should be extrapolated to humans), see Wagner, *supra* note 6, at 65. See also text accompanying notes 7–12.

Moreover, efforts to quantify risk levels in the health and safety context are limited by ethical as well as technological concerns.<sup>36</sup> Such limitations make it difficult to demonstrate with complete certainty whether a particular activity presents an unacceptable level of risk to the public health or environment such that the activity should be restricted.<sup>37</sup> It is important for agency decisions to be made on a reasoned basis, and preventing the government from acting on science unless it achieves a certain level of reliability is a desirable step toward this goal.<sup>38</sup> However, the government is still expected to protect the public from harm, and regulatory delay or inaction may result in the manifestation of predicted harms.<sup>39</sup>

When scientific research fails to indicate with absolute certainty whether a particular regulation is necessary to avoid harm, the decision of how to use the science is left to lawmakers.<sup>40</sup> Agencies may opt to deal with these uncertainties by employing the “wait and see” approach, under which no action is taken until underlying concerns are validated by either more extensive scientific research or the manifestation of anticipated harms. While it may be desirable to create regulations based on concrete

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36. See Wagner, *supra* note 7, at 1620 (citing National Research Council Risk Assessment explaining that limitations in epidemiological evidence are due in part to moral prohibition against releasing untested chemicals into the environment). Extrapolation from animal studies is often the only option and scientists disagree over how to interpret such studies. See, e.g., Jonathon Bender, *Societal Risk Reduction: Promise and Pitfalls*, 3 N.Y.U. ENVTL. L.J. 255, 290 (1995) (questioning legitimacy of rodent bioassays in assessing human cancer risks); Marvin Goldman, *Cancer Risk of Low-Level Exposure*, 271 SCIENCE 1821 (1996) (criticizing the linear extrapolation model in the context of risk assessment).

37. See McGarity, *supra* note 20, at 900 (analogizing the difficult burden of proving causation in tort law to the agency task of demonstrating that certain products and activities pose “unacceptable risks to public health and the environment”).

38. See *id.* at 900 (arguing that while agencies may not bear the technical burden of proving that certain activities or products result in harm, the practical burden of establishing a record that will survive “hard-look” review and other administrative mandates requires agencies to produce scientific information); Carla Mattix & Kathleen Becker, *Scientific Uncertainty Under the National Environmental Policy Act*, 54 ADMIN. L. REV. 1125, 1126 (2002) (“Science is more and more being touted by public officials . . . as a way to ensure that government decisionmakers are basing their decisions on sound, proven principles and not on personal opinions or whim.”).

39. These harms are particularly frustrating when the lapse of time fails to produce research that suggests the regulation was indeed too restrictive. For example, after withdrawing the new arsenic standards established by President Clinton, the Bush Administration announced that a new rule would be released in eleven months, following a study by the National Academy of Sciences. However, seven months later, the EPA reinstated the rule after finding that the risk was even greater than previously believed. Edward Walsh, *Arsenic Drinking Water Standard Issued; After Seven-Month Scientific Review, EPA Backs Clinton-Established Levels*, WASH. POST, Nov. 1, 2001, at A31.

40. See Kriebel et al., *supra* note 11; Wagner, *supra* note 7, at 1619–20 (explaining that where the limits of science prevent finding a quantitative standard of safety, “policy considerations must fill in the gaps that science cannot inform”).



results, the limitations of science mean that lawmakers are often left to base regulations on nothing more than predictions and models.<sup>41</sup> Waiting until predictions are verified by reality may lead to an irreversible harm, and no amount of regulation or government action will be able to remedy the harm caused by regulatory delay.<sup>42</sup>

Alternatively, lawmakers can take a precautionary approach by choosing to regulate even in the face of scientific uncertainty.<sup>43</sup> The underlying premise of this regulatory approach known as the “precautionary principle” is that where the probability of actual harm is unknown, such scientific uncertainty should not prevent the government from promulgating regulations which will protect both human health and the environment from foreseeable risks.<sup>44</sup>

The precautionary principle has been explicitly articulated in many nonbinding international agreements as well as binding international

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41. In fact, the choice of what model to use in guiding an agency decision also constitutes a policy choice as there may be multiple models which are viewed as “scientifically plausible.” Wagner, *supra* note 7, at 1626 (“[T]he choice of one model over another cannot be resolved by science and thus must be determined by policy factors.”).

42. For a review of instances where precautionary regulation would have been beneficial see EUROPEAN ENVTL. AGENCY, LATE LESSONS FROM EARLY WARNINGS: THE PRECAUTIONARY PRINCIPLE 1896–2000 (Harremoës et al. eds., 2001), available at [http://reports.eea.eu.int/environmental\\_issue\\_report\\_2001\\_22/en/Issue\\_Report\\_No\\_22.pdf](http://reports.eea.eu.int/environmental_issue_report_2001_22/en/Issue_Report_No_22.pdf). *But see* Jonathon H. Adler, *More Sorry Than Safe: Assessing the Precautionary Principle and the Proposed International Biosafety Protocol*, 35 TEX. INT’L L.J. 173, 196 (2000) (providing examples where utilizing the precautionary approach resulted in harmful consequences).

43. Precautionary approaches to legislation and regulation can be further divided into “pre-emptive precautionary approaches” and “risk-based precautionary approaches.” The first category characterizes decisions which are made without sufficient information to determine the level of risk. The second category covers actions which occur at the stage of risk assessment where decisionmakers may utilize more conservative techniques or assumptions when determining risk levels. *See* Bernard D. Goldstein & Russel S. Carruth, *Implications of the Precautionary Principle for Environmental Regulation in the United States: Examples From the Control of Hazardous Air Pollutants in the 1990 Clean Air Act Amendments*, 66 LAW & CONTEMP. PROBS. 247, 249–50 (2003).

44. While the precautionary principle has been articulated in several different ways, one of the most concise formulations is found in the 1992 Rio Declaration—a nonbinding international agreement drafted during the 1992 United Nations Conference on Environment and Development conducted in Rio de Janeiro. The relevant precautionary language stated that “where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation.” The United Nations Conference on Environment and Development, June 3–14, 1992, *Rio Declaration on Environment and Development*, ¶ 15, available at <http://www.unep.org/Documents.multilingual/Default.asp?DocumentID=78&ArticleID=1163>. An alternative formulation can be found in the Wingspread Statement on the Precautionary Principle. This statement was drafted and signed by a diverse group which included farmers, researchers, and attorneys. *Wingspread Statement on the Precautionary Principle* (Jan. 23–25, 1998) <http://www.gdrc.org/u-gov/precaution-3.html> (“Where an activity raises threats of harm to the environment or human health, precautionary measures should be taken even if some cause and effect relationships are not fully established scientifically.”).

treaties.<sup>45</sup> Some countries have employed the principle when promulgating domestic policies as well.<sup>46</sup> While lawmakers in Washington have been more reluctant to embrace the precautionary principle than their European counterparts,<sup>47</sup> examples of a precautionary approach can be found scattered throughout the United States Code.<sup>48</sup>

Some statutes incorporate a precautionary aim by establishing low evidentiary thresholds by which regulatory action will be triggered.<sup>49</sup> For instance, when establishing the level at which a given contaminant may be found in drinking water, the Safe Drinking Water Act directs the EPA to demonstrate that the substance “*may* have an adverse effect on the health of persons,” and is “known to occur or there is a *substantial likelihood* that the contaminant will occur in public water systems.”<sup>50</sup> In an effort to

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45. See, e.g., Stockholm Convention on Persistent Organic Pollutants, May 22, 2001, 40 I.L.M. 532, 533, available at [http://www.pops.int/documents/convtext/convtext\\_en.pdf](http://www.pops.int/documents/convtext/convtext_en.pdf) (“Acknowledging that precaution underlies the concerns of all the Parties and is embedded within this Convention.”). For a discussion of other international agreements which incorporate the precautionary principle, see Frank B. Cross, *Paradoxical Perils of the Precautionary Principle*, 53 WASH. & LEE L. REV. 851, 854 (1996) (identifying the precautionary principle in the Treaty of Rome, international climate change policies, and international principle of sustainable development).

46. In Australia, the Intergovernmental Agreement on the Environment (IGAE) explicitly identifies the precautionary principle as one of four principles that should “inform policy making and program implementation.” See Intergovernmental Agreement on the Environment, 1992 §3.5 (Austl.) available at <http://www.deh.gov.au/esd/national/igae/>. For a survey of how the precautionary principle has been used internationally, specifically with respect to foreign case law and international treaties and agreements, see Scott LaFranchi, Note, *Surveying the Precautionary Principle’s Ongoing Global Development: The Evolution of an Emergent Environmental Management Tool* 32 B.C. ENVTL. AFF. L. REV. 679 (2005).

