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THE SCIENCE CHARADE IN TOXIC RISK REGULATION

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Science has been the thorn in the side of environmental policymakers since the dawn of environmental law.[1] Sound environmental policy cannot be developed without some scientific basis; yet attempts to incorporate science into environmental regulations have met with failure. Reduced public participation, excessive regulatory delays, and the incomplete and inaccurate incorporation of science have plagued science-based environmental regulation for nearly three decades.[2]

The first serious attempts to base environmental and public health policy on science began in the 1970s with a series of ambitious federal laws. In these statutes Congress directed that regulatory standards be based on levels determined by scientists to be protective of the public health or environment.[3] By 1987, however, less than fifteen percent of

1. See, e.g., Carl F. Cranor, Regulating Toxic Substances: A Philosophy of Science and the Law 11 (1993) ("Because our present lack of scientific knowledge will probably extend for some time into the future, we are condemned to assessing and regulating toxic substances 'through a glass darkly.' "); J.D. Nyhart & Milton M. Carrow, Introduction *in* Law and Science in Collaboration 1, 1 (J.D. Nyhart & Milton M. Carrow eds., 1983) ("One of the more elusive problems of our times is the development of effective decision-making processes of regulatory agencies and courts where science and technology issues must be resolved."); Examining the Role of Science in the Regulatory Process: A Roundtable Discussion About Science at EPA, Environment, June 1983, at 6 (statement of Alan McGowan, executive editor of *Environment*) (of great concern "is how one turns science into regulation, or how one turns what is known or not known in the scientific community into regulations that protect the health and safety of individuals and the environment").

2. Representative Charles Rangel (D-NY) and the Honorable Bella S. Abzug summarized this failure in explaining Congress's departure from a science-based approach to water pollution control. "[T]he history of our water pollution control program suggests that State and Federal governments will continue to founder on the staggering complexity of this control system, which requires working mathematically back from the permitted pollution levels in a waterway to the effluent limitations at the point source needed to achieve them." H.R. Rep. No. 911, 92nd Cong., 2d Sess. 396 (1972). See generally infra Part IV.

3. For a list of science-based mandates, see infra note 15.

the necessary standards had been promulgated under science-based statutory mandates,[4] and the development of even these few standards suffered from limited participation by the general public[5] and charges of scientific incompetence against the implementing agencies.[6]

With the agencies' failure inevitable under science-based mandates, Congress has begun to abandon attempts to base environmental standards on science.[7] In the reauthorization of several major environmental laws, acceptable levels of toxic pollutants[8] are determined

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4. The 15 percent calculation was reached by dividing the total number of science-based standards or regulatory actions under the Clean Air Act, the Safe Drinking Water Act, the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), the Toxic Substances Control Act (TSCA), and the Occupational Safety and Health Act, see infra notes 240–241, by the total number of toxic substances considered by the Office of Technology Assessment to be significant candidates for regulation. See Office of Technology Assessment, U.S. Congress, Identifying and Regulating Carcinogens: Background Paper 20 fig. 1.2 (1987) (listing number of Annual Report chemicals for which there has been "action" and "no action") [hereinafter OTA Paper].

5. See infra Part IV.A.

6. See infra Part IV.C.1.

7. In hoth the control of water and air toxics, Congress not only switched to a technology basis for initial toxics regulation, but expressly specified the initial list of toxic substances for which standards must be promulgated. See 33 U.S.C. § 1311(b)(2)(C)–(D) (1988) (referencing House Committee Report for list of 126 toxic substances for which technology-based standards must be promulgated); 42 U.S.C. § 7412(b) (Supp. V 1993) (list of 189 air toxins for which technology-based standards must be promulgated). Congress was again indicating that it did not have faith in the agency to make expedient scientific determinations in any phase of standard setting. See Oliver A. Houck, The Regulation of Toxic Pollutants Under the Clean Water Act, 21 Envtl. L. Rep. (Envtl. L. Inst.) 10,528, 10,537 (Sept. 1991).

The agencies have also attempted on at least two occasions to "convert" science-based statutory mandates into mandates that allow standards to be based instead on technology. The first instance occurred through a court-entered settlement under the water toxics provision of the Clean Water Act. See Ridgway M. Hall, Jr., The Evolution and Implementation of EPA's Regulatory Program to Control the Discharge of Toxic Pollutants to the Nation's Waters, 10 Nat. Resources Law. 507, 519–25 (1977). In a relatively recent regulation, the Environmental Protection Agency (EPA) interpreted a mandate under the Resource Conservation and Recovery Act (RCRA), 42 U.S.C. § 6924(m) (1988), requiring the promulgation of treatment standards for hazardous wastes disposed onto land as permitting a technology basis for regulation. See Hazardous Waste Management System: Land Disposal Restrictions, 55 Fed. Reg. 6640, 6640 (1990) (explaining technology basis for standards for hazardous waste land disposal is necessary "until [agency] . . . develops acceptably certain threshold concentration levels"). In affirming EPA's admittedly creative interpretation of what appeared to he a science-based regnlatory mandate, the D.C. Circuit Court stated: "EPA's catalog of the uncertainties inherent in the alternative approach using [health-based] screening levels supports the reasonableness of its reliance upon BDAT [Best Demonstrated Available Technology] instead." Hazardous Waste Treatnent Council v. EPA, 886 F.2d 355, 363 (D.C. Cir. 1989).

8. For purposes of this Article, the terms "toxic," "hazardous," and "toxin" refer to substances believed to be hazardous to health and the environment. Many of these "hazardous" substances have been specifically identified by EPA under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA). See 42 U.S.C. § 9601(14) (1988); 40 C.F.R. § 302.4 (1994).

by technological or economic feasibility,[9] without any preliminary scientific determination of what levels might be necessary to protect public health and the environment.[10] While this circumvention of science in contemporary toxics regulation is expedient,[11] scholars predict[12] and Congress has indicated[13] the need for a more finely calibrated, science-based approach to the regulation of toxics.

Despite growing pressure for an improved science-based regulatory system, however, surprisingly little effort has been dedicated to

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9. Standards based on technological or economic feasibility, as opposed to science, will hereinafter be referred to as "technology-based standards."

10. See infra note 303 and accompanying text.

11. These alternatives to science-based approaches have resulted, on average, in the promulgation of three times more final standards over the same length of time. See infra note 245.

12. See John S. Applegate, Worst Things First: Risk, Information, and Regulatory Structure in Toxic Substances Control, 9 Yale J. on Reg. 277, 315–16 (1992) (concluding that a significant flaw in technology-based approach is that "it is merely a surrogate, and not necessarily an accurate one, for the underlying trade-off of health *versus* cost") (footnotes omitted); Troyen A. Brennan, Environmental Torts, 46 Vand. L. Rev. 1, 35 (1993) (arguing that although technology-based approach leads to "manageable costs, . . . it does not provide 'an ample margin of safety' " and thus significant health problems resulting from exposure to toxics will persist); Houck, supra note 7, at 10,541 ("BAT [Best Available Technology] standards for toxic discharges, already limited in scope, are becoming obsolete."); id. at 10559–60 (discussing preferred alternative which sets a timetable for the elimination of toxic discharges); see also infra notes 308–313 and accompanying text; cf. John D. Graham et al., In Search of Safety: Chemicals and Cancer Risk 199 (1988) ("[S]cience plays a vital role in legitimizing protective regulation . . . . [W]ithout science there is no basis for regulation.").

13. Although enforceable toxic pollutant limits in the Clean Water and Clean Air Act are based on the best technology, Congress simultaneously instituted in both statutes a parallel system in which discharge and emission standards should ultimately be based on science. In the Clean Water Act, if the water quality is degraded below levels that have been set by the state, effluent limits for toxic water pollutants discharged into that degraded segment must be more stringent than the applicable technology limitation. See 33 U.S.C. §§ 1313(c)(2)(B), 1314(l) (1988). In attempting to impose a science-based backup system for the technology-based standards, Congress admitted that "[i]f we are going to repair the damage to those water bodies that have become highly degraded as a result to [sic] toxic substances we are going to have to move forward expeditiously on this beyond-BAT [best available technology] program." 2 Environment and Natural Resources Policy Division, Library of Congress, 100th Cong., 2d Sess., A Legislative History of the Water Quality Act of 1987, at 1309 (Comm. Print 1988). In the Clean Air Act, the EPA is directed to research and set more stringent, science-based standards for specific air toxics where such protection is needed. See 42 U.S.C. § 7412(f)(2)(A) (Supp. V 1993) ("Administrator shall . . . promulgate [more protective] standards . . . if promulgation of such standards is required in order to provide an ample margin of safety to protect public health in accordance with this section . . . or to prevent, taking into consideration costs, energy, safety, and other relevant factors, an adverse environmental effect."). Unfortunately, however, under both the Clean Water and Clean Air Acts this science-based backup system is difficult, if not impossible, to enforce. See infra note 303. Under the Safe Drinking Water Act, Congress has instituted parallel technology- and science-based standards, but the technology-based standards are only relied upon when compliance with the maximum contaminant level goals is not economically or technologically feasible. See 42 U.S.C. § 300g-1(b)(4) (1988).

determining why past science-based regulatory strategies have failed.[14] This Article squarely confronts this question by positing that these past failures are at least partly attributable to a pervasive "science charade," where agencies exaggerate the contributions made by science in setting toxic standards in order to avoid accountability for the underlying policy decisions. Although camouflaging controversial policy decisions as science assists the agency in evading various political, legal, and institutional forces, doing so ultimately delays and distorts the standard-setting mission, leaving in its wake a dysfunctional regulatory program.

The argument that a "science charade" pervades the regulatory process and impedes the ability of agencies to promulgate science-based toxic risk standards is developed in five parts. The complex mix of science and policy inherent in toxic risk questions is explored in Part I. While contemporary science can provide only partial answers to pressing environmental problems, this limitation is esoteric and often escapes the lay observer, leaving the capabilities of science susceptible to successful overstatement. In Part II, examples of the agencies' overreliance on, and at times deliberate exaggeration of, the role of science in setting toxic standards are introduced to show that a science charade has pervaded toxics regulation for several decades. In Part III, multiple, overlapping incentives that cause standard-setting agencies to engage in a science charade are identified, leaving little question that under the current system, exaggeration of the contributions of science constitutes administratively rational behavior. In Part IV, the practical consequences of the science charade are explored. These consequences range from administrative delays bordering on paralysis as experts debate incomplete science, to significant limitations on the ability of the public, the courts, and even public officials to participate in the policy choices embedded in scientific-sounding standards. Finally, a package of legal reforms is presented in Part V. Although not a complete cure, a legal remedy that requires agencies to separate science from policy and entrusts the courts with reviewing the accuracy of these science-policy delineations may be an effective means of combatting the charade.

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14. The literature on the nature and extent of scientific uncertainty in toxics regulation is extensive, see Alyson C. Flournoy, Legislating Inaction: Asking the Wrong Questions in Protective Environmental Decisionmaking, 15 Harv. Envtl. L. Rev. 327, 327 n.1 (listing books and articles on subject), and yet discussions of why these uncertainties adversely affect environmental policy are rare. The most significant works are: Committee on the Institutional Means for Assessment of Risks to Public Health, National Research Council, Risk Assessment in the Federal Government: Managing the Process (1983) [hereinafter NRC Risk Assessment]; Graham, supra note 12; Ted Greenwood, Knowledge and Discretion in Government Regulation (1984); Marc K. Landy et al., The Environmental Protection Agency: Asking the Wrong Questions (1990); Mark E. Rushefsky, Making Cancer Policy (1986); Flournoy, supra; Thomas O. McGarity, Substantive and Procedural Discretion in Administrative Resolution of Science Policy Questions: Regulating Carcinogens in EPA and OSHA, 67 Geo. L.J. 729 (1979).

I. THE SCIENCE-POLICY NATURE OF TOXIC RISK PROBLEMS

Any analysis of why attempts to incorporate science into toxics regulation have consistently failed first requires an in-depth examination of the nature of the toxic risk problems themselves. These problems can be resolved only incompletely by science, but the scientific limitations are generally identifiable only by experts. This combination of features presents unprecedented challenges to administrative decisionmaking.

A. *The Mixture of Science and Policy*

Science-based regulations are typically based on a vague statutory mandate that requires the agency to set standards or take action at the point at which a chemical substance "presents or will present an unreasonable risk of injury to health or the environment."[15] The initial step of translating "unreasonable risk" into a quantitative goal is often resolved with a single, express policy choice, such as a risk averse goal that no more than one in one million persons be adversely affected.[16] The second and final step—determining the concentration at which any particu-

15. Toxic Substances Control Act § 6(a), 15 U.S.C. § 2605(a) (1994); see also Federal Insecticide, Fungicide, and Rodenticide Act § 3(c)(5)(D), 7 U.S.C. § 136a(c)(5)(D) (1994) (prohibiting pesticides that "cause unreasonable adverse effects on the environment."); Clean Water Act § 303(c)(2)(A)-(B), 33 U.S.C. § 1313(c)(2)(A)-(B) (1988) (states' water quality standards must ensure that states' designated use of waters will be protected); Clean Water Act § 307(a)(1), 33 U.S.C. § 1317(a)(1) (1975) (amended 1977) (effluent level for toxic pollutants "shall take into account toxicity of the pollutant, its persistence, degradability, the usual or potential presence of the affected organisms . . . and the nature and extent of the effect of the toxic pollutant on such organisms"); Safe Drinking Water Act § 1412(b)(4), 42 U.S.C. § 300g-1(b)(4) (1988) (maximum drinking water contaminants are "set at the level at which no known or anticipated adverse effects on the health of persons occur and which allows an adequate margin of safety"); Clean Air Act § 109(b)(1), 42 U.S.C. § 7409(b)(1) (1988) (standards for commonplace "criteria" air pollutants must "allow[ ] an adequate margin of safety . . . requisite to protect the public health"); Clean Air Act § 112(a)(1), 42 U.S.C. § 7412(a)(1) (1988) (amended 1990) (standards for toxic air pollutants should be set at levels lower than "may reasonably he anticipated to result in an increase in mortality or an increase in serious irreversible, or incapacitating reversible, illness"); Comprehensive Environmental Response, Compensation, and Liability Act § 121(b)(1), 42 U.S.C. § 9621(b)(1) (1988) ("The President shall select a remedial action that is protective of human health and the environment . . . ."); cf. Occupational Safety and Health Act § 6(b)(5), 29 U.S.C. § 655(b)(5) (1988) (permanent standards for toxics should be set at a level "which most adequately assures, to the extent feasible . . . that no employee will suffer material impairment of health or functional capacity"); Resource Conservation and Recovery Act § 3004(m), 42 U.S.C. § 6924(m)(1) (1988) (standards for treatment of hazardous wastes disposed onto land shall "substantially diminish the toxicity of the waste or substantially reduce the likelihood of migration of hazardous constituents from the waste so that short-term and long-term threats to human health and the environment are minimized"). For a more extended discussion of the science-based mandates under the Clean Air Act and TSCA, see Flournoy, supra note 14, at 338–46.

16. See Flournoy, supra note 14, at 347 (noting that phrases such as "unreasonable risk" or "adequate margin of safety" in science-based mandates are vague and often involve a value judgment as to socially acceptable level of harm).

lar toxic substance actually poses a predetermined quantitative heath risk[17]—requires a more extended inquiry and presents several significant challenges. These difficulties and their implications for policymaking are considered below.

1. *Limits of Science.* — First, and despite appearances to the contrary, contemporary science is incapable of completely resolving the level at which a chemical will pose some specified, quantitative risk to humans.[18] In assessing the health risks of formaldehyde, for example, scientific experimentation can establish the effects of high doses of formaldehyde on the total number of nasal tumors in laboratory mice, but quantification of the effects of low doses on humans currently lies beyond the reach of science.[19]

Nuclear physicist Alvin Weinberg first identified these gaps in knowledge as "trans-science"—"questions which can be asked of science and yet which *cannot be answered by science.*"[20] In contrast to the uncertainty that is characteristic of all of science, in which "the answer" is accompanied by some level of unpreventable statistical noise or uncertainty,[21] trans-scien-

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17. The extent to which various physical symptoms actually constitute an adverse health effect is generally included in the second step since it involves the mixing of policy and science. See generally R. Shep Melnick, Regulation and the Courts: The Case of the Clean Air Act 247–49 (1983) (discussing four types of policy choices that define acceptable risk but that have scientific dimensions). Differing standards of proof required of agencies under various toxic regulatory statutes will obviously present greater or lesser burdens. See Flournoy, supra note 14, at 348–51.

18. See, e.g., NRC Risk Assessment, supra note 14, at 11 ("Because our [scientific] knowledge is limited, conclusive direct evidence of a threat to human health is rare."). For an overview of the major scientific uncertainties that typically occur during the standard-setting process, see Giandomenico Majone, Science and Trans-Science in Standard Setting, Sci., Tech., & Hum. Values, Winter 1984, at 15, 17 (concluding that uncertainties "exemplif[y] how, in standard setting, 'regulatory judgment' is as important as 'engineering judgment' ").

19. See Graham et al., supra note 12, at 46–47 (noting that because "existing state of theoretical and empirical work on chemical carcinogenesis" is incomplete, "[s]cientists debating the question whether there 'is' a threshold for formaldehyde in rodents are actually addressing the mixed science-policy question whether . . . formaldehyde ought to be treated for regulatory purposes *as if* it exhibited such a threshold in humans"); NRC Risk Assessment, supra note 14, at 25–27 (discussing the difficulty of using current methods in animal-to-human dose extrapolations).

20. Alvin M. Weinberg, Science and Trans-Science, 10 Minerva 209, 209 (1972). As Dr. Weinberg points out, it is not that scientists have not tried to answer trans-scientific questions, or even that they have not been given the funds to answer these questions, it is simply that science can only go so far in answering them. See id.

21. Scholars in science and the philosophy of science agree that contemporary science cannot resolve *any* problem completely. See, e.g., Thomas S. Kuhn, The Structure of Scientific Revolutions 94 (1970) ("[T]here is no standard higher [for scientific truth] than the assent of the relevant community."). Despite this lack of an underlying "truth" in scientific conclusions, there is virtual unanimity that the scientific process does assist in determining truth by sorting out some "falsehoods" through testing and through the replication of tests. "Science" thus consists of the development of a hypothesis, the testing of the hypothesis, and the validation of the results. See Committee on Science and Creationism, National Acad. of Sci., Science and Creationism: A View from the National

tific questions are uncertain because scientists cannot even perform the experiments to test the hypotheses.[22] This can be due to a variety of tech-

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Academy of Sciences 8–9 (1984); Karl. L. Popper, The Logic of Scientific Discovery 40–41 (Routledge 1992) (1959); cf. Daubert v. Merrell Dow Pharmaceuticals, Inc., 113 S. Ct. 2786, 2795–96 (1993) (noting that " 'scientific' implies a grounding in the methods and procedures of science"; in determining admissibility of scientific evidence, critical factor is whether evidence can be validated through scientific method).