47. For example, during meetings to prepare an international agreement regulating persistent organic pollutants, the United States fought to ensure that the term “precautionary approach” was used in place of “precautionary principle,” as the former term was seen as a more flexible phrase providing regulated entities with leeway to consider factors other than the environment before taking action. MARCO A. OLSON, ANALYSIS OF THE STOCKHOLM CONVENTION ON PERSISTENT ORGANIC POLLUTANTS 99–100 (2003).

48. Legislation need not explicitly adopt the precautionary principle in order to be interpreted in a precautionary manner. See Goldstein & Carruth, *supra* note 43, at 253–54 (identifying the amendments to the 1990 Clean Air Act regulating Hazardous Air Pollutants as precautionary due to its focus on technology-based standards rather than risk-assessment). Further, the amendments can be seen as precautionary in that they shift the burden to regulated entities by requiring an affirmative demonstration that a listed pollutant “may not reasonably be anticipated to cause any adverse effects to the human health or adverse environmental effects.” CAA § 112(b)(3)(C), 42 U.S.C. § 7412 (b)(3)(C) (2000). For examples of other statutes which use technology-based controls to regulate emissions see Clean Water Act (CWA) § 301(b)(2)(A), 33 U.S.C. § 1311(b)(2)(A) (2000) (requiring sources of water pollutants to apply the “best available technology economically achievable”); CWA § 306(a)(1), 33 U.S.C. § 1316(a)(1) (2000) (requiring new sources of water pollutants to utilize the “best available demonstrated control technology”); CAA § 111, 42 U.S.C. § 7411 (2000) (authorizing federal government to regulate air emissions from new sources using technology-based standards).

49. See Wagner, *supra* note 6, at 85 (“Many of the mandates governing EPA similarly require only limited scientific evidence to justify regulatory intervention . . .”).

50. 42 U.S.C. § 300g-1(b)(1)(A)(i)-(iii) (2000) (emphasis added).

regulate hazardous wastes, the Resource Conservation and Recovery Act allows the EPA to define a certain waste as hazardous where “its quantity, concentration, or physical, chemical, or infectious characteristics *may* cause or *significantly contribute* to an increase in mortality.”<sup>51</sup>

Other statutes are worded such that agencies are directed to resolve uncertainties in favor of protecting public health.<sup>52</sup> Still others allow the government to take steps toward corrective action before verification of liability in an effort to immediately remedy situations which present a hazard to health or safety.<sup>53</sup> In permitting agencies to utilize this approach where authorized to do so, court decisions reflect judicial recognition of the policies justifying such approaches.<sup>54</sup>

While these international and domestic examples suggest that the precautionary principle has become widely accepted as a means of dealing with scientific uncertainty, critics of this approach are prevalent.<sup>55</sup> Some maintain that the precautionary approach stifles scientific research by discouraging the pursuit of complete scientific understanding.<sup>56</sup> Others have argued that while the competing costs and benefits of regulation are

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51. 42 U.S.C. § 6903(5) (2000) (emphasis added).

52. See, e.g., Food Quality Protection Act of 1996, 21 U.S.C. § 346a (b)(2)(A)(ii) (2000) (“As used in this section, the term “safe”, with respect to a tolerance for a pesticide chemical residue, means that the Administrator has determined that there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue.”); Toxic Substance Control Act, 15 U.S.C. §§ 2604(f)(1), 2605(a) (2000) (authorizing the Administrator to regulate new and existing toxic substances where “there is a reasonable basis to conclude that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or mixture, or that any combination of such activities, presents or will present an unreasonable risk of injury to health or the environment.”). CWA § 303, 33 U.S.C. § 1313(c)(2)(A) (2000) (requiring that states set water quality standards so as “to protect the public health or welfare”).

53. See, e.g., Comprehensive Environmental Response, Compensation, and Liability Act § 113(h), 42 U.S.C. § 9613(h) (2000) (preventing judicial review of EPA cleanup orders until after the cleanup has been completed).

54. See, e.g., *Ethyl Corp. v. EPA*, 541 F.2d 1, 28 (D.C. Cir. 1976) (en banc) (“Where a statute is precautionary in nature, the evidence difficult to come by, uncertain, or conflicting because it is on the frontiers of scientific knowledge . . . we will not demand rigorous step-by-step proof of cause and effect.”); *Reserve Mining Co. v. EPA*, 514 F.2d 492, 528 (8th Cir. 1975) (recognizing Congress’s intent to act in a precautionary manner when it authorized the United States to abate discharges into interstate waters which “endanger[ed] . . . the health or welfare of persons”).

55. See, e.g., Cross, *supra* note 45 (criticizing the precautionary principle and its failure to address the negative effects that precautionary regulation may have on public health); Goldstein & Carruth, *supra* note 43, at 247 (taking a “cautionary approach to the Precautionary Principle”); Don Mayer, *The Precautionary Principle and International Efforts to Ban DDT*, 9 S.C. ENVTL. L.J. 135, 136–38 (2002) (arguing that utilizing the precautionary principle in efforts to ban DDT has led to unpredictable results due to inconsistent applications of the approach).

56. See, e.g., Adler, *supra* note 42 (arguing that excessive regulation of biotechnology can stifle the research and development of products that will actually improve health and safety); Goldstein & Carruth, *supra* note 43, at 258 (warning that the precautionary principle provides an excuse to avoid acquiring complete scientific understanding).

often fervently debated, the benefits of regulatory restraint are often overlooked.<sup>57</sup> For example, the increased costs of implementing precautionary regulations may be felt most acutely by consumers and individual workers who must deal with higher prices or lower wages, respectively.<sup>58</sup> Relying on studies showing a correlation between health and wealth, some commentators argue that while precautionary regulations may improve some public health problems, others will be exacerbated by the financial impact of implementing such regulations.<sup>59</sup>

To date, the most effective attacks on precautionary regulations have been framed as concerns about agencies making decisions based on “junk science”—a pejorative phrase used to characterize the rationale behind numerous agency decisions.<sup>60</sup> By classifying agency decisions that adopt a precautionary approach as scientifically inadequate, cost-benefit arguments are avoided.<sup>61</sup> As this strategy became more prevalent in the 1990s, Congress passed two pieces of legislation which established legal avenues for challenging agency science.<sup>62</sup>

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57. See, e.g., Adler, *supra* note 42, at 195 (“[B]y focusing on one set of risks—those posed by the introduction of new technologies with somewhat uncertain effects—the precautionary principle turns a blind eye to the harms that occur, or are made worse, due to the lack of technological development.”); Frank Cross, *When Environmental Regulations Kill*, 22 *ECOLOGY L.Q.* 729, 731 (1995) (“[A] regulation that reduces disposable income might have an incidental effect of increasing death, illness, and injury.”). See also *Am. Trucking Ass’n, Inc. v. EPA*, 175 F.3d 1027, 1051–52 (D.C. Cir. 1999), *rev’d on other grounds*, 531 U.S. 457 (2001) (finding that when setting air quality standards, the EPA failed to consider the alleged health benefits of tropospheric ozone as a shield from the harmful effects of ultraviolet sunlight).

58. See Cross, *supra* note 45, at 915–20 (1996) (arguing that the true financial costs of increased regulation are borne by consumers and workers via increased prices, job cuts, and/or reduced wages).

59. *Id.* at 916 (“Unobserved, indirect costs may well dwarf the obvious direct compliance costs of environmental and other public health regulation.”). Cross goes on to address the potential health implications of decreased economic opportunities by citing studies that indicate wealthier nations have longer life expectancies, and that in the United States, those with higher incomes have lower mortality rates. *Id.* at 918.

60. PETER HUBER, *GALILEO’S REVENGE: JUNK SCIENCE IN THE COURTROOM* (1991). As a fellow at the Manhattan Institute, Huber argued that many of the causal associations between toxic exposure and disease were largely based on what he termed “junk science.” The Council on Competitiveness, created by then-President George H.W. Bush, embraced this term in promoting their regulatory and tort liability reform proposals. McGarity, *supra* note 20, at 905. For an interesting discussion of the motives which generated the “sound science” reform movements in the context of both administrative and tort law see McGarity, *supra* note 20.

61. See McGarity, *supra* note 20, at 904–08 (explaining industry claims portraying health and environmental regulations as too costly and burdensome presented a “hard sell” to the American public, but by replacing efficiency justifications with appeals to agency science, regulatory reformers garnered more public support).

62. These two statutes are known as the Data Access Amendment, Omnibus Consolidated and Emergency Supplemental Appropriations Act of 1999, Pub. L. No. 105-277, 112 Stat. 2681 (1998), and the Information Quality Act, Treasury and General Government Appropriations Act for Fiscal

## II. THE INFORMATION QUALITY ACT AND PEER REVIEW

At the turn of the century, two pieces of legislation passed through Congress virtually unnoticed but have subsequently generated significant discussion in the regulatory arena.<sup>63</sup> The Data Access Act was a single-sentence rider to the 1999 appropriations bill and enabled the public to request access to data produced by federally-funded studies.<sup>64</sup> Just under 250 words, the IQA was similarly embedded within a voluminous appropriations bill and passed through Congress with very little legislative discussion.<sup>65</sup> The current debate over the IQA and its implementing guidelines suggests that the lack of legislative discussion was due to unawareness of the bill rather than universal acceptance.<sup>66</sup>

The IQA authorizes the OMB to issue guidelines which provide “policy and procedural guidance to Federal agencies for ensuring and maximizing the quality, objectivity, utility, and integrity of information . . . disseminated by Federal agencies.”<sup>67</sup> Each agency is required by the

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Year 2001, Pub. L. No. 106-554, § 515(a), 114 Stat. 2763, 2763A-153-54 (2001). *See infra* notes 64–69 and accompanying text.

63. *See, e.g.*, Hornstein, *supra* note 5; O’Reilly *supra* note 22; Wendy Wagner, *Importing Daubert to Administrative Agencies Through the Information Quality Act*, 12 J.L. & POL’Y 589. *See also Improving Information Quality in the Federal Government Before the Government Reform Subcommittee on Regulatory Affairs*, 109th Cong. (2005), available at <http://reform.house.gov/RA/Hearings/EventSingle.aspx?EventID=29622>.

64. 112 Stat. 2681. Introduced as part of the 1999 appropriations bill by Senator Richard Shelby (R-AL), the Data Access Amendment (also known as the Shelby Amendment) received very little legislative attention. *See* Hornstein, *supra* note 5, at 230 (explaining that the Data Access Act was “all but invisible throughout the legislative process”). *But see* Shelby, *supra* note 19, at 379 (defending the passage of the bill and explaining that there was no effort to “conceal” the Data Access provision).

65. § 515(a), 114 Stat. 2763, 2763A-153-54. Like the Data Access Amendment, very little legislative history exists surrounding the passage of the IQA. *See* Nat’l Acad. Of Sci., *Ensuring the Quality of Data Disseminated by the Federal Government: Workshop #1*, at 9 (Mar. 11, 2002), [http://www7.nationalacademies.org/stl/4-21-02\\_transcript.doc](http://www7.nationalacademies.org/stl/4-21-02_transcript.doc) [hereinafter NAS Workshop] (“The [Information Quality Act] was enacted as a rider to an appropriations bill without any hearings or extensive legislative history.”) (comments of OMB director John Graham). In fact, the first hearings on the Act were not conducted until July 20, 2005. *Improving Information Quality in the Federal Government Before the Government Reform Subcommittee on Regulatory Affairs*, 109th Cong. (July 20, 2005). *See generally* MOONEY, *supra* note 21, at 102–20 (providing a more comprehensive look at the events surrounding the passage of the IQA).

66. *See* Hornstein, *supra* note 5, at 232 (“As with the [Data Access Act] the [IQA] hardly commanded widespread legislative attention.”); Michelle V. Lacko, Comment, *The Data Quality Act: Prologue to a Farce or a Tragedy?*, 53 EMORY L.J. 305, 307 (2004) (lamenting the “dearth of legislative history” surrounding the passage of the IQA); NAS Workshop, *supra* note 65, at 32 (“[The IQA] came up as part of a very large appropriations act that most people didn’t even know contained this particular piece of legislation in it.”) (comments of Alan Morrison).

67. § 515(a), 114 Stat. 2763, 2763A-153-54. The Act goes on to explain that these guidelines are an effort to help meet the goals of the Paperwork Reduction Act. *Id.* The Paperwork Reduction Act requires the Director of the OMB to “develop and oversee the implementation of policies, principles, standards, and guidelines to apply to Federal agency dissemination of public information.” 44 U.S.C.

IQA to establish procedures by which members of the public can seek correction of information that fails to meet these information quality standards.<sup>68</sup>

The IQA contains no reference to peer review as a helpful tool towards obtaining this desired quality and integrity of agency data.<sup>69</sup> Nevertheless, in its initial guidelines interpreting the IQA, the OMB encouraged agencies to engage in peer review, and provided general guidance to agencies aiming to conduct such reviews.<sup>70</sup> In September 2003, the OMB took this recommendation a step further when it proposed to supplement the IQA guidelines with peer review requirements for important scientific information relevant to regulatory policy decisions.<sup>71</sup>

In response to numerous comments and discussions with interested parties, the OMB issued a Revised Information Quality Bulletin on Peer Review (“Revised Bulletin”) on April 28, 2004, to address some of these concerns.<sup>72</sup> The major changes in this set of guidelines included (1)

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§§ 3504(d)(1), 3506(a)(1) (2000). Another law that is often cited as providing the OMB with the authority to issue regulatory requirements to agencies is Executive Order 12,866. This order, issued by President Clinton in 1993, requires agencies to base decisions on the “best reasonably obtainable . . . information,” and further requires the OMB to provide agencies with the guidance necessary to engage in regulatory planning. Exec. Order No. 12,866 §§1(b)(7), 2(b), 58 Fed. Reg. 51,735 (Oct. 4, 1993). Commentators have questioned whether the IQA was intended to grant such a broad power to the OMB. *See, e.g.,* McGarity et al., *Truth and Science Betrayed: The Case Against the Information Quality Act*, Center for Progressive Regulation, March 2005 at 2, <http://www.progressiveregulation.org/articles/iqa.pdf> (“The terse statutory language and absence of legislative history support the conclusion that Congress did not intend the IQA to serve as a kind of ‘uber statute’ providing OMB with the overarching authority to deflect agencies from their statutory responsibilities to implement the country’s health, safety and environmental laws.”).

68. § 515(a), 114 Stat. 2763, 2763A-153-54. The IQA requires each federal agency subject to the guidelines to “establish administrative mechanisms allowing affected persons to seek and obtain correction of information maintained and disseminated by the agency.” *Id.*

69. *Id.* The Act itself provides no guidance on how agencies should define the terms “quality” and “integrity.” To obtain these definitions, agencies must look to the implementing guidelines issued by the OMB, which define quality as “an encompassing term comprising utility, objectivity, and integrity.” IQA Implementing Guidelines, 67 Fed. Reg. at 8459. In the IQA Implementing Guidelines, integrity is defined as “the security of information—protection of the information from unauthorized access or revision, to ensure that the information is not compromised through corruption or falsification.” *Id.* at 8,460.

70. *See* IQA Implementing Guidelines, 67 Fed. Reg. at 8459–60 (establishing a general presumption of objectivity for data which has been subjected to external peer review).

71. Proposed Bulletin, 68 Fed. Reg. at 54,026 (“To best serve the President’s policy of improving our federal regulatory system . . . [OMB] now proposes to ensure that agencies conduct peer reviews of the most important scientific and technical information relevant to regulatory policies that they disseminate to the public, and that the peer reviews are reliable, independent, and transparent.”).

72. OMB, Revised Information Quality Bulletin on Peer Review, 69 Fed. Reg. 23,230 (Apr. 28, 2004) [hereinafter Revised Bulletin]. The OMB received 187 comments and participated in a public workshop at the National Academy of Sciences while also conducting an interagency review which led to substantial revisions from the proposed guidelines issued in September of 2003. *Id.* The summary of

providing a more detailed explanation of why peer review guidance is needed,<sup>73</sup> (2) increased discretion for agencies to decide what method of peer review to employ,<sup>74</sup> (3) an exemption for time-sensitive regulatory information,<sup>75</sup> (4) clarification that no new litigation rights against federal agencies were created by the IQA,<sup>76</sup> (5) defining a more “transparent” process for public participation in the planning stages,<sup>77</sup> and (6) limiting the most rigorous form of peer review to only “highly influential scientific assessments.”<sup>78</sup>

With significantly fewer comments generated following the April 2004 guidelines,<sup>79</sup> the OMB issued its Final Information Quality Bulletin for Peer Review (“Final Bulletin”) on January 14, 2005.<sup>80</sup> Recognizing that many agencies have existing peer review requirements, the guidelines explain that the new regulations establish minimum standards for peer

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public comments compiled by OMB provides a succinct overview of the contested elements of the initial proposal, as well as the actions OMB took to address these concerns. Office of Mgmt. & Budget, Summary of Public and Agency Comments on Proposed Bulletin on Information Quality and Peer Review, Including Responses by OMB (Apr. 15, 2004), [http://www.whitehouse.gov/omb/inforeg/peer\\_review\\_comment.pdf](http://www.whitehouse.gov/omb/inforeg/peer_review_comment.pdf) [hereinafter Summary of Comments and OMB Responses].

73. Revised Bulletin, 69 Fed. Reg. at 23,232 (explaining the need for uniform standards of peer review in order to achieve consistency and transparency in agency decisionmaking).