Fortunately, the epistemological question of the truth value of science is not an obstacle to the current distinction between "science" and "trans-science." Questions that can currently be resolved using the scientific method, such as the statistical incidence of liver tumors in a species of rat exposed to a high level of a specified organic chemical, are identified as "science" questions. Questions that scientists uniformly agree *cannot* currently be answered by experimentation and instead must be based exclusively or primarily on untested inferences are identified for purposes of this Article as "trans-science" questions.

22. See McGarity, supra note 14, at 734. Trans-science thus can be placed on the end of a spectrum, with mechanistic science on the other end. Mechanistic science is characterized by almost universal agreement among scientists on certain theories, such as the rate of acceleration of falling objects on earth. The hypotheses are well established, the tests have been run thousands of times, and the interpretation of the data is generally noncontroversial. See Bert Black et al., Science and the Law in the Wake of *Daubert*: A New Search for Scientific Knowledge, 72 Tex. L. Rev. 715, 764 (1994) (stating that the molecular composition of matter and the evolution of organisms are now said to be facts). "Because this kind of question is by definition uncontroversial, it is rarely litigated in an administrative proceeding and is therefore of little importance to an analysis of how agencies resolve science policy issues." McGarity, supra note 14, at 747.

In the middle of the scientific spectrum is scientific judgment. Two scientists may dispute the proper methodology or the proper interpretation of the same data, but their dispute is based on differences in scientific judgment, which are in turn grounded primarily in each scientist's unique scientific experience. See id. at 741–42.

Trans-science is distinguished from scientific judgment primarily by the fact that in trans-science one of two conditions is met: 1) scientists would ultimately agree that selection of the most appropriate hypothesis among a range of possible alternatives is based not on data or scientific experimentation, but instead on nonscientific factors; or 2) the magnitude of the difference between warring "camps" of scientific judgment is substantial. Although traditionally these significant "scientific disputes" might be left indefinitely to the scientists, particularly because of the scientists' own characterization of their differences as within the bounds of their scientific expertise, see Thomas F. Gieryn, Boundary-Work and the Demarcation of Science from Non-Science: Strains and Interests in Professional Ideologies of Scientists, 48 Am. Soc. Rev. 781, 782 (1983), the "better" view is that resolution in the near term must be based on nonscience. See McGarity, supra note 14, at 743 ("Situations occasionally arise, however, when even after distilling out the pure scientific judgment question, eminent scientists still disagree over how to interpret the data, and the regulator's resolution of the issue once again must be policy-dominated."). For this reason trans-science will be defined in this Article over-broadly to include significant splits in the scientific community that are identified by scientists as major controversies over "scientific judgment." This does not avoid line drawing, but it does avoid a taxonomic dispute over which areas of science fall closer to the trans-science or the scientific judgment line.

For a slightly different organization of science questions that have embedded uncertainties due to the unavailability of information, see NRC Risk Assessment, supra note 14, at 28; Ted Greenwood, The Myth of Scientific Incompetence of Regulatory Agencies, Sci., Tech., & Hum. Values, Winter 1984, at 83, 85–86.

nological, informational, and ethical constraints on experimentation.[23] For example, ethical mores prohibit direct testing on humans, leaving investigators to extrapolate the effects of a toxic substance on humans from studies conducted on animals.[24] Even when some segment of the human population has been exposed to a toxic substance, isolating that substance's impact may be statistically impossible because of the many other factors that adversely affect human health.[25]

Since trans-scientific issues arise from a variety of practical and theoretical limitations on scientific experimentation,[26] the ability of science to

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23. For a colorful illustration of these various obstacles in the context of determining water quality standards, see Houck, supra note 7, at 10529–30; see also Committee on Risk Assessment of Hazardous Air Pollutants, National Research Council, Science and Judgment in Risk Assessment 86 (1994) [hereinafter Science and Judgment] (explaining that uncertainties result from inability to test key inputs to scientific models and from gaps in knowledge that make it impossible to know which of several competing models is correct); Harvey Brooks, The Resolution of Technically Intensive Public Policy Disputes, Sci., Tech., & Hum. Values, Winter 1984, at 39, 43 (discussing occasions in which "there appears to be no practical basis for experimental resolution" of a question put to science).

24. See, e.g., NRC Risk Assessment, supra note 14, at 22 (explaining that limitations in epidemiological evidence are due in part to moral prohibition against releasing untested chemicals into the environment); cf. McGarity, supra note 14, at 743 & n.67 (observing that while carcinogenicity testing on humans is morally unacceptable, some officials at EPA nevertheless proposed study to feed massive doses of cancer-causing fungicides to Mexican citizens and to convict-volunteers at Tennessee state prison). Thus, for public health studies scientists must be satisfied with extrapolations from studies on animals—an extrapolation which cannot in most cases be based completely on scientific inferences. See id. at 744–45.

25. See, e.g., Troyen A. Brennan, Causal Chains and Statistical Links: The Role of Scientific Uncertainty in Hazardous-Substance Litigation, 73 Cornell L. Rev. 469, 507 (1988) ("An epidemiological study . . . is not really an experiment. Researchers cannot control the factors that affect the quality of the data."). For example, "an attempt to control for the confounding effects of social class and cigarette smoking complicates studies of the relationship between air pollution and lung cancer." Id. at 519.

26. There are many other reasons why science may be incapable of answering or resolving a hypothesis in a viable way. Practical limitations on experimentation typically arise as a result of the extraordinary expense associated with running a particular definitive experiment. For example, in order

> to demonstrate with ninety-five percent confidence that the carcinogenic response rate [in animals] is less than one in a million, an experimenter need only feed three million animals at the human exposure rate and compare the response with three million control animals that have been raised under identical conditions but with no exposure to the chemical.

McGarity, supra note 14, at 733–34 (footnote omitted). Quite obviously such "mega-mouse" experiments are never undertaken since "it would require feeding and caring for six million rodents for eighteen to twenty-four months." Id.

Time constraints may also require rapid regulatory action before all of the data can be collected. See, e.g., Nicholas A. Ashford et al., A Hard Look at Federal Regulation of Formaldehyde: A Departure from Reasoned Decisionmaking, 7 Harv. Envtl. L. Rev. 297, 313–14 (1983) ("Depending on the available data base, a study may take from two to forty years to complete. . . . In the many situations where a delay will be inappropriate, the agency will have to treat the question of carcinogenic risk as if it were a trans-scientific issue."); McGarity, supra note 14, at 736 ("[A]s in the case of trans-scientific questions,

quantify adverse health effects of low levels of toxins can be quite limited.[27] To reach a final quantitative standard, policy considerations[28] must fill in the gaps that science cannot inform.[29] This combination of science and policy necessary to the resolution of issues concerning toxics regulation has led to the classification of these issues as "science-policy" problems.[30]

2. *The Fragmented Contributions of Science.* — A second problem arising in the attempt to quantify health risks is that those insights which science is able to provide are fragmented and occur sporadically throughout the larger investigation. The search for a "safe" concentration of a chemical, which poses only minimal risks to human health, immediately breaks down into a sequence of smaller sub-questions that often alternate between questions that can be resolved with science and others that cannot.[31] See Figure 1.

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regulators occasionally will have to decide questions on the basis of incomplete information even though these questions are, in theory, scientifically resolvable.").

A bona fide split in the theories accepted by the scientific community on a particular point can also present theoretical limitations on the ability of science to resolve a question if the controverted theories cannot be tested directly through scientific experimentation. "These rather high-sounding abstractions can manifest themselves in very specific conflicts over, for example, what statistical methods to use and hence, implicitly, where to place the burden of proof." Marc J. Roberts et al., Mapping Scientific Disputes That Affect Public Policymaking, Sci., Tech., & Hum. Values, Winter 1984, at 112, 113; see also Nicholas A. Ashford et al., supra, at 314 ("Even when dealing with a scientific issue rather than a trans-scientific one, scientists may disagree on the proper scientific interpretation of the data .... For these issues, as for trans-scientific issues, science cannot now provide an answer.").

27. See, e.g., Rushefsky, supra note 14, at 182 ("Regulatory science was sufficiently developed to identify potential carcinogens (though of course that too was disputed), but it was not sufficiently developed to identify cause-and-effect relationships at the level of human exposure. Science [thus] ... was able to identify a possible problem but unable to propose definitive solutions.").

28. For purposes of this Article, the term "policy" is used broadly to include virtually every type of decision that is not based on the results of one or more experiments in the natural sciences. "Policy" considerations thus include not only the reasoned weighing of various economic and social outcomes, but also could include the conscious or subconscious biases, guesses, and intuition of decisionmakers.

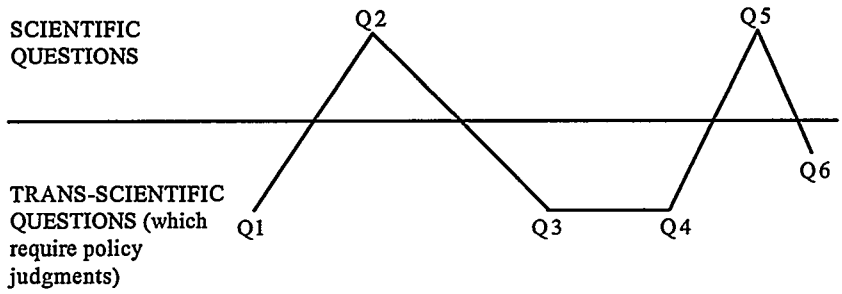
29. See, e.g., Science and Judgment, supra note 23, at 82 (concluding that "the choice of principles to guide risk assessment, although it requires a knowledge of science and scientific judgment, ultimately depends on policy judgments"); Majone, supra note 18, at 15 ("Far from being an almost mechanical process safely relegated to technicians, the setting of health, safety, and environmental standards is in reality a microcosm in which conflicting epistemologies, regulatory philosophies, national traditions, social values, and professional attitudes are faithfully reflected."); McGarity, supra note 14, at 736 (noting that "a regulator must make a subjective, or policy-dominated decision" to answer these questions); Weinberg, supra note 20, at 209, 216, 220 (noting that the process of making trans-scientific decision must be political).

30. See Ashford et al., supra note 26, at 310–11; McGarity, supra note 14, at 732–49, 750.

31. See Ashford et al., supra note 26, at 315 (noting that agency often engages in two levels of analysis in risk assessment, which involves on one level resolving " 'hard' scientific issues" that can be resolved with "currently available methodologies" and on a second level

FIGURE 1

INQUIRY: At what concentration does formaldehyde in drinking water cause a 1×10^{-6} risk of cancer?



Note: For a discussion of the types of questions which might arise for Q1 through Q6, see text accompanying notes 36-43.

Even for those questions that cannot be resolved by science, however, science plays a small but important role in defining the scientifically plausible "default options" available at each trans-scientific juncture.[32] For example, although the ultimate selection of an extrapolatory model that predicts the effects of a substance at low doses based on high dose data must be based on policy factors,[33] the types of curves which are possible originate in scientific theory.[34] See Figure 2. As a result, the contri-

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resolving science-policy issues that cannot be determined solely by technical considerations).

32. See Science and Judgment, supra note 23, at 7 (default options "are used in the absence of convincing scientific knowledge on which of several competing models and theories is correct").

33. Policy considerations are necessary because of "the huge range of estimates which the [extrapolatory] models produce." See James P. Leape, Quantitative Risk Assessment in Regulation of Environmental Carcinogens, 4 Harv. Envtl. L. Rev. 86, 103 (1980). In the risk assessment of saccharin, for example, the risk range resulting from exposure to the identical amount of saccharine varied from one death per billion persons exposed to 1200 cancer cases per one million persons exposed, depending on the type of extrapolatory model selected. See id.

34. While scientific experiments cannot be conducted to determine how a chemical might affect human health at low doses, scientists can use existing knowledge and theories of biological mechanisms to develop alternative predictive models. For example, the National Research Council of the National Academy of Sciences (NRC) discusses the factors that should be acknowledged in selecting a model (in this case the linear model) for extrapolating from high doses to low doses:

> The [selection of a linear model] is not a claim that it is known that the relationship between dose and response is linear; that the true relationship between dose and response is uncertain and could be nonlinear is readily acknowledged. Rather, the [selection of a model] is based (1) on the scientific conclusion that the linear model has substantial support in current data and biologic theory and that no alternative model has sufficient support to warrant departure from the linear model for most chemicals identified as carcinogens;

butions of science and policy, although generally separable,[35] are mixed in complicated ways.

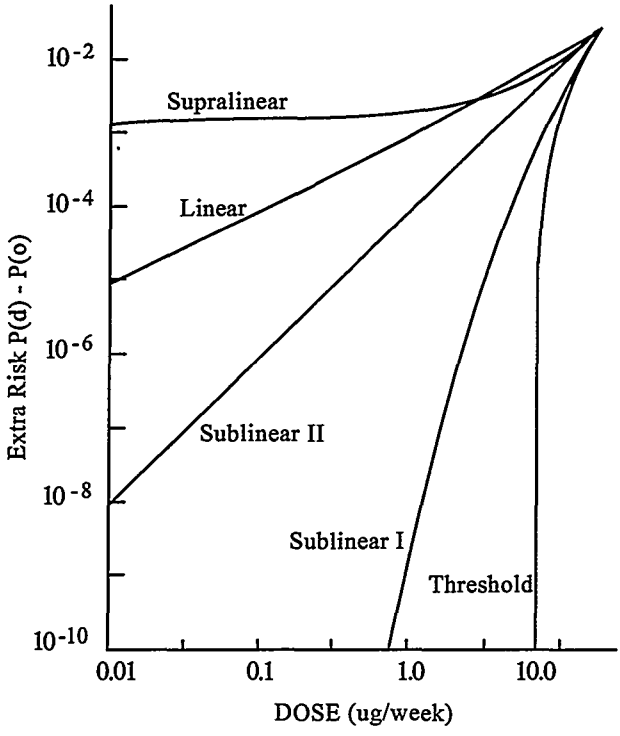
(2) on the further scientific conclusion that the linear model is more conservative than most alternative plausible models; and (3) on the policy judgment that a conservative model should be chosen when there is model uncertainty.

Science and Judgment, supra note 23, at 90. In some cases, then, some scientifically plausible options are more likely to be accurate based on the prevailing theories than other options. See NRC Risk Assessment, supra note 14, at 25 (observing that although five models for low-dose extrapolations "may fit experimental data equally well, they are not equally plausible biologically").

35. Although scholars examining science-policy problems are not unanimous as to the separability of science from policy, see, e.g., Joel Yellin, Science, Technology, and Administrative Government: Institutional Designs for Environmental Decisionmaking, 92 Yale L.J. 1300, 1310 (1983) (arguing that "environmental controversies cannot be split into technical and legal parts"), most agree that the science and policy components are separable at some level. See, e.g., Rushefsky, supra note 14, at 14 ("While those who write in this area admit the practical difficulties of separating the various stages, the separation is accepted, at least conceptually, as a goal to be achieved."); Howard Latin, Good Science, Bad Regulation, and Toxic Risk Assessment, 5 Yale J. on Reg. 89, 105 (1988) (advocating more detailed description of scientific uncertainties and more explicit statement of policy implications in regulating toxic risks); William Ruckelshaus, Science, Risk, and Public Policy, 221 Science 1026, 1027 (1983) (arguing that care must be taken to separate the scientific process of assessing risk from the use of such assessments in the management of risks through regulatory action); see also infra note 376. A subset of these scholars not only believe that separation can be accomplished, but urge that a scientific panel or court be used to establish the scientific baseline for the resulting policy determinations. See, e.g., Alan Kantrowitz, The Science Court Experiment, 17 Jurimetrics J. 332, 333 (1977). But see Barry M. Casper, Technology Policy and Democracy: Is the Proposed Science Court What We Need?, 194 Science 29, 29 (1976) (arguing that science court proposal is misguided given political nature of most technical questions).

FIGURE 2

Alternative Dose-Response Models for Extrapolations from High to Low Doses



Source: EPA, Principles of Risk Assessment: A Nontechnical Review IV-5 (1985), reprinted in Robert V. Percival et al., Environmental Regulation: Law, Science, and Policy 487 (1992)

This mix of science and policy can be illustrated by depicting a few hypothetical stages in an agency's effort to determine the maximum concentration of a carcinogen, such as formaldehyde, acceptable in public drinking water. See Figure 1. Typically, the best information available on carcinogenicity consists of laboratory studies in which animals have been exposed to high concentrations of the specified chemical.[36] One of the first trans-scientific questions that arises (Q1) is whether to count all tumors found in test animals after exposure or only those tumors that prove to be malignant. Although the decision will dramatically affect quantification of the hazard posed by the chemical, guidance provided by science

36. Even the selection of the type of animal can involve some policy choices with regard to the conservativeness of the estimate. Rats and mice, for example, experience a different incidence of nasal tumors when exposed to similar doses of formaldehyde. See Graham et al., supra note 12, at 182.

in selecting among the options is limited.[37] Once this trans-scientific question has been resolved with a nonscientific determination, the statistical results will provide valuable quantitative information on the effects of high levels of the substance on animals (Q2). Extrapolating these results to potential effects of low levels of the substance on humans then presents the next two trans-scientific junctures, which are often collapsed into one. First (Q3), an extrapolatory model must be selected that will predict low-dose effects on animals based solely on high-dose data.[38] Although there are several scientifically plausible extrapolatory models, see Figure 2, the choice of one model over another cannot be resolved by science and thus must be determined by policy factors.[39] This policy choice will have significant implications for the level ultimately chosen as adequate to protect public health.[40] Second (Q4), since the similarities between animals and humans with regard to their sensitivity to carcinogens are largely unknown and incapable of being studied directly,[41] a policy choice must again be made. For example, in many standard-setting efforts decisionmakers adopt the risk averse assumption that humans are one hundred times more sensitive to the adverse effects of a carcinogen than test animals.[42] After these trans-scientific junctures have been bridged with policy choices, further resolution of the inquiry then turns back to science for estimates of the average daily adult intake of water (Q5) and scientifically plausible models for absorption of the carcinogen in an adult (Q6).[43] The absorption model ultimately selected will again be based on policy considerations.

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37. See NRC Risk Assessment, supra note 14, at 34 (available options of whether to count benign tumors differ in conservatism with counting benign tumors being more conservative approach); Science and Judgment, supra note 23, at 85–86 (noting that science does not know "how much importance to attach to experiments that show that exposure to a substance causes only benign tumors in animals").

38. Animals are not tested directly for low dose effects because conducting the necessary "mega-mouse" experiments is prohibitively expensive. Millions of test and control animals must be monitored over several years in order to detect statistically significant adverse effects of low doses of a toxin. "Scientists therefore test significantly fewer animals at much higher dosage rates." McGarity, supra note 14, at 734.

39. See, e.g., Science and Judgment, supra note 23, at 85 ("[W]hen there is evidence of a carcinogenic effect at a high concentration (for instance, in the workplace or in animal testing), we do not know for certain how strong the effect (if any) would be at the lower concentrations typically found in the environment.").