74. Revised Bulletin, 69 Fed. Reg. at 23,234. The guidelines give agencies discretion to determine the timing and intensity of the peer review, whether to use individual letter reviews from several experts or a panel review, the scope of the review, the criteria for selecting peer reviewers, and the degree of public disclosure and participation. *Id.* Additionally, agencies are permitted to employ alternative procedures, provided they have been approved by the Office of Information and Regulatory Affairs (“OIRA”) Administrator as consistent with the goals of information quality. *Id.* at 23,237.

75. Revised Bulletin, 69 Fed. Reg. at 23,238 (“The Bulletin does not cover time-sensitive medical, health, and safety disseminations, or disseminations based primarily on data from a recent clinical trial that was adequately peer reviewed before the trial began.”). This exemption was eventually broadened such that it is no longer restricted to medical data from clinical trials that were subject to adequate peer review prior to the start of the trial, but this language is retained as an example. *See* Final Bulletin, 70 Fed. Reg. at 2677.

76. Revised Bulletin, 69 Fed. Reg. at 23,242 (“This Bulletin is . . . not intended to create any new right or benefit, substantive or procedural, enforceable at law or in equity, against the United States, its departments, agencies, or other entities, its officers or employees, or any other person.”).

77. Revised Bulletin, 69 Fed. Reg. at 23,241 (“Agencies shall establish a mechanism for allowing the public to comment on the adequacy of the peer review plans and designations . . . [and] must consider public comments on peer review plans.”).

78. Revised Bulletin, 69 Fed. Reg. at 23,240–23,241 (identifying the type of information which qualifies as a “highly influential scientific assessment” and explaining the more rigorous peer review requirements applicable to this type of information).

79. Fifty-seven comments were generated by the revised draft. Final Bulletin, 70 Fed. Reg. at 2664. To view the OMB’s response to these comments, see OMB’s Response to Comments on the Revised Peer-Review Bulletin (Dec. 15, 2004), [http://www.whitehouse.gov/omb/inforeg/peer2004/peer\\_response.pdf](http://www.whitehouse.gov/omb/inforeg/peer2004/peer_response.pdf).

80. The OMB explained that the final bulletin represents “minor revisions responsive to the public’s comments.” Final Bulletin, 70 Fed. Reg. at 2664.

review.<sup>81</sup> However, the Final Bulletin mandates that “important scientific information *shall* be peer reviewed” by qualified experts before the government disseminates this information.<sup>82</sup> Even more stringent peer review requirements are required for “highly influential scientific assessments.”<sup>83</sup> In addition to establishing deadlines by which agencies are to comply with the guidelines,<sup>84</sup> the Final Bulletin provides agencies with guidance as to the type of scientific information subject to review,<sup>85</sup> the type of people who can or should serve as peer reviewers,<sup>86</sup> and the various mechanisms by which review may be employed.<sup>87</sup>

The Final Bulletin generally requires agencies to ensure that all aspects of the peer review process are made available to the public including the peer reviewers’ names, reports, and agency response to the reports.<sup>88</sup> Potential peer reviewers must also meet certain credentials and requirements with an emphasis on utilizing individuals with relevant expertise while avoiding conflicts of interest.<sup>89</sup>

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81. Final Bulletin, 70 Fed. Reg. at 2666 (“This Bulletin establishes minimum standards for when peer review is required for scientific information and the types of peer review that should be considered by agencies in different circumstances.”).

82. Final Bulletin, 70 Fed. Reg. at 2665 (emphasis added). The Final Bulletin goes on to define scientific information as the “factual inputs, data, models, analyses, technical information, or scientific assessments based on the behavioral and social sciences, public health and medical sciences, life and earth sciences, engineering, or physical sciences.” *Id.* at 2675. For the OMB’s definition of “influential,” see Initial IQA Guidelines, 67 Fed. Reg. at 8560 (defining “influential” as “information that will have or does have a clear and substantial impact on important public policies or important private sector decisions”).

83. Final Bulletin, 70 Fed. Reg. at 2675. Regulatory information is subject to the additional requirements when the agency determines the information to be a scientific assessment that: “(i) could have a potential impact of more than \$500 million in any year, or, (ii) is novel, controversial, or precedent-setting or has significant interagency interest.” *Id.*

84. The Final Bulletin established two different deadlines by which the planning requirements of the Bulletin would go into effect. Final Bulletin, 70 Fed. Reg. at 2664. As in the Revised Bulletin, agencies had twelve months to implement peer review planning requirements for “influential scientific information.” *Id.* The Final Bulletin extended the deadline for “highly influential scientific assessments” from four months, Revised Bulletin, 69 Fed. Reg. at 23,238, to six months. Final Bulletin, 70 Fed. Reg. at 2664.

85. Final Bulletin, 70 Fed. Reg. at 2675–76 (defining “scientific information,” “influential scientific information,” and “scientific assessment”). The regulations go on to clarify the forms of information which will be subject to peer review requirements.

86. Final Bulletin, 70 Fed. Reg. at 2675 (emphasizing experience and independence as important criteria for selecting peer reviewers). The guidelines provide similar criteria for choosing peer reviewers of “highly influential scientific assessments.” *Id.* at 2676.

87. Final Bulletin, 70 Fed. Reg. at 2675–76 (listing factors to consider when choosing a particular peer review method while also providing agencies with the opportunity to implement “alternative procedures”).

88. Final Bulletin, 70 Fed. Reg. at 2675.

89. Final Bulletin, 70 Fed. Reg. at 2669 (indicating that while expertise is the “primary consideration,” diverse perspectives with respect to the topic at hand may result in a “sharper, more focused peer review”).



These guidelines will very likely create new duties for agencies as agencies are required to develop peer review agendas and make them available to the public.<sup>90</sup> These heightened requirements impose an additional procedural layer on agencies and raise questions about the legitimacy of such action.<sup>91</sup> One of the major concerns surrounding peer review is that it will further slow the already time-consuming regulatory process, resulting in agencies hesitant to even initiate a rulemaking process that will cost substantial time and resources.<sup>92</sup> Efficiency and accuracy are important goals of the administrative process but it is also important to ensure that agencies carry out the legislative intent of Congress. Arguably, peer review guidelines interfere with congressional directives that instruct agencies to act in a precautionary manner.<sup>93</sup>

### III. THE IMPLICATIONS OF PEER REVIEW FOR PRECAUTIONARY LEGISLATION

The IQA and its agency-wide mandate of peer review conflict with existing precautionary legislation. In passing the IQA, Congress authorized the OMB to ensure that a certain level of “integrity” was preserved in agency decisionmaking and the OMB has broadly interpreted

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90. Final Bulletin, 70 Fed. Reg. at 2672 (requiring agencies to “begin a systematic process of peer review planning for influential scientific information” and make these plans publicly available through a Web-accessible listing). For examples of peer review guidelines established by various agencies, see, e.g., U.S. Environmental Protection Agency, Peer Review Agenda, [http://cfpub.epa.gov/si/si\\_pr\\_agenda.cfm](http://cfpub.epa.gov/si/si_pr_agenda.cfm) (last visited Feb. 26, 2006); U.S. Department of Labor Occupational Safety and Health Administration, Peer Review Agenda, [http://www.osha.gov/dsg/peer\\_review/peer\\_agenda.html](http://www.osha.gov/dsg/peer_review/peer_agenda.html) (last visited Feb. 26, 2006).

91. It is important to distinguish the peer review guidelines from another proposed method of reform which relates to judicial review. This method would subject agency science to the same evidentiary standard that has been employed by courts since *Daubert v. Merrill Dow Pharm.*, 509 U.S. 579 (1993). For a discussion of this proposal, see generally Raul & Dwyer, *supra* note 30. See also Wagner, *supra* note 6, at 70.

92. See Noah, *supra* note 28, at 1069 (predicting that peer review process will lead to delays in rulemaking). Peer review is just one additional procedure that may create disincentives for issuing or revising rules. The judicial practice of “hard-look review” has been the subject of criticism for its potential to delay the rulemaking process. See generally Thomas McGarity, *Some Thoughts on “Deossifying” the Rulemaking Process*, 41 DUKE L.J. 1385 (1992); Mark Seidenfeld, *Bending the Rules: Flexible Regulation and Constraints on Agency Discretion*, 51 ADMIN. L. REV. 429, 455–58 (1999). But cf. William S. Jordan, III, *Ossification Revisited: Does Arbitrary and Capricious Review Significantly Interfere with Agency Ability to Achieve Regulatory Goals Through Informal Rulemaking?*, 94 NW. U. L. REV. 393, 444–45 (2000) (finding that hard-look review has not significantly interfered with the rulemaking process).