40. See supra note 33.

41. In extrapolating from animals to humans, several methods are used to adjust for differences in size and metabolic rates. Although some conversion methods are used more frequently than others, "a scientific basis for choosing one over the other is not established." NRC Risk Assessment, supra note 14, at 24–27; see also Science and Judgment, supra note 23, at 86 (same).

42. See Graham et al., supra note 12, at 151.

43. See, e.g., NRC Risk Assessment, supra note 14, at 35–36 (observing that science may provide a series of "different [possible] assumptions about the frequency and duration of human exposure to an agent or medium, rates of intake or contact, and rates of absorption"); Science and Judgment, supra note 23, at 86 (noting that scientific uncertainties include "calculating the doses received by individuals [which] might require

Since dozens of such issues arise in determining the concentration at which a chemical causes adverse health effects, the number of scientific and trans-scientific subquestions that must be addressed in the course of a single standard-setting project is substantial, and the cumulative effect of these subquestions can have profound policy implications.[44] Fortunately, the National Research Council of the National Academy of Sciences identified most, if not all, of these subquestions in its 1983 study and specifically listed the dozens of trans-scientific questions that must be resolved with policy considerations. See Appendix.

B. *The Need for Experts in Separating Science and Policy*

These dual characteristics of science-policy problems substantially complicate policymaking by limiting those capable of separating science and policy to persons proficient in science. Although trans-scientific questions cannot be answered by science, they generally appear to outside observers to be resolvable by contemporary science and thus are often mistaken for straightforward scientific questions.[45] In fact, virtually all trans-scientific questions are capable of being framed as working scientific hypotheses, and in many cases the experiments needed to answer these hypotheses can be designed in theory.[46] As a consequence, distinguishing between questions resolvable by science and those that must remain trans-scientific requires familiarity with the current capabilities and limitations of scientific experimentation.[47]

The difficulties in identifying which questions are trans-scientific and which can be addressed by scientific experimentation are exacerbated by the fact that the gaps in scientific knowledge are not clustered at the beginning or end of the inquiry, but are located at numerous, intermittent points, often alternating with questions that science can resolve.[48] Moreover, while resolution of a trans-scientific question must ultimately be determined by policy considerations, the plausible options available for resolving a trans-scientific question often originate in scientific theory.[49]

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knowledge of the relationship between emission of a substance by a source and the ambient concentration of that substance at a particular place and time").

44. See, e.g., Albert L. Nichols & Richard J. Zeckhauser, The Perils of Prudence: How Conservative Risk Assessments Distort Regulation, Regulation, Nov./Dec. 1986, at 13, 18 (noting that the "series of 'little' decisions" embedded in a single risk assessment can "matter a great deal," often more "than decision makers or the public are likely to realize"); see also infra note 133.

45. See Weinberg, supra note 20, at 209 (explaining that trans-scientific questions are "epistemologically speaking, questions of fact and can be stated in the language of science").

46. The barrier to scientific resolution arises primarily because the experiments simply cannot be performed, often due to practical limitations on testing. See supra notes 23–26 and accompanying text.

47. See Weinberg, supra note 20, at 216 ("One must establish what the limits of scientific fact really are, where science ends and trans-science begins.").

48. See supra notes 31, 36–43 and accompanying text.

49. See supra notes 32–34 and accompanying text.

Thus, even with some appreciation of the limits of scientific experimentation, a nonscientist would have a difficult time identifying all of the questions that cannot be resolved by science and the scientifically plausible options available for each trans-scientific question.

When setting toxic risk regulations, these complications in distinguishing between the scientific and nonscientific issues can have serious policy implications. First, in order to ensure that science and policy issues have been adequately separated, policymakers must be well-grounded in science; yet a scientific background is typically neither a prerequisite for developing toxics policy nor an attribute commonly found among policymakers.[50]

Second, and equally important, if policy decisions are to receive appropriate public scrutiny, science-policy decisionmakers must be extremely forthright in distingmishing policy judgments from scientific facts. Indeed, the esoteric nature of science-policy problems in toxic risk regulation makes it possible for these decisionmakers to blur distinctions between science and policy without the distortions being detected by most lay observers, including elected or appointed officials. In fact, scientists have been known to deliberately misidentify the hazy line between science and policy in the past. Sociologists of science suggest that these efforts by scientists to recharacterize the demarcation between questions of science and nonscience occur in order to prevent religious, institutional, and governmental intrusions into their scientific provinces,[51] or in order to further the scientists' "pursuit of authority and material resources."[52] That science-policy decisionmakers might also be capable, either intentionally or inadvertently, of shifting the bounds between science and trans-science to suit their institutional ends when developing toxic risk standards seems equally plausible. The next two parts will present evidence that science-policy decisionmakers are doing exactly that; they are engaging in a science charade in which they carelessly or deliberately characterize policy choices as matters resolved by science in order to survive a variety of strong political, legal, and institutional forces.

II. The Prevalence of the Science Charade

In a perfect world, scientists and policy specialists would strive to separate trans-scientific issues from issues that can be resolved with scientific

50. See infra Part III.C.1.

51. See Gieryn, supra note 22, at 782 (examining a number of examples of "ideological efforts *by scientists* to distinguish their work and its products from non-scientific intellectual activities" for professional gain); Weinberg, supra note 20, at 216 (noting that establishing limits of science "often requires the kind of selfless honesty which a scientist or engineer with a position or status to maintain finds hard to exercise"); id. at 220 (current environmental debates illustrate that "scientists often appear reluctant to concede limits to the proficiency of their science").

52. Gieryn, supra note 22, at 793.

experimentation.[53] Policy choices would be made at each trans-scientific juncture, the basis for each choice would be explained, and the public would find the agency's policy decisions clear and accessible.

Not surprisingly, in the real world a completely different picture emerges. Agency scientists and bureaucrats engage in a "science charade" by failing first to identify the major interstices left by science in the standard-setting process and second to reveal the policy choices they made to fill each trans-scientific gap.[54] Toxics standards promulgated under science-based mandates are covered—from the preamble to the regulatory impact analysis—with scientific explanations, judgments, and citations.[55] Major policy decisions that undergird a quantitative toxic risk

53. See, e.g., Cranor, supra note 1, at 131 ("Agencies can acknowledge explicitly, if they have not already, the number of policy considerations implicit in risk assessment. And they should rely upon them more than they do. Substantial uncertainties can be addressed by policy choices."); Landy et al., supra note 14, at 303 (recommending that "[l]eaders who operate at the interface between technical competence and political authority . . . expound[ ] an explicit strategy . . . [to] give those both inside and outside their agencies a clear sense of what is really at issue and how the agency's efforts should be judged").

54. Occurrences of the science charade have been observed, although in most cases without express acknowledgement of the phenomenon, by the NRC, see Science and Judgment, supra note 23, at 7 ("[C]ommittee did agree . . . that EPA often does not clearly articulate in its risk-assessment guidelines that a specific assumption is a default option and that EPA does not fully explain in its guidelines the basis for each default option."), and by a number of leading science-policy scholars. See, e.g., Harvey Brooks, Foreword to Graham et al., supra note 12, at vii, viii ("The authors' most important conclusion is that the problem they describe so clearly is the result in part of excessive and unrealistic expectations of science—not in its ultimate aspirations but in its current state of development as related to the information needs of regulators."); Greenwood, supra note 14, at 18–19 (noting that agencies sometimes rely "on the technical conclusions or policy recommendation of an expert panel," which leads to "[k]nowledge and discretion [being] frequently confounded, resulting in confusion, obfuscation, and evasion of political responsibility"); Landy et al., supra note 14, at 279 ("EPA repeatedly treated 'safety' as if it were a scientific notion definable by experts, rather than a social construct necessarily based on values as well as science."); Melnick, supra note 17, at 261 ("There is, in short, no simple answer to the question of how the EPA sets air quality standards. Medical evidence cannot offer definitive guidance. . . . The EPA itself has refused to deal with the problem in a forthright manner, hiding its policy choices behind its interpretation of scientific evidence."); Rushefsky, supra note 14, at 6 ("Science, in its regulatory incarnation, is used to forward political goals by all sides in the disputes."); Latin, supra note 35, at 95 ("EPA's carcinogen guidelines, for example, are likely to be the most influential statement of federal risk-assessment practices for years to come, and yet they have not been scrutinized from public policy and legal perspectives.").

55. For example, in estimating cancer risks agencies typically err on the side of more stringent standards in order to be conservative. But "instead of always calling the upper limit an upper limit," which would indicate a clear policy choice, "agencies sometimes call it an 'estimate' from the linearized multistage model." Graham, supra note 12, at 158. EPA's stated regulatory policies for general risk assessments further its apparent desire to have standards appear as scientific as possible, even when the science is highly controverted or the alternative bases for a standard cannot be tested scientifically. See EPA Guidelines for Carcinogen Risk Assessment, 51 Fed. Reg. 33,992, 33,992 (1986) (agency required to conduct risk assessments "us[ing] the most scientifically appropriate interpretation").

standard are at best acknowledged as "agency judgments"[56] or "health policies,"[57] terms that receive no elaboration in the often hundreds of pages of agency explanations given for a proposed or final toxic standard[58] and appear in a context that gives readers the impression they are

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The prevalence of the science charade in agency standard-setting is evident in most, if not all, of EPA's recent protective standard-setting efforts. The proposed and final rulemakings for Maximum Contaminant Level Goals (MCLGs) promulgated under the Safe Drinking Water Act, which must be based on levels deemed protective of the public health and environment, provide an excellent illustration. In final rulemakings, EPA referred exclusively to scientific studies and quantitative factors as the basis for MCLGs and dismissed public comments which asserted that the standards were scientifically indefensible. See, e.g., Final Rulemaking, 56 Fed. Reg. 30,266, 30,269 (1991) (admitting to scientific uncertainty but basing MCLGs for Aldicarb, Aldicarb Sulfoxide, and Aldicarb Sulfone "on clinical signs" "[b]ecause the controversy has not yet been fully resolved"); id. at 30,270 (MCLG for Pentachlorophenol based on animal studies which EPA determined to be adequate despite public comments to the contrary); see also 57 Fed. Reg. 31,776, 31,784–88 (1992) (providing quantitative and scientific justifications for final MCLGs of inorganic chemicals, consisting of Antimony, Beryllium, Cyanide, Nickel, Sulfate, and Thallium); id. at 31,788–97 (same for organics); 56 Fed. Reg. 30,272 (same for Barium); 56 Fed. Reg. 26,460, 26,467–70 (1991) (same for Lead); id. at 26,470–72 (same for Copper); 56 Fed. Reg. 3526, 3535–39 (1991) (same for inorganic compounds); id. at 3539–42 (same for volatile organic contaminants); id. at 3543–46 (same for pesticide/PCBs); id. at 3546–47 (same for other synthetic organic contaminants).

In proposed rulemakings EPA similarly failed to disclose its policy judgments in an accessible way. At best, EPA admitted defaulting to quantitative estimates or a single uncertainty factor when data was limited without explaining its import to the final quantitative standard, identifying the range of error, or discussing alternative assumptions or series of assumptions that are equally plausible. See, e.g., 53 Fed. Reg. 31,516, 31,525 (1988) (citing quantitative calculations and scientific data that form basis for Copper MCLG); 55 Fed. Reg. 30,370, 30,376–84 (1990) (same for inorganic chemicals); see also 56 Fed. Reg. 3531–32 (agency employs single "uncertainty factor" in determining MCLGs which range from 1 to 1000 depending on extent of scientific information available on compound); 53 Fed. Reg. 31,524 (zero standard proposed for Lead MCLG based on agency's "policy" of "setting MCLGs at zero for compounds classified as Group A or B carcinogens," a classification which is ultimately based on scientific judgment).

56. See, e.g., Revisions to the NAAQS for Photochemical Oxidants, 44 Fed. Reg. 8202, 8203 (1979) (explaining that because adverse health effect threshold concentration cannot be identified with certainty, EPA refers to "probable effects levels," which is adverse health effect threshold in EPA's "*best judgment*") (emphasis added). A variation on the theme was used in other rulemakings for the lead air standard: "While the margin of safety [was] based on available scientific information, this factor is *judgmental* in that the Administrator must weigh the acceptability of estimated risks." National Primary and Secondary Ambient Air Quality Standards for Lead, 43 Fed. Reg. 46,246, 46,255 (1978) (emphasis added).

57. See, e.g., NAAQS for Ozone—Final Decision, 58 Fed. Reg. 13,008, 13,009 (1993) (noting that EPA's approach to providing an adequate margin of safety "is a *policy choice left specifically to the Administrator's judgment*") (emphasis added) (citing Lead Industries Ass'n v. EPA, 647 F.2d 1130, 1161–62 (D.C. Cir. 1980)); Proposed Reaffirmation of the NAAQS for Nitrogen Dioxide, 49 Fed. Reg. 6866, 6872 (1984) (because of scientific uncertainties, "EPA believes that it would be *prudent public health policy* to maintain the current annual standards") (emphasis added).

58. Although the uncertainties or disputes on the available scientific information appear to be mentioned at least obliquely in the preamble to the agency's proposed and final rulemakings, any nonscientific considerations, such as economic costs and

based on science.[59] Although this science charade appears to pervade virtually every toxics rule promulgated since the late 1970s,[60] whether the agency engaged in the charade deliberately or inadvertently appears to vary from standard to standard.

A. *The Unintentional Charade*

In many instances agency officials charged with formulating toxic standards seem to engage in a science charade rather unwittingly.[61] A

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distributional benefits, are referenced in several sentences at best. See, e.g., Revisions to the National Ambient Air Quality Standards for Photochemical Oxidants, 44 Fed. Reg. 8202, 8209 (1979) (failing to explain policy factors influencing standard); see also infra notes 79–84 and accompanying text.

59. References to "policy" are used almost uniformly in the context of a discussion of the available scientific information, reinforcing the impression that the ultimate "judgments" of the agency on policy factors are guided by scientific judgment rather than nonscientific considerations. For example, the EPA explains its "policy judgments" for a revision of the carbon monoxide standard as follows:

> EPA's objective in reviewing primary standards, therefore, has been to determine whether new or revised standards are appropriate, based on the existing scientific evidence, assessment of the uncertainties in this evidence, understanding of underlying biological mechanisms, and the need to make a reasonable provision for scientific and medical knowledge yet to be acquired, in order to protect sensitive population groups with an adequate margin of safety.

Review of NAAQS for Carbon Monoxide, 50 Fed. Reg. 37,484, 37,488 (1985); see also Retention of NAAQS for Nitrogen Dioxide, Final Rule, 50 Fed. Reg. 25,532, 25,537 (1985). But see Proposed Revisions to the NAAQS for Particulate Matter, 49 Fed. Reg. 10,408, 10,409 (1984) (after conceding that standard requires a "judgment" by the Administrator, EPA "invites public comment" regarding the lack of scientific answers and whether it would be an acceptable social policy judgment to pick numbers from among several scientifically justified values).

60. The science charade appears to permeate more than just the field of toxics regulation. For evidence of a similar charade occurring in laws governing the protection of natural resources, see Steven L. Yaffee, Prohibitive Policy: Implementing the Federal Endangered Species Act 70 (1982) (noting that in implementing Endangered Species Act "administrative experts use a mix of science, art, and politics" yet their decisions "appear to the outside world to define a technical decisionmaking process"), and in the field of bioethics, see, e.g., Mark Perl & Earl E. Shelp, Sounding Board: Psychiatric Consultation Masking Moral Dilemmas in Medicine, 307 New Eng. J. Med. 618, 620 (1982) (arguing that physicians' consultations with psychiatrists for assistance with patients is not simply transferring problem to another field of medicine, but is and can be used as "a subtle lever to coerce patients to comply with the primary physician's moral judgments or treatment preference" under guise of technical expertise); Robert D. Truog et al., Sounding Board: The Problem with Futility, 326 New Eng. J. Med. 1560, 1563 (1992) (arguing that although decision of when medical treatment becomes "futile" is traditionally treated as technical decision, physicians' "assertions of futility may camouflage judgments of comparative worth that are implicit in debates about allocation of resources").

61. See, e.g., Latin, supra note 35, at 125 (concluding that in EPA's regulation of benzene "[t]here was no unifying logic in the Agency's treatments of different scientific uncertainties," "EPA has never provided a coherent public explanation of its disparate practices," and in the regulatory record there was "little indication that Agency risk assessors recognized the diversity or social implications of their responses to uncertainty"). But see id. at 139 (concluding "[i]t is unclear whether EPA's disregard of [scientific

statutory mandate that appears to require protective standards to be based at least in part on science,[62] coupled with a deficient understanding of the science-policy nature of risk assessment,[63] may lead these officials to reach for science in setting protective standards. In such cases, and without any apparent bureaucratic reflection, the agency officials mechanically assign the standard-setting task to agency scientists and associated technocrats.[64]

Once given responsibility for setting a single, quantitative standard, agency scientists generally take one of two approaches:[65] 1) they continue indefinitely to look to science to resolve the trans-scientific questions; or 2) they substitute their own values for the policy choices needed at the trans-scientific junctures and characterize the final science-policy decisions as the result of scientific experimentation and scientific judgment.[66] In either case, the results are disturbing.

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uncertainties] . . . in the carcinogen guidelines represents an instance of scientific tunnel vision or a deliberate attempt to impede effective regulation").

62. See supra note 15 and infra Part III.B.4.

63. See supra Part I.B.

64. See, e.g., Greenwood, supra note 14, at 133–34 (describing predominant science background of EPA and Occupational Safety and Health Administration (OSHA) departments charged with "analyzing regulatory options" for setting toxic risk standards); id. at 170 (concluding that EPA normally accepted the recommendations of its agency scientists on standards as "authoritative" and usually adopted their conclusions and recommendations); Melnick, supra note 17, at 258 (pointing out that regulatory effort begins with scientists and that "EPA devotes far more attention to surveying the scientific literature on the effects of pollution, subjecting its findings to peer group review, and writing the criteria document than to other stages of the process"); John D. Graham, The Failure of Agency-Forcing: The Regulation of Airborne Carcinogens Under Section 112 of the Clean Air Act, 1985 Duke L.J. 100, 117 n.116, 123 (listing of toxic pollutant under section 112 of Clean Air Act proceeds through five stages within EPA and each stage is supervised predominantly by agency scientists); Latin, supra note 35, at 145–46 (concluding that risk managers appear to turn risk assessment uncritically over to scientists/risk assessors); Thomas O. McGarity, The Internal Structure of EPA Rulemaking, 54 Law & Contemp. Probs., Autumn 1991, at 57, 73–75, 86–89, 93 (noting that important decisions, including significant policy decisions, often made by EPA technical staff instead of upper-level political appointees).

65. In their investigation of the role of scientists in the regulation of formaldehyde in the early 1980s, Graham et al. observe two science camps that illustrate these extremes. See Graham et al., supra note 12, at 19. One group of scientists "were disturbed that federal agencies were not moving more quickly to regulate formaldehyde based on the animal results" and wrote letters to several federal agencies stressing "the necessity of reducing human exposure to formaldehyde, even though confirming epidemiological data were not available." Id. The second camp of scientists "argued that [the Consumer Product Safety Commission's] . . . regulatory analysis gave insufficient attention to epidemiology and made excessive use of the . . . animal data." Id. A scientist in this group also sent a letter to the Commission stating that the data "weigh heavily against the view that formaldehyde constitutes any considerable risk" and suggested that more studies were needed. See id.