93. Many commentators have questioned the legality of OMB’s broad reading of the IQA. See generally McGarity et al., *supra* note 67 (criticizing OMB’s interpretation of the IQA). This, however, is not intended to be the focus of this Note. Instead, I specifically address how the peer review guidelines interfere with precautionary mandates.

this power.<sup>94</sup> While the impact of these recently promulgated guidelines is still largely speculative,<sup>95</sup> mandated peer review has the potential to greatly interfere with agency decisionmaking, specifically with respect to precautionary legislation.<sup>96</sup>

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94. While the peer review guidelines have been a topic of debate, the Information Quality Act as a whole has also been the subject of criticism. On July 20, 2005, the first hearing on the IQA was conducted before the subcommittee on Regulatory Affairs. *Improving Information Quality in the Federal Government Before the Government Reform Subcommittee on Regulatory Affairs*, 109th Cong., 7–11 (2005) [hereinafter *IQA Hearings*] (testimony of Sidney Shapiro, Scholar Center for Progressive Reform). In his comments, Shapiro explained how petitioners have used the IQA to bypass Freedom of Information Act (FOIA) procedures in order to access data. *Id.* at 7. He also provides an example of industry exploiting an agency's failure to abide by IQA procedures, regardless of the alternative procedures to which various studies may have been subjected. *Id.* at 9. In this way, industries have been able to successfully delay agency rulings by initiating a separate challenge to agency action by way of the IQA. *Id.* Shapiro then argues that while there is no evidence that Congress intended the IQA to establish substantive legal standards, petitioners have succeeded in effectively imposing such standards by bringing IQA challenges. *Id.* at 9. Lastly, Shapiro argues that regulatory challenges have been brought under the IQA instead of, or in addition to, the procedures already provided by the administrative system resulting in increased delays. *Id.* at 11. *See also* Urs Gasser, *Information Quality and the Law, or, How to Catch a Difficult Horse*, in INFORMATION QUALITY REGULATION: FOUNDATIONS, PERSPECTIVES, AND APPLICATIONS, 213–45 (Urs Gasser ed., 2004), available at <http://cyber.law.harvard.edu/home/2003-08> (classifying OMB's interpretation of "information" as broad); McGarity et al., *supra* note 67 (questioning OMB's interpretation of the IQA); Sidney A. Shapiro, *OMB's Dubious Peer Review Procedures*, 34 ENVTL. L. REP. (ENVTL. L. INST.) 10064 (2004) (questioning OMB's authority to require peer review).

95. Agencies have had time however, to gain experience with other requirements of the IQA. The initial guidance regarding implementation of the IQA was issued by the OMB in February 2002. In these guidelines, the OMB defined the terms of the IQA and directed agencies to create their own information quality guidelines. Final IQA Guidelines, *supra* note 23, 67 Fed. Reg. at 8452. *See, e.g.*, Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency, Oct. 2002, [http://www.epa.gov/quality/informationguidelines/documents/EPA\\_InfoQualityGuidelines.pdf](http://www.epa.gov/quality/informationguidelines/documents/EPA_InfoQualityGuidelines.pdf); Department of the Interior Information Quality Guidelines Pursuant to Section 515 of the Treasury and General Government Appropriations Act for Fiscal Year 2001, <http://www.doi.gov/ocio/guidelines/515Guides.pdf>. The actual number of requests generated by the IQA is in dispute. In a Fiscal Year 2003 report to Congress, the OMB identified the number of correction requests to be "about 35." OMB, *Information Quality: A Report to Congress, Fiscal Year 2003*, 8, available at [http://www.whitehouse.gov/omb/infoereg/fy03\\_info\\_quality\\_rpt.pdf](http://www.whitehouse.gov/omb/infoereg/fy03_info_quality_rpt.pdf). Another group, however, found that the number of substantive IQA requests was actually much closer to 100. OMBWatch, *The Reality of the Information Quality Act's First Year: A Correction of OMB's Report to Congress* (July 2004) DQ-5. Under either interpretation, the EPA has received a disproportionate number of requests. EPA, *Information Quality Guidelines—Requests for Correction (RFC) and Requests for Reconsideration (RFR) Submitted to EPA*, <http://www.epa.gov/quality/informationguidelines/iqg-list.html> (documenting over thirty-five IQA requests).

96. *See* Salzman & Ruhl, *supra* note 28, at 40 (identifying the potential to delay regulatory decisionmaking as one of three major critiques lodged against the peer review guidelines). For example, when Congress has allowed an agency such as the EPA to categorize a substance as hazardous under the Resource Conservation and Recovery Act, the scientific evidence need only show that a particular solid waste "may cause or significantly contribute to" an increase in mortality or serious illness. RCRA § 1004(5), 42 U.S.C. § 6903(5) (2000). Inserting a requirement of peer review into this process could force agencies to delay this classification until peer review is completed. *See also* Wagner, *supra* note 6, at 100–02 (discussing other components of the IQA that may interfere with statutory mandates).

As discussed in Part I, the United States Code is replete with examples of precautionary legislation, specifically where public health and safety are concerned.<sup>97</sup> It is important that agencies make regulatory decisions based on the best science possible, but where Congress has directed agencies to act in a precautionary manner, Congress manifested an intent to regulate even in the face of uncertainty.<sup>98</sup> This suggests that Congress was less concerned about the consequences of dealing with regulation that might prove to be unnecessary than about the potential consequences of inaction. From this, it follows that where safety and public health are of primary concern, timely promulgation is also desired.

It is not clear that the IQA peer review guidelines *directly* interfere with the legislative intent of precautionary legislation. Precautionary statutes typically authorize a lower burden of scientific proof, enabling agencies to make decisions based on even a small bit of evidence that a particular harm may result.<sup>99</sup> Peer review does not raise this burden or require agencies to engage in *more* scientific research.<sup>100</sup> Instead, the guidelines mandate that the studies used be subjected to external review so that inconsistencies or uncertainties can be exposed.<sup>101</sup> Those who support peer review have suggested that it could actually improve agency

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97. See, e.g., RCRA § 3004(e)(1), 42 U.S.C. § 6924(e)(1) (2000) (precluding the Administrator from finding a method of land disposal protective of human health and the environment “unless . . . it has been demonstrated to the Administrator, to a *reasonable degree of certainty*, that there will be no migration of hazardous constituents from the disposal unit or injection zone for as long as the wastes remain hazardous”) (emphasis added); Safe Drinking Water Act, 42 U.S.C. § 300g-1(b)(1)(A)(i)-(iii) (2000) (authorizing regulation of contaminants where EPA has found such contaminants “*may* have an adverse effect on the health of persons”) (emphasis added). See also *supra* text accompanying notes 48–52.

98. See *supra* note 52.

99. See Wagner, *supra* note 6, at 85 (“Most of the protective statutes were passed with the explicit purpose of by-passing heavy burdens of proof and allowing agencies to regulate on the basis of limited scientific evidence.”). Wagner goes on to provide an example of precautionary legislation implemented by the FDA. *Id.* at 85. This statute, known as the Delaney Clause, requires the FDA to ban a food or color additive where just a single study shows that this additive is cancerous to animals. 21 U.S.C. §§ 348(c)(3)(A), 379e(b)(5)(B) (2000).

100. In fact, in the scientific world, peer review is not intended to be a replication of results through independent research, but is instead meant to evaluate the methods employed by researchers. See Salzman & Ruhl, *supra* note 28, at 13. Salzman and Ruhl identify ten factors which the scientific journal *Ecology* has advised reviewers to address when conducting peer review: “(1) importance and interest to this journal’s readers; (2) scientific soundness; (3) originality; (4) degree to which conclusions are supported; (5) organization and clarity; (6) cohesiveness of argument; (7) length relative to information content; (8) whether material should be moved to the digital appendices; (9) conciseness and writing style; and (10) appropriateness for the targeted journal and specific section of the journal.” *Id.*

101. Final Bulletin, 70 Fed. Reg. at 2665. (explaining that peer review “can filter out biases and identify oversights, omissions, and inconsistencies,” and “also may encourage authors to more fully acknowledge limitations and uncertainties”).

efficiency by reducing the likelihood of subsequent legal challenges.<sup>102</sup> While the OMB may use this argument in an effort to deflect criticism, it is far too speculative to sufficiently address concerns.

Moreover, subjecting agencies to these additional requirements may serve to *indirectly* slow the regulatory process. Initially, government regulators will have to direct their attention to implementing a “peer review plan.”<sup>103</sup> Even the OMB acknowledged that this would be a time-consuming process, and in the Final Bulletin the deadline by which agencies must meet planning requirements for “highly influential scientific assessments” was extended to accommodate these concerns.<sup>104</sup> Additionally, redirecting agency resources could slow down the implementation of other regulations.<sup>105</sup> Moreover, a peer review is only deemed completed once the agency has considered and addressed the comments of the reviewers, extending the process even further.<sup>106</sup> While many factors may contribute to an agency being forced to redirect resources, it is problematic when this directive comes not from Congress, or even the agency itself, but instead from a separate agency.<sup>107</sup>

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102. The OMB provides a cost-benefit analysis to explain that delays incurred as a result of developing peer review panels may be outweighed by the potential benefits of more stable decisions. *See* Summary of Comments and OMB Responses, at 13 (“[A] study may reduce the probability that the policy is reversed or may lead to creative policy innovations that increase benefits and/or reduce costs.”).

103. Final Bulletin, 70 Fed. Reg. at 2676. The guidelines require agencies to post agendas of peer review plans and describe the components that must be included in each plan. For example, agencies must identify whether the dissemination is influential or highly influential, the method that will be used to conduct the review, and the way in which reviewers will be selected. *Id.*

104. Final Bulletin, 70 Fed. Reg. at 2664. Under the guidelines implemented in April 2004, the planning requirements for highly influential scientific assessments were to go into effect four months after publication of the final guidelines, while planning requirements for influential scientific information would go into effect one year after publication. Revised Bulletin, 69 Fed. Reg. at 23,238. The Final Bulletin extended the former deadline to six months, but kept the one year deadline for influential scientific information. Final Bulletin, 70 Fed. Reg. at 2664.

105. In fact, on January 7, 2004, a letter signed by twenty former agency officials was sent to the OMB, arguing that the peer review proposal would result in “increased costs and delays in disseminating information to the public and in promulgating health, safety, and environmental and other regulations.” Letter from Carol M. Browner et al., Former Administrator, Environmental Protection Agency, to Joshua B. Bolten, Director of Office of Management and Budget (Jan. 9, 2004) (on file with author), available at [http://www.progressiveregulation.org/articles/Letter\\_Bolten\\_Sig.pdf](http://www.progressiveregulation.org/articles/Letter_Bolten_Sig.pdf).

106. Final Bulletin, 70 Fed. Reg. at 2670 (“A peer review is considered completed once the agency considers and addresses the reviewers’ comments.”).

107. Further evidence that regulatory peer review lacked full congressional support is provided by the fact that efforts to pass a bill requiring such across-the-board mandates failed in the late 1990s. *See, e.g.,* Regulatory Improvement Act of 1999, S. 746, 106th Cong. (1999); Science Integrity Act, H.R. 574, 106th Cong. (1999) (bill would require “peer review of scientific data used in support of Federal regulations, and for other purposes”).

Additionally, agencies may be forced to subject studies to peer review before using these studies to make decisions.<sup>108</sup> Alternatively, agencies may choose to refrain from utilizing this information entirely, in the hopes of avoiding potential IQA challenges.<sup>109</sup> In fact, the EPA has already fielded IQA challenges that have attacked agency decisions in part because of inadequate peer review.<sup>110</sup> The OMB purports to give agencies discretion to choose an adequate peer review mechanism considering a variety of factors, including “the extent of prior reviews.”<sup>111</sup> However, the OMB goes on to qualify this otherwise broad agency discretion by pointing out that an agency may find itself in circumstances that require “a more rigorous or transparent review process.”<sup>112</sup> Such language makes an agency susceptible to challenges on the basis of its decision to determine that a particular study is valid, in addition to challenging the science itself.<sup>113</sup>

Those who support peer review expect this additional layer of review to strengthen regulatory decisions by reducing the appearance of conflict of interest.<sup>114</sup> These advocates argue that those who work in agencies have inherent biases that show forth in certain regulations, and peer review will allow unbiased scientists to evaluate the data and make sure decisions are

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108. See, e.g., Letter from Wood Preservative Science Council (WPSC) to EPA Information Quality Guidelines Staff, 6 (Oct. 17, 2005) [hereinafter October Letter from WPSC], available at <http://www.epa.gov/quality/informationguidelines/documents/06001.pdf> (arguing that, unless or until peer review is conducted of EPA study evaluating safety and efficacy of wood treatment coatings, the study “should not be cited or relied upon”).

109. Wagner, *supra* note 6, at 100 (“To the extent that Congress explicitly requires EPA to consider all ‘available information’ in promulgating protective standards, the exclusion of studies under the good-science reforms conflicts with EPA’s mandate.”).

110. See, e.g., Letter from WPSC to EPA Information Quality Guidelines Staff (Sept. 2, 2005), available at <http://www.epa.gov/quality/informationguidelines/documents/05007.pdf> (criticizing lack of external peer review of EPA documents related to cancer risks of inorganic arsenic); October Letter from WPSC; CRE Petition filed with EPA re: Diisononyl Phthalate, 2–3 (Oct. 16, 2003), available at <http://www.epa.gov/quality/informationguidelines/documents/13166rfc.pdf> (referencing OMB peer review guidelines and requesting external peer review of information underlying proposed Toxics Release Inventory listing).

111. Final Bulletin, 70 Fed. Reg. at 2671. Other factors to which agencies are directed to give “due consideration” include the novelty and complexity of the particular study, the impact of the study on decisionmaking, and the costs and benefits of conducting additional review. *Id.*

112. Final Bulletin, 70 Fed. Reg. at 2671.

113. It is true that the OMB has established that the peer review guidelines do not create any additional enforcement mechanism. However, this has not stopped those opposed to certain regulations from submitting challenges to agencies, and while agencies may technically be able to ignore such challenges, it would be a politically destructive route and few administrative bodies would be willing to wait and see what consequences would result from such action.

114. Proposed Bulletin, 68 Fed. Reg. at 54025 (“Evaluation by external reviewers thus can enhance the credibility of the peer review process by avoiding both the reality and the appearance of conflict of interest.”).

still sufficiently “sound.”<sup>115</sup> However, it is more likely the case that exploiting these unavoidable scientific uncertainties<sup>116</sup> will serve to undermine regulations which, despite inconclusive evidence, may still be warranted.<sup>117</sup>

OMB also attempts to counter suggestions that the guidelines will slow the promulgation of regulation by explaining that peer review is meant to be conducted early in the process and in this way will not interfere with the timely promulgation of decisions.<sup>118</sup> However, agencies may be slowed down by lengthy peer review that may not be initiated until later in the regulatory process.<sup>119</sup> The guidelines concede that adding review at this juncture could have very little impact on the rulemaking process.<sup>120</sup> This would essentially render the review an unnecessary expenditure of agency time and resources.<sup>121</sup>

The consequences of foregoing such review remain unclear, but give rise to several troubling implications: first, it will increase the chance that the new regulation will be subjected to legislative challenges, which would slow implementation to a greater degree;<sup>122</sup> second, by requiring annual reports on peer review, the OMB is able to keep close tabs on agency compliance (or lack thereof) with the guidelines.<sup>123</sup> In its “Response to Comments on the Revised Peer-Review Bulletin” the OMB countered concerns that the Bulletin lacked an enforcement mechanism by emphasizing the annual reporting requirement and the ability of the public to monitor agency activities through the peer-review planning process.<sup>124</sup>

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115. See Salzman & Ruhl, *supra* note 28, at 13 (explaining personal bias may play role in altering neutrality of agency scientists focused on furthering a specific statutory mission).

116. See Doremus, *supra* note 12.

117. EPA’s arsenic standard, discussed *supra* note 39, provides an example where a particular administrative action turned out to be justified despite initial uncertainties.

118. Summary of Comments and OMB Responses, at 12 (“Even a lengthy peer review would not necessarily delay an agency action if the review is conducted on a parallel track with other work of the agency on that action.”).

119. Summary of Comments and OMB Responses, at 12 (recognizing that “delay in government decision-making . . . can result from peer review”).

120. Final Bulletin, 70 Fed. Reg. at 2668 (“If review occurs too late, it is unlikely to contribute to the course of a rulemaking.”).

121. The OMB has conceded this as well, recognizing that “if a policy or regulation is delayed and the peer review does not lead to changes in the policy or regulation, then the benefits . . . could be delayed.” Summary of Comments and OMB Responses, at 12.

122. Summary of Comments and OMB Responses, at 12. These concerns are analogous to those raised with respect to “hard-look” review of agency decisions. As more and more factors can be considered under judicial review, agencies will spend more and more time making sure each of these factors have been addressed. See *supra* note 38.

123. Final Bulletin, 70 Fed. Reg. at 2677 (“Each agency shall provide to OIRA, by December 15 of each year, a summary of the peer reviews conducted by the agency during the fiscal year.”).

124. OMB’s Response to Comments on the Revised Peer-Review Bulletin, 3 (Dec. 15, 2004),

The OMB suggested that those who are dissatisfied with an agency's peer review mechanisms can utilize these tools to alert policy officials in the agency.<sup>125</sup> While the OMB is vague about what consequences might result, decisions to forego peer review requirements could be a risky venture from an agency perspective.

The guidelines carefully establish that in making decisions regarding the dissemination of information, "agencies are not expected to cede their discretion . . . to peer reviewers."<sup>126</sup> Instead, the results of peer review are simply intended to be another factor in the decision of whether to disseminate information.<sup>127</sup> However, while agencies may not be handing over their decision-making power to outside peer reviewers, the guidelines may indirectly alter the ability of an agency to implement statutory mandates with a precautionary goal. By requiring agencies to engage in this additional procedural step before relying on certain information in making regulatory or policy decisions, the OMB has arguably removed some degree of agency discretion.<sup>128</sup> For example, a request for correction was recently filed challenging many perceived deficiencies in an EPA study, naming the lack of peer review as one such deficiency.<sup>129</sup> The EPA must handle this correction request before proceeding,<sup>130</sup> and if the agency determines that peer review is required, it could be months before the EPA is able to take action in reliance on this study.<sup>131</sup>

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[http://www.whitehouse.gov/omb/inforeg/peer2004/peer\\_response.pdf](http://www.whitehouse.gov/omb/inforeg/peer2004/peer_response.pdf).