66. See, e.g., Graham et al., supra note 12, at 163 (quoting Brian MacMahon, a leading epidemiologist from Harvard, challenging benzene risk assessment as "the presentation of dressed-up guesses [which] . . . serves no useful purpose"); Roberts et al.,

A cautious scientist typically takes the first, more "scientific" approach and declines to impose her values on a national toxic risk standard that has wide-ranging economic and related public policy consequences.[67] In so doing, however, the scientist nevertheless continues the charade by embarking on an endless search for nonexistent scientific answers,[68] thereby halting many standards in the research phase and leaving significant gaps in the regulation of toxics.[69] The small number of toxic risk standards promulgated under science-based mandates, coupled with

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supra note 26, at 112 ("Scientists, of course, may allow their policy preferences to influence their technical positions either consciously or unconsciously."). Expert panels experience similar problems:

> Expert panels often do not admit (and may not even recognize) when they go beyond science or engineering knowledge in reaching their conclusions. Moreover, the credentials of their members and often the terms of their mandate imply that their conclusions are based purely on knowledge. The result is to obscure the distinction between knowledge and discretion.

Greenwood, supra note 14, at 229.

In a report prepared by scientists in the U.S. Life Sciences Research Office, an advisory arm of the Food and Drug Administration, the committee called attention to the lack of neutrality of scientific experts. See Life Sciences Research Office, Insights on Food Safety Evaluation 27 (1982). The scientists nevertheless recommended that these subjective biases be corrected with better expert education and selection, rather than by incorporating policymakers into the decisionmaking process. See id.

67. Academic and research scientists are stereotypically more "inclined to refrain from reaching conclusions within their professional specialty until adequate evidence is available." Greenwood, supra note 14, at 195; see also Howard Latin, Regulatory Failure, Administrative Incentives, and the New Clean Air Act, 21 Envtl. L. 1647, 1663–64 (1991) ("Good scientists are often unwilling to guess about indeterminate issues, even if good regnlators should not be.").

68. Additional information requirements may also be imposed as a result of administrative philosophy. See infra note 109 and accompanying text; see also Greenwood, supra note 14, at 241 (noting that the "escalating requirements for analysis contained in the executive orders of Presidents Nixon, Ford, and Carter" caused perceptible regulatory delays in standard-setting).

69. When sufficient evidence is not available, "an advisory committee of academic researchers is likely to act as an inhibitor of regulation." Greenwood, supra note 14, at 195 (reporting that on at least two occasions Science Advisory Board (SAB), noted for its academic biases, "refused to endorse inferences reached by the agency's risk assessment staff from sparse and uncertain evidence that substances were carcinogens and should be regulated"). In the case of air toxins, for example, SAB's involvement produced splits between agency scientists and SAB over the "nature and adequacy of scientific information necessary to support a listing decision." See Comptroller General, U.S. General Accounting Office, Delays in EPA's Regulation of Hazardous Air Pollutants at iii (1983). Since the absence of an internal consensus substantially weakened the legitimacy and likely success of proposed regulations, the disagreements typically resulted in substantial delays with regard to toxic regulatory standards. See id. at iii–iv; see also David Collingridge & Colin Reeve, Science Speaks to Power: The Role of Experts in Policy Making 41–42 (1986) (discussing "endless technical debate which surrounds the health effects of lead" and prevents improvements in policies concerning control of lead); Sheila Jasanoff, The Fifth Branch: Science Advisers as Policymakers 207 (1990) (in EPA's attempt to regulate formaldehyde under TSCA, protracted risk assessment and review by SAB produced regulatory result which was so late in coming that significant regulatory control had already been passed to OSHA).

the fact that the standard-setting task often begins and ends with agency scientists, supports the likelihood that at least some standards have been stalled in this way.[70]

If the second path is followed, significant public policy judgments are made by technocrats who have not been appointed as policymakers and who are unlikely to be held accountable for their decisions.[71] In some cases a scientist may become convinced that the highly controversial issues will never be resolved unless she steps in and resolves the trans-scientific questions herself.[72] In other cases a scientist may enjoy being

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70. See infra Part IV.B.1. Several of the leading authorities on science-policy problems have suggested that in some cases additional research will not only stall regulatory progress while it is being done, but it may actually increase the policy conflict because the studies often end up asking more questions than they answer. See Collingridge & Reeve, supra note 69, at 49; Graham et al., supra note 12, at 192–93. But see id. at 193–94 (noting that in some instances additional research does assist with resolution of policy).

71. See Jasanoff, supra note 69, at 81 ("It has been amply documented that technically trained adversaries can exploit uncertainties in the scientific knowledge base to construct evaluations consistent with their political objectives."); McGarity, supra note 64, at 93 (observing that EPA decisionmaking often originates with a team at the staff level which allows staff to "apply different policies than those preferred by upper-level decisionmakers [and] . . . to disguise policymaking behind the veneer of professional consensus"); Kenneth J. Shaffer, Comment, Improving California's Safe Drinking Water and Toxic Enforcement Act Scientific Advisory Panel Through Regulatory Reform, 77 Cal. L. Rev. 1211, 1225 (1989) (concluding, after examining scientific panel used for California Proposition 65, that the "Panel's [exclusively scientific] members have often resorted to nonscientific value judgments to resolve the issues before them"). In their study, Graham et al. concluded that a scientist's discipline and theoretical views had a great effect on whether or how they reacted to science-policy questions. See Graham et al., supra note 12, at 187–89; see also Greenwood, supra note 14, at 192 (characterizing EPA officials charged with setting air toxic standards as predominantly engineers, which imbues them with "a sensitivity to cost," while characterizing OSHA health professionals charged with setting OSHA toxic work standards as having "motivations and orientations" which caused them to act as "zealots"); Nicholas A. Ashford, Advisory Committees in OSHA and EPA: Their Use in Regulatory Decisionmaking, 9 Sci., Tech., & Hum. Values 72, 77 (1984) (discussing effects of disciplinary bias on policy judgments). Graham et al. also suggest that some of the policy overreaching by scientists actually may be the result of overly simplistic questions asked by policymakers. As a result, scientists may reframe a vague regulatory question in more answerable, scientific terms, which ultimately transforms the question from one of mixed science-policy to one within the sole province of scientists. See Graham et al., supra note 12, at 184–86.

72. Mark Rushefsky hypothesizes that scientific panels frequently pick a somewhat arbitrary mid-point in order to form scientific consensus. See, e.g., Rushefsky, supra note 14, at 10 (in developing a model to determine carcinogenic effects of low doses of ionizing radiation, scientific subcommittee agreed on a linear quadratic model which fit between the two extreme models previously discussed by committee (linear and quadratic)); see also Melnick, supra note 17, at 250 (describing a category of agency scientists as "advocates" who "believe that scientists should do more than describe risks; they should make recommendations consistent with the mission of their profession, the protection of public health"); id. at 251 (reporting that 1974 National Academy of Sciences report on air pollution noted that "a minority of members on the [scientific] committee 'take the view that all pollution is bad and should be eliminated' ").

the source of public policy, particularly when her hidden value choices are likely to be free from oversight by high level governmental officials and the public at large.[73] Finally, a scientist may deceive herself into believing that her scientific expertise gives her the professional legitimacy to resolve a vast range of trans-scientific questions without assistance from appointed officials or other designated policymakers.[74]

There are many examples of scientists serving as policymakers in setting toxic standards. In his study of the promulgation of air toxic standards under the Clean Air Act, Dr. Greenwood concludes that scientists were the predominant decisionmakers throughout the standard-setting process: "[D]espite elaborate procedures designed in part to centralize authority in the administrator . . . , the risk assessment offices [which were staffed heavily, if not exclusively, with scientists] . . . actually appropriated a sizable share of the agency's authority to exercise discretion."[75]

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73. See Latin, supra note 35, at 145 ("[T]he scientists most responsible for conducting EPA risk assessments evidently recognize that risk managers accept their quantitative estimates uncritically . . . ."); see also Landy et al., supra note 14, at 52, 81 (describing conduct of "Shy panel" in advocating retention of 0.08 parts per million (ppm) ozone standard which appeared motivated by protectionist stance); Melnick, supra note 17, at 295 (noting that when asked to provide technical answers to policy questions, medical health professionals generally adopt conservative, worst-case assumptions and that when consensus is reached among professionals at lower levels of bureaucracy, "it is difficult for political executives to reject their recommendations").

74. For example, a portion of the NRC committee charged with the recent report on EPA's risk assessment contended that the committee should develop principles to guide EPA in its selection of policy choices ("default options") embedded within a risk assessment. These members "urged that the choice of risk-assessment principles is one of the most important decisions to be made in risk assessment and one on which risk assessment experts, because of their expertise on the scientific issues related to the choice, ought to make themselves heard." Science and Judgment, supra note 23, at 82. The majority of committee members on the NRC panel, however, were concerned that their expert biases might not coincide with public values and declined the opportunity to offer suggestions for policy choices at the trans-scientific gaps. See id.

75. Greenwood, supra note 14, at 175. Dr. Greenwood went on to conclude that assiguing risk assessments to agency scientists was particularly common in EPA setting of air toxic standards and was based in large part on "the reputation for competence of the [technical] offices, [and] the lack of technical competence on the part of the administrators." Id. EPA did employ a policy office to oversee the promulgation of air toxic standards. See id. at 144. While the office did "raise questions that from time to time forced [the sister science department] to seek more data, to sharpen its analysis, or to revise its conclusions and recommendations," the office also convinced the scientists to "perform a quantitative risk assessment," id., which undoubtedly enhanced rather than exposed the science charade. But see id. at 176 (concluding that "[t]he lack of a reputation for competence on the part of the OSHA program office and the agency's structural characteristics prevented this [scientific] office from acquiring much independent authority after the mid 1970s).

Other science-policy scholars have similarly observed that agency scientists have freely taken the lead in resolving policy choices at trans-scientific junctures. Based on his analysis of EPA's selection of an air standard for lead, Professor Melnick concluded that:

> the long review process that has evolved partly in response to court decisions has increased the autonomy and the influence of the scientists responsible for writing

Scientists, in fact, have appeared at times to be quite aggressive in usurping responsibility for both scientific and policy decisions. A debate among Dr. Roy Albert, the Chairman of the Environmental Protection Agency's (EPA's) Carcinogen Guideline Committee, Dr. James Swenberg, a scientist with the Chemical Industry Institute of Toxicology, and Mr. Michael Taylor, an attorney in private practice in Washington, D.C., regarding a presentation of EPA's draft Carcinogen Risk Assessment Guidelines given by Dr. Albert illustrates the prominent role some scientists have defined for themselves in risk assessment policy:

> SWENBERG: The database for the one-hit hypothesis is poor at present and appears to be diminishing. You ought to be thinking of the future instead of the past.
> ALBERT: A federal regulatory agency should not swing about like a weathervane in a gusty wind; it is supposed to sense when the trend of scientific evidence becomes sufficiently established to be adopted. . . . Carcinogen risk assessment is an attempt to pull together what there is in the way of scientific evidence and take a position on it. To say, "Let's forget about the science," doesn't serve the purposes of risk assessment.
> TAYLOR: No. My point is that when the scientific data do not reveal what is happening at that low level, some policy component has to come into play that says you either take a conservative approach or you make your best guess about what you think the truth is. EPA's policy judgment, as I understand it, is not to take a best guess about what the truth is, but to take a conservative approach. I think this is sound public health policy, but don't mistake that for a scientific decision.[76]

Even in instances where the hand of a particular scientist cannot be traced directly to the selection of a protective health standard, the agency provides only a scientific explanation for the standard, leaving no insight into the bases for the embedded policy judgments. In selecting a 30 microgram safety level for lead concentrations in blood from among equally plausible levels ranging from 30 to 38, for example, EPA's explanation was stated obliquely: "The maximum safe blood lead level should be somewhat lower than the threshold for a decline in hemoglobin levels"

> the criteria document and making policy recommendations to agency political executives. If a rough consensus on where to set the standard emerges at early stages of this process, this recommendation will come before the administrator with substantial institutional momentum.

Melnick, supra note 17, at 280; see also id. at 272 (noting that physicians and researchers within EPA and the SAB "immediately plunged into addressing" four policy issues embedded within the setting of a lead standard); id. at 277 (concluding that "technical personnel in [EPA] . . . were essentially on their own" in identifying air standard for lead); Rushefsky, supra note 14, at 183 (noting that many of the policy entrepreneurs making toxic risk assignments regarding cancer policy were prominent scientists and that the views of these scientists often differed depending on whom they were representing).

76. Roy E. Albert, U.S. Environmental Protection Agency Revised Interim Guideline for the Health Assessment of Suspect Carcinogens, *in* Risk Quantitation and Regulatory Policy 307 app. at 328 (David G. Hoel et al. eds., 1985).

(40 micrograms per deciliter) and "at an even greater distance below the threshold for risks of nervous system deficits" (50 micrograms per deciliter).[77] "Prudent health policy" and "sound principles of preventive medicine," rather than straightforward statements of economics and related public policy, were provided as the sole justification for the 30 microgram standard.[78]

Pervasive agency use of hypertechnical risk assessment guidelines and complex computer models to set toxic risk standards also suggests an administrative preference for scientific precision and a simultaneous obliviousness to the multiple policy judgments needed to inform toxic risk calculations.[79] The National Research Council (NRC) has repeatedly

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77. National Primary and Secondary Ambient Air Quality Standards for Lead, 43 Fed. Reg. 46,246, 46,253 (1978).

78. See Melnick, supra note 17, at 274. In attempting to dig beneath these superficial scientific explanations for the lead standard, Professor Melnick concludes that the 30 microgram standard must have been chosen in part because it was "a round number 25 percent below the previously recognized threshold . . . . [N]ew evidence on the health effects of lead [had] changed most EPA and SAB scientists' subjective impressions of what constituted a reasonably precautionary estimate of the safe blood lead level for children—without demanding this level as a matter of logic." Id.

Professor Melnick discovered a similar "best guess" approach used by the scientists in determining an air lead-blood correlation, another trans-scientific juncture that had to be bridged in setting a lead air standard. See id. ("Not knowing how to choose among these numbers and at a loss to determine how much lead is transmitted to the blood through ingestion, the EPA opted for another good round number—2.") EPA presented only the scientific components of the decision, however, making it appear to be based on scientific rather than policy judgment. After discussing existing scientific studies, EPA concludes that "these studies as well as others reported in the criteria document support the document's conclusion that: 'ratios between blood lead levels and air lead exposures were shown to range generally from 1:1 to 2:1.' " National Primary and Secondary Ambient Air Quality Standards for Lead, 43 Fed. Reg. 46,246, 46,254 (1978). Interestingly, in determining the proper policy choice for yet a third trans-scientific question encountered in the standard setting process—the relative air and nonair sources of lead—EPA did admit in the proposed rule that its figure constituted a "policy choice reflecting how much of the lead pollution problem should be dealt with through control of air sources," Proposed National Ambient Air Quality Standard, 42 Fed. Reg. 63,076, 63,080 (1977), although EPA did not discuss those factors it considered in reaching this policy judgment. See id.

79. One computer model may contain dozens of hidden policy assumptions, which exert a profound effect on the resulting numerical standard. See Grabam et al., supra note 12, at 158; see also id. at 159 (table comparing formaldehyde risk estimates for rats based on alternative mathematical models); Charles D. Case, Problems in Judicial Review Arising from the Use of Computer Models and Other Quantitative Methodologies in Environmental Decisionmaking, 10 B.C. Envtl. Aff. L. Rev. 251, 276 (1982) ("There is often a tendency on the part of these experts . . . to give an inadequate disclosure of the actual methodologies used and the limitations of the results that their studies produce."). The choice of a model, however, is rarely if ever presented in its full mixed science-policy light. See Graham et al., supra note 12, at 167. Although policymakers may encourage the repeated use of computer models and quantitative data, the responsibility for this trend likely rests as much with the scientists, since "[t]he statistical techniques in these calculations are sophisticated and can be so involved that risk assessors themselves do not fully understand the details." Peter N. Preuss & Paul D. White, The Changing Role of Risk

criticized EPA's affinity for "a single point estimate"[80] of risk, which "suppresses information about sources of error that result from choices of model, data sets, and techniques for estimating values of parameters from data" and makes the agency's selection of default options difficult to discern or understand.[81] Howard Latin provides several examples of EPA's proclivity for discussing only the most superficial scientific justifications for risk assessment assumptions in his analysis of EPA's 1986 generic carcinogen risk assessment guidelines.[82] Latin observed that in each instance the significant policy implications of EPA's risk assessment assumptions were not discussed by EPA and appeared from the rulemaking to have been completely overlooked.[83] In their study of the 1979 Inter-

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Assessment in Federal Regulation, *in* Risk Quantitation and Regulatory Policy, supra note 76, at 331, 335.

80. Point estimates are single quantitative figures that are not accompanied by error bars, standard deviations, or other indications of the range of experimental error.

81. See Science and Judgment, supra note 23, at 184. The NRC suggests that instead EPA should "make uncertainties explicit and present them as accurately and fully as is feasible." Id. at 185; see also NRC Risk Assessment, supra note 14, at 7–8 (recommending that agencies prepare "written risk assessments that explicitly state the basis of choice among inference options"); cf. Preuss & White, supra note 79, at 331 cmt. at 340–42 (scientists expressing concern that point estimates mislead decisionmakers, but EPA scientist, Dr. Roy Albert, arguing that scientist's job is to "take a position" regarding the risk and "if it isn't that position [point estimate], then it's got to be another one").

82. In its default selection of the "multistage model" over several equally valid models used to extrapolate from high-dose effects to low-dose effects, for example, EPA justified the decision based on the model's better fit with available experimental evidence and its compatibility with current knowledge about biological processes related to cancer causation, see Latin, supra note 35, at 100, apparently forgetting its previous admissions that "[g]oodness-of-fit . . . is not an effective means of discriminating among models," and that "mechanisms of the carcinogenesis process are largely unknown and data are generally limited." EPA Guidelines for Carcinogen Risk Assessment, 51 Fed. Reg. 33,992, 33,997 (1986); see also Latin, supra note 35, at 104 (EPA chooses default scaling factor for extrapolation from animal test dosages on grounds that "certain pharmacological effects commonly scale according to surface area," but EPA provided neither scientific nor policy justification for this position). See generally id. at 95–105 (discussing failings of EPA's "good science" in carcinogen risk assessment guidelines).

83. Although policy choices were adopted at many points in the creation of the guidelines, they were generally referred to as scientific judgments. See, e.g., Latin, supra note 35, at 100 (noting that policy assumptions underlying choice of multistage model not discussed); id. at 103 (noting that EPA's decision to require proof of statistically significant number of tumors in specific organs in carcinogen guidelines was "mid-range position . . . [which] reflect[ed] an implicit social policy choice that is not required by the norms of good science and that cannot be resolved solely on the basis of scientific judgments").