125. *Id.* ("If the public and/or OMB are not satisfied with agency compliance under the Bulletin, they can raise these concerns with policy officials in the agency.")

126. Final Bulletin, 70 Fed. Reg. at 2666.

127. *Id.* ("Peer review reports are an important factor in information dissemination decisions but rarely . . . the sole consideration."). In supporting this assertion, the OMB analogizes the role of an agency official to the role of the editor of a scientific journal in that both consider peer review in making decisions, but the final decision must be made by the agency official or editor—an individual who can be held accountable. *Id.*

128. Final Bulletin, 70 Fed. Reg. at 2667.

129. See October Letter from WPSC, *supra* note 108. The study in question was conducted to evaluate the effectiveness of various coatings in preventing the release of toxic chemicals from treated wood. This request was filed on behalf of the WPSC, a trade association of manufacturers of wood preservatives often used in this treatment process. *Id.*

130. WPSC acknowledged that this study would likely be used by the EPA to regulate the use and maintenance of wood-treated products in the home and recreational areas such as parks and playgrounds. *Id.* at 2. Regardless of whether the EPA determines that corrective action is necessary, the agency must at least address the request and provide notice of its decision. See Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency, Oct. 2002, [http://www.epa.gov/quality/information\\_guidelines/documents/EPA\\_InfoQualityGuidelines.pdf](http://www.epa.gov/quality/information_guidelines/documents/EPA_InfoQualityGuidelines.pdf).

131. However, it appears that little in the regulations would prevent an agency from making a policy-based decision at this point, as long as the agency provided a reasoned explanation of its particular policy choice. For an interesting discussion on how the peer review regulations could help agencies better distinguish between policy and science decisions, see Salzman & Ruhl, *supra* note 28,

By carefully excluding an enforcement mechanism and articulating the desire to keep policy decisions within the hands of agencies, the peer review guidelines superficially appear to avoid interfering with statutory mandates. With no explicit consequences for failure to comply, it is hard to accuse the OMB of creating situations which will slow regulations. However, for those in favor of deregulation, it will likely prove to be an effective tool in obstructing the purposes behind precautionary statutes. Attacking an agency's inadequate peer review will simply become another weapon against regulatory actions, and agencies have already been forced to respond.<sup>132</sup> Where peer review slows the regulatory process of implementing regulations intended to have a precautionary purpose it violates statutory mandates of Congress.<sup>133</sup>

#### IV. AMENDING THE IQA

By mandating a certain level of review and research before allowing agencies to rely on certain studies, the peer review guidelines delay the point at which regulations based on these studies can be promulgated and thereby interfere with agency decision-making.<sup>134</sup> In this way, the OMB

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at 46 (explaining that by highlighting areas not supported by science, peer review could force agencies to identify the nonscientific factors that support policy decisions). *But cf.* Wagner, *supra* note 7, at 1700 (arguing peer review may actually enable agencies to mask policy decisions as scientific determinations, making it more difficult for the public to participate in the process while leaving important decisions in the hands of unaccountable scientists).

132. In a recent data quality challenge to the diesel particulate standard promulgated by the Mine Safety and Health Administration (MSHA), the lack of peer review was cited as one of the reasons why the agency's rule was inadequate. Letter from Patton Boggs LLP to Elaine Chao, U.S. Dep't of Labor (Aug. 10, 2005), available at <http://www.dol.gov/cio/programs/infoguidelines/> (requires authorization). Less than a month later, while not directly responding to this data request, MSHA published a modification of the original rule and proposed to phase in the new standard rather than require compliance by January 2006. Diesel Particulate Matter Exposure of Underground Metal and Nonmetal Mines, 70 Fed. Reg. 53,280 (Sept. 5, 2005).

133. The fact that only a few agencies have deemed it necessary to adopt peer review policies, and that they have done so only in limited situations, suggests that such a broad mandate is unnecessary. See Salzman & Ruhl, *supra* note 28, at 19 (citing policy of Fish & Wildlife Service to use peer review when making endangered species-listing decisions as one of the few examples of regulatory peer review).

134. See Marcilynn A. Burke, *Klamath Farmers and Cappuccino Cowboys: The Rhetoric of the Endangered Species Act and Why It (Still) Matters*, 14 DUKE ENVTL. L. & POL'Y F. 441, 508-09 (outlining how the guidelines have allowed the OMB to exert control over agency procedures and "advance a subversive, deregulatory agenda"); Rick Weiss, *Peer Review Plan Draws Criticism*, WASH. POST, Jan. 15, 2004, at A19 (characterizing opponents' view of peer review guidelines as government effort "to inject White House politics into the world of science and to use the uncertainty that surrounds science to delay new rules that could cost regulated industries millions of dollars"). The OMB peer review guidelines provide just one example of the Administration's efforts to resort to science as the basis for delaying regulations. For another example, see *supra* note 39.



has assumed a legislative power that Congress never clearly provided it through the IQA.<sup>135</sup>

Agencies should be left to employ the precautionary principle where Congress has authorized action despite the absence of complete scientific certainty.<sup>136</sup> The requirements of the Administrative Procedure Act (“APA”) and availability of judicial review of agency action provide safeguards to ensure that agencies make reasoned decisions.<sup>137</sup> While commentators have suggested that the peer review guidelines will force agencies to distinguish between decisions based on policy and those based on science,<sup>138</sup> rather than subject agencies to a review process that will slow the promulgation of regulations, in the face of scientific uncertainty, agencies should be left to make the decision of whether to employ a precautionary approach and regulate, or wait for the scientific evidence to confirm or refute concerns.<sup>139</sup>

If Congress decides that peer review is appropriate, these mandates should be implemented by way of legislative changes. Several examples exist where Congress has specifically called for peer review,<sup>140</sup> and such

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135. See McGarity et al., *supra* note 67, at 2 (“Even though the only explicit congressional directive was a mandate to issue guidelines on agency implementation of data correction procedures, OMB read these ministerial responsibilities extremely broadly . . . .”). In his testimony before the Subcommittee on Regulatory Affairs, Sidney Shapiro similarly questioned the OMB’s broad interpretation of a statute which had such “suspicious origins.” See *IQA Hearings*, *supra* note 94, at 13 (testimony of Sidney Shapiro).

136. See, e.g., *supra* notes 48–52. For example, the Endangered Species Act authorizes the Fish and Wildlife Service to base its decisions on “the best scientific and commercial data available,” 16 U.S.C. § 1536(c) (2000), ensuring that the agency will act on the basis of sound scientific information while leaving room for the agency to act in the absence of complete certainty.

137. Administrative Procedure Act (APA), 5 U.S.C. § 551 (2000). The APA explicitly allows for courts to overturn agency decisions that are “arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.” 5 U.S.C. § 706(2)(A) (2000). Agencies must also provide an opportunity for the public to comment on these rules and the final rule must include a response to these comments. *Id.* Courts also play an oversight role in the administrative process, by reviewing challenges to agency decisions to ensure that there is a “rational connection between the facts found and the choice made.” *Motor Vehicle Mfrs. Ass’n of the U.S. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983) (citation omitted). See also *Wagner*, *supra* note 6, at 81–82 (asserting that the ever-present threat of court challenges deters agencies from committing significant scientific errors). *But see* *Salzman & Ruhl*, *supra* note 28, at 20 (suggesting that the requirements of the APA fail to address situations where agencies have attempted to “stretch the available science in support of its policy decision farther than is justified”).

138. *Salzman & Ruhl*, *supra* note 28, at 45 (“[R]egulatory peer review . . . would encourage agencies to provide sharper delineations between scientific and policy bases for decisions.”).

139. Moreover, it is unclear whether peer review will actually encourage agencies to be more forthcoming regarding policy-based decisions, or instead provide another way for lawmakers to mask policy with science. See *Wagner*, *supra* note 7, at 1700 (explaining various ways in which peer review can enable decision-makers to hide behind the science of a decision rather than acknowledge the underlying policy choices).