The NRC similarly criticized EPA for failing to "set out individual [default] options . . . with ideal clarity." Science and Judgment, supra note 23, at 88. After listing eight fundamental default options selected by EPA in the cancer guidelines, the NRC noted that "EPA has never articulated the policy basis for those options." Id. at 88–89. The NRC could only guess at the basis for EPA's choices at each option. See id.; see also Melnick, supra note 17, at 256–57 (concluding that in 1979 ozone standard, rather than admitting that "the disappearance of thresholds requires regulators to make a political judgment about acceptable risk, the EPA has continued to justify its standards in terms of its scientific judgment about the probable location of the elusive threshold").

agency Regulatory Liaison Group (IRLG) cancer risk assessment guidelines, Marc Landy et al. similarly noted that mixed scientific and policy questions were presented as if they related to science alone: "The critical political judgments were bundled up in and concealed by words like conservative, prudent, significant, and reliably."[84]

Perhaps the most striking examples of the inadvertent science charade are the wildly different "scientific conclusions" reached by sister agencies or even sister departments of the same agency at the same time under the same administration concerning the carcinogenic potential of the same toxic substance.[85] In analyzing various agencies' efforts to regulate benzene, for example, Professor Latin discovered that EPA took a position different from the Occupational Safety and Health Administration (OSHA) on the same epidemiological studies.[86] Such dramatic inconsistencies in regulatory decisions regarding toxic risks, even under the same presidential administration, are virtually inevitable when standards reflect different scientists' unique biases and unexpressed policy judgments.[87] These inconsistencies can even include the decision about

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84. Landy et al., supra note 14, at 198; see also id. at 196 (IRLG's 1979 cancer guidelines "generally presume[ ] that questions about which tests and methods to use are scientific issues. . . . In most cases this view is simply asserted as if it were self evident, without acknowledging that there are other conceptions of how to view the problem."); id. at 196–97 (citing examples in IRLG guidelines where policy decisions are made to appear like scientific choices).

85. For example, regulation of natural carcinogens has produced a substantial split among government scientists. In a 1984 General Accounting Office study, scientists involved in the regulatory decision were divided into two groups. One was the "possibility of preventive benefit" school, which encouraged a public-wide, voluntary approach to reducing unknown cancer risks from diet. The other school was the "proof of preventive benefit" group, which demanded proof before taking action. See U.S. General Accounting Office, National Academy of Sciences' Reports on Diet and Health—Are They Credible and Consistent? 44–45 (1984). The Report summarizes:

> NAS [National Academy of Sciences] officials told us that it is not uncommon for two groups of scientists to review the same scientific data and come to different but supportable conclusions. No standard has been agreed upon among scientists or government policymakers about what scientific data are needed to support suggesting public health measures, such as dietary changes, to reduce the public's risk of developing long-term diseases such as cancer. Scientists whom we interviewed stated that they do not believe a standard of evidence is feasible because scientists could never all agree on a single set of standards and because each public health problem is unique. Because no standard exists, scientists make personal value judgments on the basis of scientific evidence which can result in legitimately different conclusions.

Id. at 30; see also Rushefsky, supra note 14, at 146 ("One task force study of some twenty-seven decisions made by various branches within EPA found considerable inconsistency in the risk assessments and risk decisions that were reached, going beyond differences created by divergent statutory mandates.").

86. See Latin, supra note 35, at 116; see also id. at 108 (concluding that in benzene regulatory proceedings from 1979 to 1984, "[d]ifferent regulatory agencies adopted different risk-assessment principles, relied on different types of scientific evidence, and reached different conclusions about the extent of benzene-related health hazards").

87. See Rushefsky, supra note 14, at 45.

whether a substance presents a risk worth regulating at all. The fear of such intra-governmental disputes has led the executive branch to create inter-agency task forces periodically when protective standards must be set for the same substance by more than one agency.[88] In this way the executive branch can informally discover and unite its agencies' varying hidden biases and policy judgments before they are disclosed to the public through embarrassing inter-agency "scientific" disputes.[89]

B. *The Intentional Charade*

In contrast to the unintentional charade, where bureaucrats inadvertently characterize the standard-setting task as a problem for science, in the intentional charade agency bureaucrats consciously disguise policy choices as science. The intentional charade typically occurs only after agency scientists have begun developing a standard. Once the wide-ranging political and/or economic implications of a standard proposed by agency scientists are understood, high-level agency officials become aware of the scientific uncertainties and begin to consider whether a weaker or a more stringent standard could be set by substituting different policy assumptions at the trans-scientific junctures. Although this means the decision on a final standard is often made arbitrarily (for example by selecting some undefined low- or mid-point between science-policy options), the result presented to the public is again masked in science, leaving no trace of the policy compromise that formed the basis for the standard.

A vivid illustration of the intentional science charade[90] can be seen when one compares EPA's actual decisionmaking process for revising the

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88. The IRLG, for example, was formed in the late 1970s in order "to develop a coherent, cross-agency approach to identifying carcinogens and assessing their risks." Jasanoff, supra note 69, at 183. Although the IRLG's guidelines proved useful to regulatory agencies, the guidelines were repudiated by the Reagan Administration, and the IRLG was disbanded in the early 1980s. See id. More recently, the National Performance Review, a task force created by the Clinton Administration to address regulatory reform, has recommended reconstituting and renaming a national scientific advisory board—the "National Science and Technology Council"—in order to improve regulatory science. This Council would offer uniform scientific advice to all agencies involved in science-based rulemakings. See Office of the Vice President, Accompanying Report of the National Performance Review: National Science Foundation and Office of Science and Technology Policy 7–9 (1993).

89. Landy et al. note the political advantages of combining agency forces in the IRLG. See Landy et al., supra note 14, at 174. Although not specifically identified by Landy et al., these political advantages undoubtedly included a more uniform inter-agency approach to standard-setting and risk assessment. The creation of the IRLG also allowed for greater pooling of agency technical expertise and reinforced the credibility of the agencies' standards. See id. As Eula Bingham, the OSHA Administrator at the time of formation of the IRLG, explained: "We saw the wisdom . . . of circling the wagons." Id. at 174 (quoting Interview with Eula Bingham, OSHA Administrator, conducted by Margaret Gerteis & Stephen R. Thomas, in Cincinnati, Ohio (Sept. 1, 1982)).

90. EPA's efforts to revise the ozone standard is not only one of the best illustrations of the intentional science charade, but it also appears to be the best-documented internal investigation of any toxic standard-setting effort. This could suggest that equally vivid

ozone standard under the Clean Air Act[91] with the agency's public account of that decision published in the Federal Register.[92] Scientific knowledge about ozone was so limited at the time of the EPA revision in the late 1970s that agency scientists were unable to reach consensus on a single quantitative standard,[93] leaving scientifically justified possibilities ranging from 0.25 parts per million (ppm) to 0.08 ppm.[94] In selecting a final standard, the EPA Administrator essentially struck a compromise between White House concerns for the economy on the one hand[95] and public health concerns on the other.[96] Administrator Costle later admitted that in selecting 0.12 ppm over the leading alternatives of 0.08, 0.10, or 0.15, "[i]t was [going to be] a political loser no matter what you did .... The minute you picked a number ... everybody can argue that it can't be that number, or it could just as easily be another number ... *[It] was a value judgment.*"[97]

Despite the Administrator's subsequent candor, EPA's public account of its rationale in selecting the 0.12 standard revealed none of the underlying policy considerations, but rather gave readers the opposite impression that the standard was selected based on scientific evidence.[98]

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accounts of the intentional science charade are missing only because of the limited number of in-depth case studies of agency standard-setting.

91. 42 U.S.C. § 7409(d) (1988). Both Landy et al., supra note 14, at 63–82, and Melnick, supra note 17, at 281–94, contain excellent behind-the-scenes accounts of the setting of the revised ozone standard.

92. See Proposed Revisions to the National Ambient Air Quality Standard for Photochemical Oxidants, 43 Fed. Reg. 26,962 (1978) [hereinafter Proposed Revisions]; Final Rulemaking, Revisions to the National Ambient Air Quality Standards for Photochemical Oxidants, 44 Fed. Reg. 8202 (1979) [hereinafter Final Rulemaking].

93. See Melnick, supra note 17, at 284, 288–89.

94. See id. at 287–88 tbl. 8-2.

95. The White House staff was joined by the Council on Wage and Price Stability, which presented data indicating that the costs of further control of ozone rose and the benefits of reductions dropped sharply at a standard of 0.16 ppm. See id. at 290.

96. Leading the health advocates was EPA Assistant Administrator David Hawkins who had joined EPA directly from the Natural Resources Defense Council (NRDC), one of the most prominent environmental public interest organizations. Hawkins insisted that the existing evidence did not warrant a relaxation of the existing 0.08 ppm standard for ozone. See id. at 289.

97. Landy et al., supra note 14, at 71 (quoting Interview with Douglas M. Costle, EPA Administrator, conducted by Marc Roberts, in Cambridge, Mass. (July 31, 1981) (emphasis added)). The common sense justification for 0.12 over alternative standards was EPA's conclusion that health risks were detected at ozone levels of 0.15 ppm, and thus selection of a standard of 0.12 would protect health with an "adequate margin of safety" required by the statute. See Melnick, supra note 17, at 291; see also Landy et al., supra note 14, at 71 (observing that an Assistant Administrator of EPA had a "feeling that there was a 'pretty clear' threshold around 0.15 ppm ... [a]bove 0.15 ppm the evidence was more clear cut"). Costle's decision may also have been influenced by the fact that a number of major cities had ozone concentrations in the range of 0.12 to 0.15 ppm and EPA wanted to maintain its control over state programs to ensure some further improvement in these areas. See Melnick, supra note 17, at 291–92.

98. While admitting that selection of the standard with an adequate margin of safety must be based on "*judgment*," see Final Rulemaking, supra note 92, at 8209, EPA

EPA concluded its fifteen page presentation of mind-numbing scientific justification in the final rulemaking[99] with a single acknowledgment that to the extent "[t]here is no collection of facts or medical evidence that permits selecting an undisputed value for the standard level," "[t]he Administrator must exercise the informed *scientific judgment* that Congress has authorized him to bring to bear on these difficult problems."[100] The economic impact of the selected standard or alternate standards, which

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misleadingly implied that this judgment was based solely on medical evidence. See, e.g., id. at 8213 (listing five scientific factors to guide agency's ozone standard setting); id. at 8216–17 (listing eight scientific factors considered by EPA in setting ozone standard). EPA also defended its standard by repeatedly stating that it was using its best judgment using the latest scientific knowledge. See id. at 8213 (responding to public concerns that SAB did not approve EPA's proposed standard); id. at 8215–17 (discussing scientific basis for primary standard); id. at 8217–18 (attempting to scientifically justify secondary ozone standard).

In contrast to the final rulemaking, in the proposed rulemaking EPA appeared more forthright and conceded that the "choice of a standard between zero and a level at which health effects are virtually certain (0.15 ppm) is necessarily subjective." Proposed Revisions, supra note 92, at 26,967. EPA quickly made up for its honesty by introducing in the next paragraph all of the scientific justifications (such as its "new understanding of the study that served as the primary basis for the 0.08 standard") for its ultimate conclusion that the "standard of 0.08 ppm does not appear necessary . . . [but] a standard above 0.10 ppm would not adequately protect public health." Id. In their analysis of the ozone standard, Landy et al. reach the same conclusion regarding the scientific appearance of both the proposed and final rulemaking, which they argue made it difficult to "understand either the science or the policy issues." Landy et al., supra note 14, at 75.

99. A superb example of EPA's incomprehensible regulatory doubletalk is its explanation of how it reached the all-important "probable effects level":

> Thus, adverse health effect thresholds for sensitive persons are difficult or impossible to determine experimentally, while the threshold for healthy persons or animals is not likely to be predictive of the response of more sensitive groups. In this notice of rulemaking EPA uses the terminology "probable effects level" to refer to the level that in its best judgment is most likely to be the adverse health effect threshold concentration. It is the fact that the adverse health effect threshold concentration is actually unknown that necessitates the margin of safety required by the Act.

Final Rulemaking, supra note 92, at 8203. EPA appears to acknowledge the tremendous scientific uncertainties in setting a probable effects level, yet suggests that the level has nevertheless been based on some number reached using EPA's "best judgment" in light of the available scientific data.

100. Id. at 8217 (emphasis added). Also tucked away on this fifteenth page is EPA's attempt to explain its decision to raise the standard from 0.10 to 0.12 ppm in less than seven months. After stating that EPA was swayed by "informed scientific opinion disputing the interpretation and application of [certain] studies" received "[d]uring the comment periods," id. at 8217, it went on to explain that:

> [b]ased on its current understanding of these studies, EPA has concluded that they do not dictate as wide a margin of safety as was established in the proposal. EPA does believe, however, that these studies do suggest the real possibility of significant human adverse health effects below 0.15 ppm. Consequently, the Administrator has determined that a standard of 0.12 ppm is necessary and is sufficiently prudent unless and until further studies demonstrate reason to doubt that it adequately protects public health.

Id.

were clearly considered by the Administrator,[101] were publicly disregarded by EPA as statutorily irrelevant[102] and summarized in four sentences near the end of the lengthy preamble.[103] In reviewing a chal-

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In fairness to EPA, the general counsel staff may have recommended that the agency present only a scientific justification for the regulation based on their reading of the narrow statutory mandate. In fact, in 1980 the D.C. Circuit did hold that Congress specifically precluded the agency from considering economic or associated policy factors in setting ambient air quality standards under Section 109 of the Clean Air Act, 42 U.S.C. § 7409 (1988). See infra notes 102 and 201 and accompanying text.

101. The Administrator met repeatedly with White House officials. See Landy et al., supra note 14, at 72–73. Costle even reportedly "postponed a previously scheduled press conference on the standard in order 'to review more economic data.' " Id. at 73. The involvement of the White House in standard-setting did not go unnoticed by challengers, however. In suing EPA for an unreasonably lax standard, the NRDC brought this involvement to the court's attention in challenging the standard. See American Petroleum Inst. v. Costle, 665 F.2d 1176, 1191 (D.C. Cir. 1981). NRDC's challenge was rejected because they had "failed to exhaust the administrative remedy specifically required by the Act," id. at 1192, but such involvement was upheld on the merits in another case. See Sierra Club v. Costle, 657 F.2d 298, 408 (D.C. Cir. 1981) (concluding that Presidential involvement in regulation is permissible if outcome is supported by factual record because court does "not believe that Congress intended that the courts convert informal rulemaking into a rarified technocratic process, unaffected by political considerations or the presence of Presidential power"). Congress also took notice. See Executive Branch Review of Environmental Regulations: Hearings Before the Subcomm. on Environmental Pollution of the Senate Comm. on Environment and Public Works, 96th Cong., 1st Sess. 232 (1979) (both chairman and ranking minority member of committee expressing concern over White House meddling in standard-setting process).

102. EPA noted that "the Clean Air Act specifically requires that National Ambient Air Quality Standards be based on scientific criteria . . . [and that] EPA interprets the Act as excluding any consideration of the cost of achieving such a standard in determining the level of the primary standard." Final Rulemaking, supra note 92, at 8219. In truth, however, the agency was split between the "strict constructionists" who viewed the Clean Air Act as precluding consideration of economic and technological factors and those favoring a more flexible interpretation. See, e.g., Jasanoff, supra note 69, at 105. EPA's public interpretation was later upheld by the D.C. Circuit in Lead Indus. Ass'n v. EPA, 647 F.2d 1130, 1148 (D.C. Cir. 1980) (concluding that "economic considerations play no part in the promulgation of ambient air quality standards under Section 109" of the Clean Air Act).

103. The only information provided on economic factors in the 19 page Federal Register preamble is as follows:

> Because the attainment problem in most urban areas is so severe, the relaxation of the standard is not expected to change the level of control requirements in the near term. The move to a 0.12 ppm standard will, however, eliminate the theoretical need for major control programs in many rural and wilderness areas that currently exceed the present standard.
>
> With the relaxation of the standard, EPA's economic impact analysis indicates that most urban areas are expected to achieve the standard by 1987. Even with aggressive control programs, however, it will be very difficult for some urban areas to achieve the standard within the next 10 years.

Final Rulemaking, supra note 92, at 8219. This "economic impact" statement is virtually identical to the statement EPA provided in its proposed rulemaking recommending a lower, 0.10 ppm ozone standard. See Proposed Revisions, supra note 92, at 26,969. The underlying economic analysis for the final rule was available only upon written request. See Final Rulemaking, supra note 92, at 8219. The paucity of information readily available

lenge brought by both industrial and environmental groups, the District of Columbia Circuit Court of Appeals refused to overrule the Administrator's decision, finding that in selecting the 0.12 standard EPA had taken "into account all the relevant studies . . . [and] did so in a rational manner" using "informed judgment."[104]

Less tangible but equally compelling proof of the intentional science charade is found in Mark Rushefsky's comparison of toxic risk guidelines issued by different presidential administrations. Rushefsky notes that although the guidelines appeared to be based completely on scientific considerations, they varied predictably from administration to administration and had clearly been influenced by differing political ideologies.[105] Rushefsky concludes that "[g]uidelines issued during the entire period under discussion (1976–1984) were permeated with values, even if they were not explicit."[106]

C. *The Premeditated Charade*

A final agency approach to standard-setting is to make a specific policy choice, whether it is pro-industry or favors overprotection of public health and the environment, and to introduce science only after the fact

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to the public on the economic factors resulting from the rulemaking or considered by the Administrator is particularly troubling given the large uncertainties in the science illuminated near the end of the preamble. See id. at 8215–17.

104. *American Petroleum Inst.*, 665 F.2d at 1187. The court's great deference to the agency's science in a situation where science had not determined the selection of the ultimate protective standard is likely attributable in large part to the recently decided *Lead Industries*, 647 F.2d 1130, which confirmed that EPA could not consider cost and technological feasibility in setting or revising ambient air quality standards. See *American Petroleum Inst.*, 665 F.2d at 1185.

105. See Rushefsky, supra note 14, at 41–44 tbls. 2.5 & 2.6. Rushefsky concludes that the existence of inferential gaps in the science, coupled with radical differences in the assumptions used for these inferences, provides unrebutted proof that different value judgments were used from year to year or from administration to administration. Further evidence of these intra-administration transitions, which appear to follow the political pulse on environmental issues more generally, can be seen in EPA's evolving assumptions for carcinogen risk assessment. During the early Reagan years when Ann Gorsuch was Administrator of EPA, EPA explicitly abandoned significant portions of the IRLG guidelines for cancer risk assessment, which were drawn up by Carter appointees. See Landy et al., supra note 14, at 268–69. When Ruckelshaus, the new Administrator of EPA, arrived to repair the agency's reputation, which had been tarnished under Gorsuch, the EPA position shifted again to advocate partial reacceptance of some of the IRLG principles for risk assessment (although the shift did not progress to adopt all aspects of the IRLG guidelines). See id. at 269. Despite fluctuations in political views, which appear to undergird these changes in carcinogen risk assessment, EPA's stated position throughout this period was puhlicly based on differences in scientific judgment rather than economic philosophies. See id. at 268–69; see also Latin, supra note 35, at 96 (similarly concluding that social policies and values adopted by agencies under Reagan Administration which lead to greater risks were typically not "made explicit nor applied in a consistent manner").

106. Rushefsky, supra note 14, at 175.

in order to scientifically justify the predetermined standard.[107] In contrast to the intentional charade, which has been identified as those instances where gaps in scientific knowledge become apparent only near the end of a standard-setting endeavor, the premeditated charade occurs when policy decisions are made in advance and guide selection of the science ultimately cited as support for a quantitative standard. The standard may not only exploit the policy flexibility permitted by the trans-scientific junctures, but also may disregard the available scientific evidence. Nevertheless, the standard, or the decision not to promulgate a standard, is presented to the public clothed in the mantle of science and supported by studies carefully selected to favor the agency's position.

Accounts of the premeditated charade in the early years of the Reagan Administration are the most abundant.[108] During that period

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107. See, e.g., Collingridge & Reeve, supra note 69, at 34 (proposing that in some cases "science is used to legitimate or rationalize political choices which have already been taken"); Greenwood, supra note 14, at 255 ("Regulatory agencies sometimes select a strategy before examining relevant scientific and engineering knowledge, then tailor their risk assessments and analyses to be consistent with that choice.").

The selective use of science advisory panels provides a counterintuitive illustration of the premeditated use of science to fortify policy choices. In its determination to treat carcinogens as nonthreshold pollutants, for example, EPA recoguized the essential nonscientific nature of the problem, but "cbose to rely totally on one expert panel whose conclusion was consistent with the one it wanted to reach and ignored other expert panels whose conclusions would have been inconsistent. The agency then claimed it was implementing the academy panel's recommendation, thereby disguising its ad hoc exercise of discretion." Id. at 229. Professor Ashford provides a similar account of the premeditated use of advisory committees:

> Governments have sometimes used advisory committees for little more than implementing a decision made before the committee was established, either by appointing members who will merely "rubber stamp" government decisions, or by appointing influential community leaders whose support is needed for implementation of a government decision.

Ashford, supra note 71, at 76–77.

108. See Rushefsky, supra note 14, at 175 (describing "political use of science" during Reagan administration). Perhaps coincidentally, the bulk of research done by Graham et al., supra note 12, occurred during the Reagan Administration. It is difficult to determine to what extent this might narrow their generalized conclusion that "actors in the policy process [of both formaldehyde and benzene regulation] tended to embrace the numbers when they supported their predetermined policy position and ignored or criticized the numbers when they led to contrary policy implications." Id. at 197. For accounts of the premeditated science charade occurring under President Reagan, see Control of Carcinogens in the Environment: Hearing Before the Subcomm. on Commerce, Transportation, and Tourism of the House Comm. on Energy and Commerce, 98th Cong., 1st Sess. 99, 101, 109 (1983) (statement of Frederica P. Perera, Senior Staff Scientist, Natural Resources Defense Council) (identifying Reagan's scientific assumptions which guaranteed risk-tolerant regulatory policy in cancer gnidelines); Jonathan Lash et al., A Season of Spoils: The Reagan Administration's Attack on the Environment 141 (1984) (reporting that EPA Administrator Gorsuch was committed to rescinding lead-in-gasoline rules before she had even seen any analysis of effects of the rule change or listened to advice of independent experts); id. at 173 (EPA senior science adviser testified that Assistant Administrator "Todhunter proposed that she alter her risk estimate according to a scientific theory that she had never heard of, before or since, to get a smaller risk figure

high-level officials attempted to eliminate or substantially weaken protective standards, and in each case these decisions were framed as decisions based on principles of "good science" which, according to the Administration, necessitated "hard proof of damage to health" before toxic materials could be regulated.[109] One of the best examples of Reagan's premeditated charade is EPA's decision in 1982 not to regulate formaldehyde under the Toxic Substances Control Act (TSCA)[110] because of the lack of conclusive data on the risk formaldehyde presented to human health.[111] EPA presented its decision as based almost exclusively on science[112] and insisted that risk assessment was a " 'scientific and

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[for fumigant EDB]."); Eliot Marshall, EPA's High-Risk Carcinogen Policy, 218 Science 975, 975 (1982) (quoting then-Rep. Albert Gore, Jr. who similarly criticized Reagan Administration's tendency to use science to justify political decisions to relax regulatory standards in order to reduce the burden on industry).

Although not ultimately charged, the Reagan Administration was also investigated by the House Committee on Science and Technology for composing an alleged "hit list" of EPA's scientific advisors to be used in order to achieve pre-determined policy goals for science-based environmental regulations. Over 90 scientists were identified and listed according to their ideology towards the regulation of risks, apparently to ensure that only those who supported more lax protective standards would be selected for prominent SAB positions. See Jasanoff, supra note 69, at 89.

109. See Lash et al., supra note 108, at 131; see also id. at 149 ("Scientists critical of the shift [to Good Science under Reagan] called it a 'covert' attempt to radically revise and soften regulations."); Latin, supra note 67, at 1662 & n.40 ("[T]here is abundant evidence that administrators [of EPA under Reagan] frequently chose to 'study' uncertain issues as a way to avoid resolving them.") (citing examples in footnote); Marshall, supra note 108, at 976 (noting that Reagan Administration allowed manufacturers of Ethylene bisdithiocarbamates (EDBC's) to apply for new production licenses because some of the scientific findings were inconclusive, even though EDBCs appeared to be carcinogenic); Frederica Perera & Catherine Petito, Formaldehyde: A Question of Cancer Policy?, 216 Science 1285, 1290 (1982) ("[I]t appears that EPA [under Reagan] is informally revising its cancer policy to decrease reliance on animal studies—a step that could have the effect of substantially delaying or indeed barring altogether protective action on substances such as formaldehyde, pending the development of positive epidemiological data.").

110. 15 U.S.C. § 2603(f) (1994).

111. EPA's public announcement of its decision was made on February 12, 1982, with a release of an internal, 16 page memorandum by John A. Todhunter, EPA Assistant Administrator for Pesticides and Toxic Substances, which provided the justification for the agency's decision. See Ashford et al., supra note 26, at 326. The memo is printed in its entirety in House Comm. on Science and Technology, Review of the Scientific Basis of the Environmental Protection Agency's Carcinogenic Risk Assessment on Formaldehyde, H.R. Rep. No. 216, 98th Cong., 1st Sess. app. B (1983) [hereinafter House Report on Formaldehyde Risk Assessment]. An earlier, four page memorandum by Don Clay, the Director of EPA's Office of Toxic Substances, to John Todhunter also set forth reasons for not regulating formaldehyde. Clay concluded that the available exposure data did not support a finding of " 'serious' " or " 'widespread' " harm. See Ashford et al., supra note 26, at 327 (quoting Memorandum from Don Clay to John Todhunter (Sept. 11, 1981), reprinted in Hearings Before the Subcomm. on Environment, Energy and Natural Resources of the House Comm. on Government Operations, 97th Cong., 1st Sess. 193 (1981)).

112. John Todhunter's primary justification for recommending against regulation in his memo was his "scientific" conclusion that although formaldehyde is a " 'potential

not a legal matter.' "[113] EPA's supporting scientific explanations, however, deviated significantly from both the prevailing scientific evidence regarding health effects of formaldehyde[114] and accepted EPA risk assessment assumptions[115]—deviations which EPA uniformly failed to identify

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animal carcinogen,' " concerns about human carcinogenicity are tempered by the fact that " 'quantitative and possibly qualitative results of exposure to formaldehyde appear to depend highly on exposure level, species, and route; that rats seem to be particularly sensitive to formaldehyde; and that long human experience does not seem to indicate any pressing concerns.' " Perera & Petito, supra note 109, at 1287 (excerpting John Todhunter Memorandum (Feb. 10, 1982)). Todhunter then based his ultimate conclusion that formaldehyde should not be regulated under TSCA on the following findings:

> (a) formaldehyde is a carcinogen in the rat by the inhalation route; (b) its carcinogenic potential appears to vary significantly with species and route; (c) under certain exposure conditions it could present some carcinogenic risk to humans; and (d) given available data the risk estimates suggest that certain populations may experience a carcinogenic risk—albeit low—due to formaldehyde exposure. However, because of the nature of the toxicology data and the unreliability in the exposure data one cannot reasonably conclude, at this time, that formaldehyde poses a siguificant risk among the U.S. population.

Ashford et al., supra note 26, at 327–28 (excerpting John Todhunter Memorandum (Feb. 10, 1982)).

113. Marshall, supra note 108, at 976 (quoting John Todhunter); see also Ashford et al., supra note 26, at 342 ("EPA's formaldehyde deliberations powerfully illustrate the ease with which matters of policy may be confused with matters of science . . . . [EPA's] analysis purports to justify, *in the name of science,* a risk assessment policy far less protective of human health than the agency's prior policy.") (emphasis added).

114. Dr. Norton Nelson, Chairman of the Board of Scientific Counselors of the National Toxicology Program and a professor of environmental medicine at New York University, testified:

> [T]he document is remarkable in the sense that in each issue examined, an extreme position is taken relating to the probable non-siguificance of the data on formaldehyde. It would perhaps be understandable for such an analysis to be prepared by industry . . . . To be put forward as a dispassionate examination of evidence . . . must be viewed as irresponsible.

Formaldehyde: Review of Scientific Basis of EPA's Carcinogenic Risk Assessment: Hearings Before the Subcomm. on Investigations and Oversight of the House Comm. on Science and Technology, 97th Cong., 2d Sess. 29 (1982). At the same proceedings, Dr. Roy Albert, Deputy Director of the Institute of Environmental Medicine at New York University and head of EPA's scientific advisory committee on carcinogenic risk assessment, testified that "[t]he exposition of the science was clearly tailored to fit the decision. The document is far too one-sided to be regarded as a balanced assessment of the cancer risks from formaldehyde." Id. at 36; see also Ashford et al., supra note 26, at 329–32 (outlining "significant lapses in scientific judgment and methodology" in Todhunter memorandum).

115. See Ashford et al., supra note 26, at 333 (accusing agency of adopting risk assessment assumptions that "represent the views of a minority within the scientific community"); id. at 341–43 (listing deviations from traditional EPA risk assessment assumptions); see also Graham et al., supra note 12, at 31 (noting that House Committee on Science and Technology report alleged that Todhunter memorandum " 'departed from traditional and widely supported principles for carcinogenic risk assessment' ") (quoting House Report on Formaldehyde Risk Assessment, supra note 111, at 21).

or explain.[116] Close observers of the decision alleged that EPA was simply manipulating science after-the-fact in order to justify a predetermined political decision that would benefit an important industry.[117] In fact, circumstantial evidence supports the charge that EPA's decision not to regulate formaldehyde was actually made prior to its scientific reassessment of the data.[118] Not surprisingly, after a series of congressional hearings and considerable controversy within the scientific community,[119] EPA rescinded its decision[120] and determined in 1984 that formaldehyde did present a major health risk and should be regulated, a decision that

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116. See Ashford et al., supra note 26, at 333 ("While [EPA's positions on science policy] . . . may not be 'wrong' in a purely technical sense, they demand justification. EPA neither acknowledged the need for such justification nor supplied any [for its 1982 decision not to regulate formaldehyde]."); id. at 340 (stating that in his 1982 formaldehyde memorandum, Todhunter failed "to acknowledge his departure from prior agency positions on many of the science policy issues involved").

117. In their in-depth examination of EPA's 1982 formaldehyde decision, Ashford et al. concluded that "any discussion of EPA's decisionmaking process [on the formaldehyde decision] may be superfluous. Considerable evidence suggests that the incoming EPA officials had determined their policy on formaldehyde long before any 'decisionmaking process' had been completed." Ashford et al., supra note 26, at 328. At the time of the decision, formaldehyde was a component in products that accounted for approximately eight percent of the U.S. gross national product. See Graham et al., supra note 12, at 9 & n.3 (citing undated Formaldehyde Institute study). EPA officials met with representatives of the Formaldehyde Institute and members of the formaldehyde industry in several "closed meetings" in May, July, and August of 1981, over six months before Todhunter issued his memorandum in February 1982 concluding that there was no scientific basis for regulating formaldehyde. See Ashford et al., supra note 26, at 325. Interestingly, the EPA official in charge of the meetings, EPA Deputy Administrator John Hernandez, characterized the meetings as " 'exclusively scientific' " and desigued solely to " 'shed some light' " on the " 'scientific issues.' " Id. (quoting The Environmental Protection Agency—Private Meetings and Water Protection Programs: Hearings Before the Subcomm. on Environment, Energy and Natural Resources of the House Comm. on Government Operations, 97th Cong., 1st Sess. 19 (1981)).

118. Formaldehyde was dropped as a regulatory priority seven months before Todhunter's scientific memorandum. See Ashford et al., supra note 26, at 328. Even more compelling was Todhunter's own testimony before congressional hearings during which he admitted that " '[w]hen [he] arrived at the Agency, . . . [he] was . . . informed that the Agency at that time had no intention of regulating formaldehyde other than conducting an exposure assessment over a 2-year period.' " Id. at 328 n.193 (quoting John Todhunter).

Also worthy of note is the fact that EPA insulated its internal deliberations on formaldehyde regulation from scientific review. See Nicholas A. Ashford et al., Law and Science Policy in Federal Regulation of Formaldehyde, 222 Science 894, 897 (1983) (EPA science advisory board recommended in October 1981 that agency submit formaldehyde issue to the National Academy of Sciences before reaching conclusion; instead agency permitted Todhunter to issue his technical memorandum without assistance).

119. See House Report on Formaldehyde Risk Assessment, supra note 111, at 22 (concluding that process used by EPA was scientifically questionable and gave the "appearance of impriority [sic] or bias"); Ashford et al., supra note 26, at 300 (discussing controversy and citing articles and congressional hearings where EPA's 1982 formaldehyde decision was criticized).

120. See 48 Fed. Reg. 52,507, 52,507 (1983).

was based on the same scientific information available in 1982.[121] This 180-degree reversal is attributable largely, if not exclusively, to the appointment of a new EPA Administrator who was selected specifically in order to restore the agency's tarnished image.[122]

The Reagan years were not the first time agencies appeared to manipulate science to justify predetermined regulatory ends. In its administrative infancy in the early 1970s, EPA was accused of distorting scientific knowledge in its costly Community Health and Environmental Surveillance System (CHESS) study, the results of which were used to support the agency's aggressive sulfur dioxide standard and its policies on tall stacks and on the prevention of significant deterioration of air quality.[123] Although Congress did not ultimately charge EPA with the deliberate manipulation of science,[124] a panel of scientists commissioned by the U.S. House of Representatives Committee on Science and Technology concluded that numerous "technical errors in measurement, unresolved problems in statistical analysis, and inconsistency in data in the 1974 CHESS Monograph render[ed] it useless for determining what precise levels of specific pollutants represent a health hazard."[125] The panel also found that "[t]he complexity of the document . . . impeded the public from acquiring an understanding of the results of the studies associated

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121. See 49 Fed. Reg. 21,870, 21,874 (1984) ("EPA has determined that by its 1976 criteria there is sufficient evidence to conclude that formaldehyde is a potential carcinogen in humans.")

122. See Graham et al., supra note 12, at 33 (noting that "[i]t is impossible to justify the policy reversal from Gorsuch to Ruckelshaus by pointing to changes in the available data" since additional studies conducted in the interim actually made the case for regulation weaker under Ruckelshaus); id. at 34 (concluding that reversal of formaldehyde policy under Ruckelshaus was "a political opportunity"; "Ruckelshaus was appointed to restore public confidence in the agency.").

A similar decision not to regulate formaldehyde made by OSHA mirrored EPA's premeditated charade. OSHA diverged from its agency policy on risk assessment in determining that formaldehyde should not be regulated, and it also failed to disclose these deviations. See Ashford et al., supra note 26, at 352 ("The OSHA review of the MIT [Massachusetts Institute of Technology] report also departs significantly from the agency's cancer policy, again without acknowledging or explaining the departure."). After exploring the circumstances surrounding OSHA's decision, Ashford et al. conclude that "[t]he possibility of *post hoc* rationalization looms large here." Id. at 353.

123. See Staff of House Comm. on Science and Technology, 94th Cong., 2d Sess., The Environmental Protection Agency's Research Program with Primary Emphasis on the Community Health and Environmental Surveillance System (CHESS): An Investigative Report 5 (Comm. Print 1976) [hereinafter CHESS Investigative Report]. The controversy originated in the scientific community and was intensified following a series of articles in the Los Angeles Times. See, e.g., W.B. Rood, EPA Study—The Findings Got Changed, L.A. Times, Feb. 29, 1976, at 1.

124. See Staffs of House Comm. on Interstate and Foreign Commerce and House Comm. on Science and Technology, 94th Cong., 2d Sess., Report on Joint Hearings on the Conduct of the Environmental Protection Agency's "Community Health and Environmental Surveillance System" (CHESS) Studies (Comm. Print 1976).

125. CHESS Investigative Report, supra note 123, at 12.

with policies of national importance."[126] Several years later, under the Carter Administration, the IRLG was again criticized for developing risk-averse policies on protection of the public health and then "produc[ing only] evidence that would justify stiff regulatory decisions."[127]

The Reagan years are also not likely to be the last time agencies manipulate science in order to justify predetermined policy endpoints. Detailed accounts of science-based rulemaking efforts occurring under Presidents Bush and Clinton are not yet available, and thus it cannot be determined whether and to what extent agencies have engaged in premeditated charades in more recent years. The series of incentives that lead agencies to engage in the science charade, outlined in the following part, however, make it highly probable that premeditated charades, as well as unintentional and intentional charades, have been a recurring phenomenon in the regulation of toxics throughout the 1990s.

III. Political, Legal, and Bureaucratic Incentives for Agencies to Engage in the Science Charade

Despite numerous accounts of a science charade, no serious attempts have been made to isolate the phenomenon,[128] or to determine why it continues to pervade the standard-setting process.[129] Although some of the reasons agencies disguise policy choices as science seem self-evident, an in-depth analysis of the incentives that motivate an agency and its employees is necessary for a full understanding of the scope and importance of the charade in contemporary toxic risk regulation. Far from uncovering incompetence or carelessness, such an analysis reveals that the agencies are responding to multiple political, legal, and institu-

126. Id. at 11. For an extended description of the CHESS study and its repercussions on the EPA, see Richard J. Tobin, The Social Gamble: Determining Acceptable Levels of Air Quality 102–06, 139–43 (1979).

127. Rushefsky, supra note 14, at 95–96.

128. Although there are dozens of concrete examples of the science charade occurring throughout the literature, see generally supra note 54 and accompanying text, the authors rarely compared their observations with other accounts. The failure of the authors to recognize similar occurrences in other parallel works is likely the result of the absence of any extended analysis of the existence or cause of the science charade in science-policy problems. The disconnectedness of each "observation," however, lends substantial support for the cumulative hypothesis that a science charade permeates the science-based standard-setting process.