140. See, e.g., Clean Air Act, 42 U.S.C. § 7409(d) (2000) (establishing the Clean Air Scientific

decisions should remain in the hands of legislators.<sup>141</sup> In fact, before the IQA, efforts to pass legislation imposing broad peer review requirements repeatedly failed, and it hardly seems appropriate for the OMB to assume this role.<sup>142</sup>

The proposed amendments to the Endangered Species Act provide one example of legislative action that directly references the IQA.<sup>143</sup> These changes include specifically requiring compliance with the IQA guidelines while also instituting more formalized peer-review processes with respect to certain listing and habitat decisions.<sup>144</sup> At the time of submission, none of these proposals had managed to survive both houses of Congress, but if the procedures authorized under the IQA guidelines are subsequently approved, it will become difficult to argue that the legislative intent behind a precautionary statute is being contradicted.<sup>145</sup> Moreover, requiring Congress to look at how these peer review requirements will affect a

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Advisory Committee to review EPA's National Ambient Air Quality Standards under the Clean Air Act; Federal Fungicide, Insecticide, and Rodenticide Act, 7 U.S.C. § 136w(e) (2000) (mandating peer review of major scientific studies conducted by or for the EPA); Comprehensive Environmental Response, Compensation, and Liability Act, 42 U.S.C. § 9604(i)(13) (1994) ("All studies and results of research conducted under this subsection (other than health assessments) shall be reported or adopted only after appropriate peer review."). Several agencies have also established scientific advisory panels which review various aspects of agency decisionmaking. *See, e.g.*, 42 U.S.C. § 2039 (2000) (establishing advisory committee for Nuclear Regulatory Commission to review safety studies and license applications); 29 U.S.C. § 656 (2000) (establishing a National Advisory Committee on Occupational Safety and Health); 49 U.S.C. § 44912(c) (2000) (establishing a scientific advisory panel for the Federal Aviation Administration).

141. Several scholars have questioned the authority of the OMB to implement such broad guidelines. *See* McGarity et al., *supra* note 67, at 2–6 (questioning the dubious origins of the IQA and providing a historical look at the events leading up to its passage). *See also* Information Quality Hearings, *supra* note 94, at 13 (testimony of Sidney Shapiro).

142. *See, e.g.*, Regulatory Improvement Act of 1999, S. 746, 106th Cong. (1999); Science Integrity Act, H.R. 574, 106th Cong. (1999) (bill would require "peer review of scientific data used in support of Federal regulations, and for other purposes"). *See also* McGarity et al., *supra* note 67, at 10 ("The IQA says nothing about peer review, and efforts to impose such broad requirements across federal agencies have repeatedly failed in Congress throughout the last decade.").

143. The proposed changes have been aimed at improving the way federal agencies deal with scientific evidence in implementing the Act. *See* Burke, *supra* note 134, at 506–07.

144. Threatened and Endangered Species Recovery Act of 2005, H.R. 3824, 109th Cong. (2005) (directing the Secretary of the Interior to take necessary measures to ensure (1) compliance with the OMB guidelines implementing the IQA and (2) that the data consists of empirical information or that data has been subject to qualified peer review procedures). Earlier efforts at amending the bill failed to pass through both houses of Congress. *See, e.g.*, Endangered Species Data Quality Act of 2004, H.R. 1662, 108th Cong. (2004) (explicitly requiring compliance with the IQA); Sound Science for Endangered Species Act Planning Act of 2002, H.R. 4840, 107th Cong. (2002) (establishing a preference for peer reviewed data).

145. House Bill 3824 was referred to the Senate Committee on September 30, 2005. THOMAS (Library of Congress), <http://thomas.loc.gov/cgi-bin/bdquery/z?d109:h.r.03824>: (last visited Sept. 29, 2006).

particular statutory scheme will prevent broad application of peer review standards in situations where it will prove too burdensome.<sup>146</sup>

Alternatively, Congress could amend the IQA statute such that statutes with a precautionary purpose are not required to abide by these regulations. Much of the commentary in response to the IQA has expressed concern over its potential to impede an already overburdened regulatory process.<sup>147</sup> Agencies should again be given discretion to promulgate regulations without being hindered by unnecessary and unwarranted challenges.

At a minimum, the OMB regulations could be rewritten to extend an exemption to information that is used to promulgate regulations authorized by precautionary legislation. As it currently stands, the exemption is too narrow to sufficiently cover all precautionary regulations.<sup>148</sup> Moreover, the exemption itself constitutes a judgment call which could also become the subject of challenges and subsequent delay. By allowing agencies to clearly establish what sorts of regulations or statutes are considered “precautionary” such that they fall into this exemption, agencies would be able to act quickly on information that is relevant to these particular statutes. Furthermore, requiring agencies to identify statutes up front would eliminate any concerns that agencies will constantly avoid peer review requirements simply by citing the need to act in a precautionary manner.

Agencies have been entrusted to make policy choices for decades.<sup>149</sup> Under the APA, agencies are required to show a reasoned basis for

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146. Another alternative would be for Congress to propose a bill implementing peer review procedures which are similar or even identical to those put forth in the IQA guidelines. Open debate and committee discussions would allow lawmakers to address the implications of choosing to adopt or forgo an agency-wide mandate of peer review. While I still oppose adopting such a policy, at least by allowing members of Congress to engage in open debate about the concerns raised by such legislation, the resulting requirements would have more legitimacy than the current OMB-promulgated guidelines.

147. See Salzman & Ruhl, *supra* note 28, at 40 (citing the fear that peer review requirements will significantly delay regulatory requirements as a “major institutional critique of regulatory peer review”). Various aspects of the regulatory process have been cited as the source for slowing down the promulgation of regulation. For a discussion of how judicial “hard-look” review has contributed to the time-consuming nature of rulemaking, see Thomas McGarity, *The Courts and the Ossification of Rulemaking: A Response to Professor Seidenfeld*, 75 TEX. L. REV. 525 (1997).

148. See Final Bulletin, 70 Fed. Reg. at 2677 (limiting exemption to health or safety disseminations “where the agency determines that the dissemination is time-sensitive (e.g., findings based primarily on data from a recent clinical trial that was adequately peer reviewed before the trial began)”).

149. See Wagner, *supra* note 6 (recognizing that protective statutes allowed agencies to “regulate on the basis of limited scientific evidence”); Salzman & Ruhl, *supra* note 28, at 44 (recognizing that policy decisions are often made by regulatory agencies because “Congress rarely commands that an agency decision be based solely on scientific evidence conclusively proving the decision correct”).

decisions, and there are multiple safeguards in place to ensure this process is carried out.<sup>150</sup> Judicial review already provides a remedy to address arbitrary and capricious decisions, and this check on agency action has itself generated a great deal of criticism.<sup>151</sup> The rulemaking process is already incredibly time-consuming, and lawmakers should be focused on improving the efficiency of this process, rather than erecting more barriers. Where Congress has authorized an agency to act in a precautionary manner, it is inappropriate for any other branch of government to prevent implementation of rules in accordance with this policy.<sup>152</sup>

### CONCLUSION

While it is difficult to fault a process that aims, at least superficially, to improve the interpretations of scientific data, the mandate of peer review raises some major policy concerns. Ideally, an external review will have the effect of bolstering agency claims because the science behind policy decisions will have more force.<sup>153</sup> But by highlighting areas where the science remains uncertain, peer review enables affected parties to exploit these uncertainties. Where Congress has authorized agencies to make decisions based on evidence which is less than conclusive—a common occurrence in the field of scientific research—these uncertainties should not be a bar to regulation. While the OMB empowers agencies to make their own decisions regardless of what the results of the peer review are, it may provide another tool by which those unhappy with the regulations are able to attack agency decisions.

The legislature should be responsible for authorizing the incorporation of peer review policies in various statutes. The OMB guidelines have the indirect effect of slowing regulations. Where Congress has expressly

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150. See *supra* note 137.

151. See McGarity, *supra* note 147.

152. It is true that the judiciary may also play a role in preventing implementation of certain administrative decisions. However, the role of judicial review is explicitly authorized by the APA. 5 U.S.C. §§ 701–706 (2000). This explicit authorization stands in stark contrast to the vague language of the IQA and the OMB’s broad interpretation of this language. Moreover, even with the explicit grant of judicial review, commentators have questioned the legitimacy of various forms of judicial review and suggested that it goes beyond the scope of review granted by the APA. For more discussion see Jordan *supra* note 92; Richard W. Murphy, *The Limits of Legislative Control Over the “Hard-Look,”* 56 ADMIN. L. REV. 1125 (2004); Jim Rossi, *Redeeming Judicial Review: The Hard Look Doctrine and Federal Regulatory Efforts to Restructure the Electric Utility Industry*, 1994 WIS. L. REV. 763, 768 (“Deliberative democratic theory provides a compelling normative argument in favor of [hard-look] judicial review as a protector of increased citizen participation and deliberative government.”).

153. OMB suggested this in both the preamble and in its responses to comments. See *supra* note 122.

authorized agencies to exercise an approach which is precautionary in nature, a separate agency should not be able to interfere with these policy concerns by imposing burdensome procedural mandates. As a result, agencies should only be forced to subject scientific information to peer review requirements when it is clear that this review will not interfere with the timely promulgation of regulations meant to protect public health, safety, and the environment.

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