129. A variety of commentators have suggested that agencies may seek increased legitimacy or decreased political accountability by disgnising their policy judgments as science. See Majone, supra note 18, at 15 ("Traditionally, government regulators have sought legitimacy for their decisions by wrapping them in a cloak of scientific respectability."); Roberts et al., supra note 26, at 120 ("Too many of the participants [in science-policy decisions] have good reasons *not* to distinguish scientific evidence from policy preferences, *not* to analyze carefully the various sources of technical disagreement, and *not* to accept responsibility for some decisions or judgments."). Beyond these common sense observations scattered at points in articles and books, there has been surprisingly little scholarly discussion of the comprehensive existence of or reasons for a science charade in regulation.

tional incentives to cloak policy judgments in the garb of science. In fact, no rational agency or administrative official acting in her own self-interest would expose the underlying policy choices when faced with the numerous benefits of engaging in the science charade and the high price to be paid for proceeding any other way.[130] Successful reform thus must subject agencies to a strong countervailing force.[131]

A. *Political Incentives*

The vast majority of toxic risk issues delegated to the agencies have momentous public policy consequences, often involving "tragic choices"[132] or tradeoffs between lives and jobs.[133] Despite the gravity of these issues, however, agencies are typically given only vague congres-

130. Cf. Peter H. Schuck, Legal Complexity: Some Causes, Consequences, and Cures, 42 Duke L.J. 1, 26 (1992) (identifying somewhat similar "internal rationality" to maintain complexity in legal system).

131. A successful reform of the science charade within EPA has not occurred voluntarily, despite EPA's apparent recognition of its tendency to overstate the scientific support for its rulemakings. Although the National Research Council has on two occasions called attention to the failure of EPA to identify or explain the policy choices embedded in its risk assessments, see NRC Risk Assessment, supra note 14, at 7–8; Science and Judgment, supra note 23, at 7, the agency has repeatedly failed to correct the problem, see Science and Judgment, supra note 23, at 91 ("In the decade since the NRC report, EPA has never articulated clearly its criteria for a departure [from default options]."), and it appears unlikely to remedy the situation in the near future. For example, although the EPA has acknowledged NRC's suggestion that "EPA articulate these default assumptions more clearly" and in response to this suggestion has proposed to revise pending cancer guidelines to better identify "default options and reasons for departing from them in particular instances," it does not mention its intent to make policy judgments more explicit. See EPA Science Policy Council, Report in Response to NAS Study on Risk Assessment (released June 30, 1994), reprinted in 1994 Daily Env't Rep. (BNA) No. 125, at E-2 to E-3 (July 1, 1994).

132. Guido Calabresi & Philip Bobbitt, Tragic Choices: The Conflicts Society Confronts in the Allocation of Tragically Scarce Resources 18 (1978) (defining "tragic choices" as those social choices involving distributions of scarce goods which will entail suffering or death by some persons not designated as beneficiaries).

133. See Melnick, supra note 17, at 239 (describing broad discretion given to EPA in setting standards for criteria air pollutants; "If the EPA sets excessively stringent standards, billions of dollars of unnecessary control costs will be imposed on the economy. If standards are too lenient, then the health of thousands of individuals will suffer."); Latin, supra note 35, at 95 ("It is important to stress that thousands of lives and billions of dollars in regulatory costs may depend on an agency's choice of controversial risk-assessment principles."). In a summary of the uncertainty inherent in the regnlation of trichloroethylene (TCE) in drinking water, Cothern et al. commented that the "estimates [of individual risk rates] provide a range of uncertainty equivalent to not knowing whether one has enough money to buy a cup of coffee or pay off the national debt." C. Richard Cothern et al., Estimating Risk to Human Health, 20 Envtl. Sci. & Tech. 111, 115 (1986). This great range of uncertainty can be attributed in large part to the compounding effect of numerous trans-scientific sub-questions embedded within a single risk assessment. For example, in a model attempting to estimate the risk of perchloroethylene, experts used only two alternative values for each of three trans-scientific sub-questions, but the final "risk estimates varied by a factor of 35,000—ranging from a low estimate derived from a nonlinear, weight-based extrapolation from a rat study, to a high estimate derived from a

sional direction on how to resolve them,[134] and yet face mandatory deadlines for the promulgation of protective standards and inevitable judicial challenges from industrial and environmental advocates once the standards have been selected. Since the agencies' success, and even the President's to some extent, is determined by the degree to which regulations mandated by statute are promulgated satisfactorily and noncontroversially, questions arising in the regulation of toxics present the agencies with a particularly bothersome vulnerability.[135]

Compounding the agencies' unenviable task are inconsistent public expectations with regard to the regulation of toxic substances. On the one hand, the public remains concerned about the health of the domestic economy and wants less governmental regulation of and greater governmental assistance for American industries.[136] On the other hand, the public appears to demand almost absolute safety from toxic risks,[137] a demand which can be attributed at least in part to a series of biases that

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linear, surface-area-based extrapolation from a mouse study." Nichols & Zeckhauser, supra note 44, at 18.

134. Vague congressional direction may even be strategic with regard to toxic risk regulation. Robert Percival notes that after enjoying "political benefits from enacting legislation, legislators can reap additional benefits by attacking lax implementation of the laws by administrative agencies .... [L]egislators also can score points against a president from an opposing party by exposing efforts to weaken the implementation of environmental statutes." Robert V. Percival, Checks Without Balance: Executive Office Oversight of the Environmental Protection Agency, Law & Contemp. Probs., Autumn 1991, at 127, 196; see also infra note 349 and accompanying text.

135. Cf. Jerry L. Mashaw & David L. Harfst, The Struggle for Auto Safety 226 (1990) (noting that the National Highway Traffic Safety Administration is "legally and politically exposed" because "[t]hey have a political job without a political mandate, and they are subject to judicial review for 'legality' ").

136. See National Opinion Research Center, General Social Surveys, 1972–1991: Cumulative Codebook 499 (1991) (public in years 1983–1987 and 1990 indicated preference for less government regulation of business); id. at 507 (public in years 1983–1987 and 1990 indicated preference for government to provide industry with the help it needs to grow).

137. See, e.g., Peter Huber, Safety and the Second Best: The Hazards of Public Risk Management in the Courts, 85 Colum. L. Rev. 277, 280–83 (1985) (asserting that lay public views every public risk as an "absolute bad"); cf. National Opinion Research Center, supra note 136, at 500 (public in years 1983–1987 and 1990 indicated a preference for more governmental spending on environment).

plague the lay person's perception of risk[138] and are exacerbated by serious deficiencies in the scientific education of the general public.[139]

Public officials faced with resolving these conflicting demands thus must resort to the science charade out of sheer political necessity. If the public insists upon regulatory goals that are mutually exclusive, and improved public education remains only a distant goal, the best or indeed the only way to pacify the public and ensure political survival is to conceal the underlying social compromise between protection of public health and the loss of jobs under the veneer of scientific truth.[140] Due to their

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138. The lay person's perception of risk is plagued by a variety of heuristics and biases which, when added together, would appear to lead to a very low public toleration of toxic risks. First, risk reductions that are certain, such as ensuring "zero risk" by reducing the probability of harm from 0.01 to 0.00, are valued much more by the public than outcomes that simply reduce the probability of harm by the same amount, for example by reducing the risk from 0.02 to 0.01, but which do not eliminate the risk completely. See Daniel Kahneman & Amos Tversky, Prospect Theory: An Analysis of Decision Under Risk, 47 Econometrica 263, 270 (1979). Second, the lay person shows a lower tolerance for *involuntary* risks, such as exposure to a carcinogenic substance emitted into the ambient air by a third party, than for *voluntary* risks which may pose even an greater probability of harm, such as skiing. See, e.g., Paul Slovic, Perception of Risk, 236 Science 280, 281–83 (1987). Third, the public typically overestimates the frequency of death resulting from cancers and other "dramatic and sensational" causes, see Paul Slovic et al., Facts Versus Fears: Understanding Perceived Risk, *in* Judgment Under Uncertainty: Heuristics and Biases 463, 467 (Daniel Kahneman et al. eds., 1982), and thus may place greater import on eliminating the causes of these types of deaths than eliminating other more ordinary risks which in reality may be more likely to cause death. Fourth, the lay person typically has greater aversion to risks which have delayed effects and irreversible consequences, such as cancer-causing agents, than to risks which have immediate effects or consequences that are temporary in nature. See William W. Lowrance, Of Acceptable Risk: Science and the Determination of Safety 93 (1976). Fifth, the public is more concerned about risks that are uncontrollable, such as health risks resulting from the discharge of hazardous substances into the environment, than those that they can control. In fact, one study revealed that the public was willing to accept controllable risks up to 10 times more than uncontrollable risks. See D. Litai et al., The Public Perception of Risk, *in* The Analysis of Actual Versus Perceived Risks 213, 219 tbl. 6 (Vincent T. Covello et al. eds., 1983).

139. The ranking of risks by scientific experts diverges markedly from the lay person's ranking, a difference that can be attributed in part to differences in scientific education. See generally Slovic et al., supra note 138, at 281 tbl. 1 (ordering perceived risk for various activities and technologies of lay people and experts); id. at 283 (noting that difference may result from experts' more technical conception of risk). In reflecting on reasons for the Alar scare, discussed infra text accompanying notes 160–171, Ronald Gots similarly concluded that a significant cause of the problem was the "crying need for public education to ensure more informed understanding of the line between science and perception and their regulatory responses." Ronald E. Gots, Toxic Risks: Science, Regulation, and Perception 254 (1993); see also infra note 342 and accompanying text.

140. See, e.g., Jasanoff, supra note 69, at 242 ("Delegating a sensitive issue to an advisory committee remains one of the most politically acceptable options for regulatory agencies, even when the underlying motive is to transfer a fundamentally political problem to the seemingly objective arena of science. FDA has frequently been criticized for using its committees in this manner . . . ."); Latin, supra note 35, at 93–94 ("The illusion that risk assessment is a purely scientific activity reduces the visibility and political accountability of policy judgments that often guide regulatory decisions on toxic hazards."). This desire for

inadequate scientific training, the public and the media are unlikely to recognize institutional policy choices embedded in hypertechnical scientific justifications.[141] Ironically, the agency may even enjoy enhanced credibility by engaging in the science charade since the public is likely to view a regulation based on science as superior to one in which policy consequences have been balanced by agency bureaucrats in inexact ways.[142] Congress's science-sounding mandates also lend credence to a regulatory approach that appears predominantly technical.[143]

B. *Legal Incentives*

Stronger and much more troubling are the legal inducements for the science charade that emerge from the same laws intended to keep agencies publicly accountable.

1. *Decreased Public Involvement.* — The Administrative Procedure Act (APA) requires agencies to solicit and respond to public comments on proposed regulations.[144] Controversial regulations can require several

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political neutrality may have also inspired the Governor of California to characterize the implementation of California Proposition 65 as a "scientific" endeavor. See Shaffer, supra note 71, at 1224. The trade-off to engaging in the science charade, and thereby representing that decisions are based solely on science, is that the agencies' technical competence will likely be questioned. See Greenwood, supra note 14, at 105. This, however, may be a welcome relief from political controversy which attends controversial policymaking.

In his imaginative article on complexity, Peter Schuck notes that included among the many beneficiaries of maintaining a complex (which is, or at least parallels, a hypertechnical) legal system are groups that complexity insulates from public accountability. See Schuck, supra note 130, at 26.

141. See supra Part I.B.

142. Although survey data indicates that the public's faith in science and scientists has been declining over the past few decades, see generally infra Part IV.C.3, survey data also suggests that when faced with a choice between entrusting decisions to the executive branch of the federal government or to the scientific community, the public prefers the scientific community by a rather wide margin. See National Opinion Research Center, supra note 136, at 197–200.

In the field of risk assessment, Ted Greenwood observed that the use of science advisory panels to oversee or comment on agency science often appeared to provide greater political protection for the agency. Greenwood provides several examples of expert panels deflecting criticism away from the agency and diffusing charges of "incompetence" which would invariably be leveled against the agency if an expert science panel had not been employed. For example, Greenwood states that "[w]hen OSHA published its draft coke oven standard that was based on conclusions that were inconsistent with existing knowledge, the agency could divert the ensuing criticism by claiming simply to have adopted the approach of the majority of the Standard Advisory Committee on Coke Oven Emissions." Greenwood, supra note 14, at 227; cf. infra note 335.

143. See infra Part III.B.4.

144. See 5 U.S.C. § 553(c) (1994) (requiring opportunity for public comment on rulemakings). In a series of cases beginning with Kennecott Copper Corp. v. EPA, 462 F.2d 846 (D.C. Cir. 1972), the D.C. Circuit set forth basic procedures which had to be followed by the agency in promulgating toxic standards under the Clean Air Act. The elements of these procedures are now followed in all agency standard-setting efforts which take the form of final rulemakings. They include requiring the agency to make available to

rounds of public comment and may generate considerable input from watchful citizens, public interest groups, and the relevant industry.[145] The comments become part of the administrative record.[146] If the validity of a final regulation is challenged in court, the court's review will be based in significant part on how well the agency responded to the public's comments.[147]

The APA's public participation provisions create daunting requirements for an agency charged with developing a controversial protective standard. Responding to and incorporating public comments in the administrative resolution of social policy issues is no simple matter. "First, social issues are less adequately understood, precise, and measurable (scientifically) than technical concerns. Second, expert decisionmaking bodies must also confront the highly emotional normative considerations that require the effective translation of social values and objectives into public policies."[148] These difficulties are compounded by other, more general complications associated with involving the public in decisionmaking, most notably the extensive time required to consider and respond to public comments and the enhanced value conflicts that result from full information and opportunities for debate. "It would appear, then, that a bureaucrat's life would be much easier if participation were not integrated into policy analysis."[149]

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the public the underlying data and methods; to provide a detailed explanation for the standard in a preamble; and to respond to all "significant" comments in the final rulemaking. See generally William F. Pedersen, Jr., Formal Records and Informal Rulemaking, 85 Yale L.J. 38, 52–55 (1975) (describing procedures in greater detail).

145. For example, a seemingly routine labor regulation proposed pursuant to the Fair Labor Standards Act in 1981 elicited over 10,000 separate comments. See International Ladies' Garment Workers' Union v. Donovan, 722 F.2d 795, 804 (D.C. Cir. 1983). A single Pre-Manufacturer Notification rule proposed by EPA under TSCA (which would require manufacturers to notify EPA prior to large-scale production of toxic substances) "brought forth 192 commentors at 29 public meetings, and 300 pages of comment raising 400 discrete issues, *each* requiring an EPA response. [EPA's] defense comprised 300 pages of response, 800 pages of economic analysis performed at a cost of $600,000, and 500 pages of related analysis on regulatory impact." Douglas M. Costle, Brave New Chemical: The Future Regulatory History of Phlogiston, 33 Admin. L. Rev. 195, 199 (1981).

146. See, e.g., Harold H. Bruff, Coordinating Judicial Review in Administrative Law, 39 UCLA L. Rev. 1193, 1196 (1992) ("Modern 'notice and comment' rulemaking under the APA generates an administrative record that can be accorded appellate review.") (footnote omitted).

147. See 5 U.S.C. § 706(2)(A) (1994) (reviewing court will set aside agency action, findings, and conclusions found to be arbitrary and capricious based on administrative record).

148. Jack DeSario & Stuart Langton, Citizen Participation and Technocracy, *in* Citizen Participation in Public Decision Making 3, 9 (Jack DeSario & Stuart Langton eds., 1987).

149. Mary G. Kweit & Robert W. Kweit, The Politics of Policy Analysis: The Role of Citizen Participation in Analytic Decision Making, *in* Citizen Participation in Public Decision Making, supra note 148, at 19, 33; see also Dorothy Nelkin, Science and Technology Policy and the Democratic Process, *in* Citizen Participation in Science Policy 18, 35 (James C. Petersen ed., 1984) ("Demands for involvement by citizens' groups with

The science charade offers agencies an opportunity to escape a significant portion of this policy conflict. While the APA mandates a process for public involvement, it provides almost no protections to ensure that agencies will explain the substantive bases for highly complex or technical rulemakings in a way that the lay public[150] can readily understand and challenge.[151] Agencies are thus able to find refuge from APA-generated public debates by layering rulemakings with scientific terminology and citations. This resort to scientific obfuscation will limit the pool of commenters to those with at least modest fluency in the scientific and technical jargon characteristic of a particular standard. Dr. Greenwood concludes that the resulting hypertechnical rulemakings impose a high cost of entry on those members of the public who wish to participate in environmental policy debates and ultimately succeed in significantly limiting the number of "unions, consumer groups, or environmental groups [that can] participate in any particular regulatory proceeding."[152] In science-

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different assumptions disrupt procedures, preclude accommodation, and raise political dilemmas.").

Shep Melnick notes the difference between standard-setting under the Clean Air Act in 1971, before procedures requiring extensive public comment and judicial review were instituted by the courts, see supra note 144, and standard-setting over the past decade, where years are spent with "EPA officials, interest groups, and independent scientists . . . debating each proposed revision and new standard." Melnick, supra note 17, at 255–56.

150. Use of the term "general public" or "lay public" refers to unorganized or only weakly organized groups of citizens who have an interest or tangible stake in the outcome of a decision. See generally Thomas O. McGarity, Public Participation in Risk Regulation, 1 Risk: Issues in Health & Safety 103, 108–09 (1990) (listing categories of "public" which consist of interested individuals and local public interest groups). This contrasts with well-organized advocacy groups, the representatives of which may be distanced from the risks at hand. See McGarity, supra, at 109–12 (discussing role of national public interest groups, regulated industry and trade associates, affected labor groups, and competitors); infra Part III.B.2.

151. The courts appear to focus their review on whether the explanation the agency does provide is supported by the evidence or otherwise appears to be "rational." See, e.g., Richard J. Pierce et al., Administrative Law and Process 304 (2d ed. 1992) (noting that courts have reversed agency actions because an agency "failed 'to give full consideration' to a factor, dismissed a factor with an 'unconvincing assertion', attempted 'to rely on generalized and conclusory policy consideration', provided 'abbreviated analysis' of an issue, or failed to give 'thoughtful consideration' to an issue") (footnotes omitted). The additional demand that an agency's explanation for its action be clear and capable of being understood by lay commentors appears not to have been imposed by the courts, particularly when the issues appear scientific. See infra Part III.B.3.

152. Greenwood, supra note 14, at 251. In order to keep pace with the agency's explanations for its standards, interest groups must have scientists, lawyers, economists, and often engineers on their staff. See id. at 178. "The Chemical Manufacturers Association . . . doubled its professional staff . . . and increased the number of Ph.D. scientists from two in 1970 to about 12 by 1980." Id. at 180. If a group does not have the budget to hire expert staff, they generally must seek the assistance of academics in order to ensure that their comments are as effective as possible. See id. at 179. Even when the general public does participate in science-policy regulatory issues, the results from at least one study suggest that the public's science is significantly discounted. See Ann Bray Comment, Scientific Decision Making: A Barrier to Citizen Participation in Environmental

policy matters where agencies can skillfully mischaracterize the bases for their decisions, then, the APA notice and comment procedure may have the actual effect of hindering, rather than enhancing, the public's participation in administrative decisions.[153]

2. *Interest Group Oversight.* — Any deficit in regulatory participation by the general public is assumed to be offset by the vigorous oversight of dozens of interest groups that span the ideological spectrum. National organizations representing industrial, environmental, consumer, and other interests are dedicated to ensuring that agency decisions will benefit their constituencies. The skills of the high-powered lawyers and scientists who staff these organizations should virtually guarantee that any agency sleight-of-hand in attempting to disguise the basis for policy choices will not go unnoticed.

Despite, or possibly because of, their savvy in science-policy matters, however, these advocates appear rarely, if ever, to challenge the agencies' consistent overstatement of the scientific bases for fundamental policy choices.[154] Instead, they become single-mindedly engaged in presenting opposing scientific justifications, demanding outside scientific review, or attacking the competence of the agency's science when it leads to results that run counter to their own unexpressed policy preferences.[155] Industry, for example, often advocates that protective standards be reviewed by a science advisory board in large part because this scientific review commonly entails extended delays,[156] and because industry believes that these

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Agency Decision Making, 17 Wm. Mitchell L. Rev. 1111, 1129 (1991) (agency staff in Minnesota EPA interviewed with regard to their acceptance of commentors' scientific data revealed that 48% of staff believed industry data was reasonably accurate, while only 3% of staff believed same for citizen data).

153. See infra Part IV.A.

154. In fact, in *Sierra Club v. Costle*, the Environmental Defense Fund argued that policy meetings held by EPA with White House officials, industry, and congresspersons after close of the comment period were improper in EPA's determination of new source performance standards for coal-burning power plants. The D.C. Circuit dismissed this charge, insisting that "we do not believe that Congress intended that the courts convert informal rulemaking into a rarified technocratic process, unaffected by political considerations . . . ." 657 F.2d 298, 408 (D.C. Cir. 1981).

155. See Case, supra note 79, at 280 (concluding that although environmental decisions are often challenged, resolution does not turn on policy but on "evaluation of the appropriateness of the scientific data and methodology"); Thomas O. McGarity, Some Thoughts on "Deossifying" the Rulemaking Process, 41 Duke L.J. 1385, 1400 (1992) (noting that commentators typically "pick apart the agencies' preambles and background documents and launch blunderbuss attacks on every detail of the legal and technical bases for the agencies' rules"); cf. Environmental Defense Fund v. EPA, 598 F.2d 62, 79, 83 (D.C. Cir. 1978) (court rejected industry's arguments that "EPA must demonstrate the toxicity of each chemical it seeks to regulate through studies demonstrating a clear line of causation between a particular chemical and harm to public health or the environment") (citing industry brief); Ethyl Corp. v. EPA, 541 F.2d 1, 37–38 (D.C. Cir. 1976) (court rejected industry's argument that EPA's lead standard had to be based on at least one "dispositive study").

156. See Greenwood, supra note 14, at 242; Graham, supra note 64, at 122.

boards traditionally "reach conclusions that [a]re scientifically more conservative [and] hence more sympathetic to business interests, than those advocated by administrative agencies or the courts."[157] An interest group may also resort to "counter-science" arguments when faced with the alternative course of engaging in unwinnable debates over policy, such as the proper level of risk aversion for protection of public health or the appropriate social cost, expressed in dollars, of an additional cancer.[158] Finally, experts within watchdog institutions may be driven to characterize science-policy debates as predominantly technical in order to preserve or enhance the perceived expertise and importance of their jobs or organizations.[159]

One of the best examples of this scientific dueling is the Natural Resources Defense Council's (NRDC's) attempt to ban Alar, a growth regulator used widely on apples,[160] and the scientific counterattacks mounted

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157. Jasanoff, supra note 69, at 59.

158. Ted Greenwood argues this point fervently in his book and parallel article:

> To discredit an agency or to mobilize political strength to effect change, interest groups of whatever stripe cannot merely complain in public that the agency acted contrary to their preferences. Such complaints would be discounted readily as advocacy by all except those who share the critic's interests or policy preferences. To argue that an agency is incompetent, however, is to raise an issue that both commands attention and erodes the agency's authority and legitimacy. No one disagrees with the assertion that agencies should be competent.

Ted Greenwood, The Myth of Scientific Incompetence of Regulatory Agencies, 9 Sci., Tech., & Hum. Values 84, 95 (1984). Greenwood, in his study of standard-setting under OSHA, concludes that "[t]here is no question that during the 1970s industry employed with considerable success the charge of agency incompetence as a defense against regulation." Greenwood, supra note 14, at 105. The current socio-political climate may also favor disinterested or technical-sounding public interest arguments for change. See, e.g., Steven Kelman, Making Public Policy: A Hopeful View of American Government 248–70 (1987) (by complaining about over-reliance on science, advocates may ultimately be providing ample ammunition to their opponents).

159. See, e.g., Schuck, supra note 130, at 31 ("For every new regulatory program or legal complexity, there is a set of corporate officials whose jobs and occupational advancement depend upon understanding, complying with, and managing it."); cf. Boris I. Bittker, Dedication: James S. Eustice, 45 Tax L. Rev. 1, 3–4 (1989) (humorously referring to tendency of tax lawyers to perpetuate complexity for personal and financial reasons).

160. Alar, which is the trade name for the chemical daminozide, was introduced in the United States in the 1960s and used by apple growers to keep ripening apples on the trees and red during post-harvest storage. See Alar: Not Gone, Not Forgotten, 54 Consumer Rep. 288, 288 (1989). Alar was considered a pesticide and was registered by EPA under the Federal Insecticide, Fungicide, and Rodenticide Act in 1963. See Gots, supra note 139, at 248. Concern over the carcinogenicity of daminozide and its byproduct, 1,1-(unsymmetrical) dimethylhydrazine (UMDH), began in the early 1970s. See id. In 1985, following a series of reviews and meetings, EPA published a notice of intent to cancel registrations permitting the use of daminozide on foods. EPA's Scientific Advisory Panel concluded that EPA's information was inadequate for a cancellation and EPA postponed cancellation pending the development of better data. See id. at 249. In 1989, based on the results of studies conducted between 1985 and 1989, EPA again published a notice of intent to cancel daminozide, but EPA extended the use for an additional 18 months pending the cancellation proceedings. See id.

by both industry and the EPA. Although " '[a] good scientist [could] argue the [Alar] case either way,' "[161] both NRDC and the industry neglected to disclose that their points of difference with EPA were over risk assessment policy assumptions that could not be grounded in science[162] and instead, apparently for strategic reasons, presented the controversy as one over science. NRDC staff cited the quantitative results of their statistics with misleading precision, reporting in their widely disseminated study that Alar causes an "estimated 240 cancer cases per 1,000,000 population among children who are average consumers of Alar-treated food, and a whopping 910 per 1,000,000 . . . for heavy consumers,"[163] and charging in a subsequent interview on 60 Minutes that "Alar is 'a cancer-causing agent that is used on food' and 'the EPA knows [it] will cause cancer in thousands of children over their lifetime.' "[164] NRDC also orchestrated a direct attack on EPA's science, alleging that EPA had relied on outdated consumption data and had drastically underestimated the consumption of certain foods by preschoolers, but NRDC failed to indicate the tremendous scientific uncertainty regarding its own risk assessment estimates.[165] The response by industry was equally deceptive in its characterization of the Alar debate as one concerning "good sci-

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A leading national environmental organization, the NRDC, was unsatisfied with EPA's delay and launched a major media campaign against Alar. With the help of a public relations firm, NRDC targeted a number of powerful media sources, which included airing a story on the 60 Minutes television program, arranging a news conference with Meryl Streep to announce the formation of NRDC's "Mothers and Others for Pesticide Limits" campaign, and releasing a publication, Intolerable Risk: Pesticides in Our Children's Food. See Joseph D. Rosen, Much Ado About Alar, Issues in Sci. & Tech., Fall 1990, at 85, 87–88.

161. Eliot Marshall, A is for Apple, Alar, and . . . Alarmist?, 254 Science 20, 22 (1991) (quoting Charles Aldous, former EPA toxicologist who at the time was employed at California State Department of Food and Agriculture, on carcinogenicity of Alar).

162. See Leslie Roberts, Alar: The Numbers Game—The Dispute over Cancer Danger from Alar Highlights Just How Uncertain Risk Assessment Is, 243 Science 1430, 1430 (1989) ("What's lost in all the charges and counter-charges [on Alar] is a sense of just how squishy the numbers are, on either side. Risk estimates . . . really represent a best guess, built on myriad assumptions, some of which are invariably value laden.").

The major divergence between the risk assessment used by NRDC and that used by EPA stemmed from equally valid, but different selections of potency factors (the number of cancers likely to arise from a given dose) and differences in the estimated exposure (how many apples children eat). See id. For a more extensive discussion of the specific differences between risk assessment assumptions, see Gots, supra note 139, at 251 ("These differences [between NRDC, EPA, Uniroyal, and other groups regarding carcinogenicity of Alar] are based on the levels of the chemical to which experimental animals were exposed and on the numerous and often irreconcilable assumptions underlying their respective risk assessments.").

163. Rosen, supra note 160, at 87.

164. Id. at 88 (quoting 60 Minutes (CBS television broadcast, Feb. 26, 1989)).

165. See Leslie Roberts, Pesticides and Kids, 243 Science 1280, 1280–81 (1989) (discussing NRDC report); Joseph D. Rosen, supra note 160, at 87–88 (1990) (identifying weaknesses in NRDC's risk assessment, which include using arguable math, arguable food consumption data, and arguable potency factor).

ence."[166] Although EPA did not resort to direct, counter-science attacks, its initial reaction to NRDC's campaign did not assist in dispelling the characterization of the debate as one exclusively over science.[167] A confused public panicked and boycotted Alar-tainted apples[168] as a result of NRDC's powerful science-based campaign. Only a few months later, Uniroyal, the manufacturer of Alar, voluntarily withdrew the product from the market,[169] despite growing scientific consensus both within the U.S.[170] and abroad that Alar was not a potent carcinogen.[171]

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166. A nonprofit organization funded primarily by industry attempted to "set the record straight" in the Alar controversy by taking out a full-page advertisement asserting that: 1) "There is no scientific evidence that residues in food from regulated and approved use of pesticides have ever been the cause of illness or death in either adults or children," and 2) allegations that residues cause cancer are without "scientific merit" because they "are based exclusively on studies that expose rats and mice to enormous doses of chemicals." Advertisement by American Council on Science and Health, Our Food Supply is Safe, N.Y. Times, April 5, 1989, at A11, quoted in Robert V. Percival et al., Environmental Regulation: Law, Science, and Policy 494 (1992).

167. EPA immediately refuted the NRDC report in a press announcement: " 'The overall risks from pesticides in the diet are small, and the risks are outweighed by the benefits pesticides bring to society. . . . EPA is concerned about the potentially higher pesticide exposure to children and infants and routinely takes this into account when evaluating the risks such exposures may pose.' " Roberts, supra note 165, at 1280 (quoting John Moore, EPA's acting deputy administrator).

168. See, e.g., Gots, supra note 139, at 251 (reporting that New York City and Los Angeles removed apples from school cafeterias in response to Alar scare); Alar: Not gone, Not Forgotten, supra note 160, at 292 (Consumer Reports published testing results of daminozide concentrations in various brands of apple juices). Aaron Malinsky, President of Waldbaum's Supermarkets, wrote to *Consumer Reports*:

> Because of your timely report on *Alar* in apple juice . . . we were able to take prompt action to cancel a recent sale . . . and remove [certain juices] from our shelves . . . . You may be assured that those two brands will not be returned to our shelves until we are satisfied that they do not present any potential health hazard to our customers.

Aaron Malinsky, President of Waldbaum's Supermarkets, Letters, 54 Consumer Rep. 352 (1989).

169. See Gots, supra note 139, at 251 ("[I]n June, Uniroyal signed an agreement with the EPA to stop sales immediately and recall all stocks of food on which daminozide had been used.").

170. In 1991, EPA completed its toxicology analysis on Alar and concluded that it was half as carcinogenic as originally estimated in its 1989 report and well below the figure estimated by NRDC in its 1989 report. See Marshall, supra note 161, at 20. Interestingly, the resulting evidence that Alar might not only be far less carcinogenic than presented by NRDC, but even less carcinogenic than predicted by EPA in its 1989 findings has prompted apple growers in Washington State to sue the NRDC, CBS, and NRDC's media advisors for $200 million for knowingly misleading the public with regard to the risks of Alar in order to get the public's attention. See id. The court ultimately granted the network's motion for summary judgment. See Auvil v. CBS "60 Minutes", 836 F. Supp. 740, 741 (E.D. Wash. 1993).

171. The British government, through an expert panel appointed by Parliament, concluded that Alar presented " 'no risk to health.' " Marshall, supra note 161, at 22 (quoting expert panel). A United Nations panel comprised of the World Health Organization and Food and Agricultural Organization similarly concluded that Alar was

This strategic behavior by interest groups, who are believed by administrators and legislators to oversee the agencies and keep them accountable to the public, has the contrary effect of lending still greater legitimacy to the agencies' science charade. The public, Congress, the courts, and any skeptics remaining inside the agency are left with little doubt that the dispute will ultimately rest with the scientific experts.

3. *Judicial Review.* — The misrepresentation of policy issues as science would ordinarily be expected to be exposed in the end by judicial review. Such is not the case, however. A careful examination of the case law strongly suggests that the courts are exacerbating, rather than discouraging, the agencies' misidentification of toxic standard-setting as resolvable by science.[172] This implicit encouragement of the science charade is manifested in several ways.

First, and perhaps most well-established, is the courts' general insistence that agency decisions be based on "substantial evidence"[173] or at least not be "arbitrary [and] capricious."[174] For toxic standards this means that detailed technical explanations for all aspects of a final toxic

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" 'not oncogenic in mice' " and "set a high tolerance for Alar residues in food." See id. (quoting expert panel).

172. See Melnick, supra note 17, at 241, 243 ("[C]ourt decisions forced the EPA to base its actions on scientific evidence" yet this result erroneously assumed that "the standard-setting process . . . is essentially a technical task, not a political one."). The actual impact judicial review has on the behavior and strategy of the agencies is still an open question. In the setting of toxics standards, however, there seems to be general agreement that the effects are significant and generally result in substantial delays in the pace of regulation promulgations. See, e.g., Landy et al., supra note 14, at 124 ("[V]ery substantial resources were consumed [by the EPA in its standard-setting to] meet[ ] the requirements of administrative procedure and anticipating litigation."); John M. Mendeloff, The Dilemma of Toxic Substance Regulation: How Overregulation Causes Underregulation at OSHA 121 (1988) (reporting that one of OSHA's directors of health standards noted that concern over whether standard will hold up in court was leading source of delay); W. Kip Viscusi, Risk by Choice 14 (1983) (arguing that "[t]he moratorium on new health risk regulations during the final three years of the Carter administration can be traced to the uncertainties raised by the benzene case and related court tests of OSHA's authority.").

173. Administrative Procedure Act, 5 U.S.C. § 706(2)(E) (1994); see, e.g., Universal Camera Corp. v. NLRB, 340 U.S. 474, 477–91 (1951) (defining substantial evidence standard).

174. Administrative Procedure Act, 5 U.S.C. § 706(2)(A) (1994). The "arbitrary and capricious" test is generally thought to be more deferential to the agency than the "substantial evidence" test, see Abbott Lab., Inc. v. Gardner, 387 U.S. 136, 143 (1967), although some courts have suggested that the difference is only one of semantics. See Associated Indus. v. United States Dep't. of Labor, 487 F.2d 342, 349 (2d Cir. 1973).

In some cases, the courts consider in their review whether the agency has taken a "hard look" at the available evidence in reaching their decision. This test originated with Judge Leventhal in reviewing an agency's consideration of comments under the APA, see Pikes Peak Broadcasting Co. v. FCC, 422 F.2d 671, 682 (D.C. Cir. 1969), and in reviewing an agency's consideration of the environmental impacts of its activities under the National Environmental Policy Act. See Natural Resources Defense Council, Inc. v. Morton, 458 F.2d 827, 838 (D.C. Cir. 1972). The courts thus seek to ensure that the agency has produced a "fully informed and well-considered decision." Vermont Yankee Nuclear Power Corp. v. Natural Resources Defense Council, Inc., 435 U.S. 519, 557–58 (1978).

standard are required.[175] The best known example of this judicial insistence on quantitative precision is the *Benzene* decision,[176] in which the Supreme Court dismissed OSHA's argument that the science was too uncertain to determine the level at which the carcinogen benzene becomes unsafe. Alone among the other regulatory agencies, OSHA had frankly admitted that cancer risks could not be quantified with any scientific precision.[177] Justice Stevens, writing for the plurality, insisted that in order to promulgate a valid worker protection standard, "the Agency [must] show, on the basis of substantial evidence, that it is at least more likely than not that long-term exposure to 10 ppm of benzene presents a significant risk of material health impairment."[178] As a result of the Supreme Court's *Benzene* decision, OSHA has found itself forced to engage "in this exceedingly precise analysis with full knowledge that the estimates provided by existing risk assessment models could vary millionfold, depending upon the model selected."[179] Other federal agencies have also felt

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175. See Melnick, supra note 17, at 356 (reviewing courts have focused "their review on the quality of the scientific evidence supporting the EPA's standards"). Justice Scalia highlights the demands courts have placed on agencies in providing support for rulemaking: "[Reviewing courts require] that the agency publish and permit the public to comment on all data and studies on which it intends significantly to rely, and that the agency justify the rule in detail and respond to all substantial objections raised by the public comments." Antonin Scalia, Back to Basics: Making Law Without Making Rules, Regulation, July–Aug. 1981, at 25, 26.

A dramatic illustration of the courts' demand for supporting technical evidence is the Third Circuit's remand of an Emergency Temporary Standard because of OSHA's very abbreviated (less that 100 words) technical justification for the standard. See Dry Color Mfr. Ass'n v. United States Dep't of Labor, 486 F.2d 98, 105–06 (3d Cir. 1973); see also Public Citizen Health Research Group v. Tyson, 796 F.2d 1479, 1481 (D.C. Cir. 1986) (OSHA's rationale for not issuing short-term exposure limit for ethylene oxide was not supported by substantial evidence); Asbestos Info. Ass'n v. OSHA, 727 F.2d 415, 424–26 (5th Cir. 1984) (enforcement of emergency temporary standard for asbestos stayed because no substantial evidence to support OSHA's conclusion that risk is "grave" or standard is "necessary"); Environmental Defense Fund, Inc. v. EPA, 636 F.2d 1267, 1283 (D.C. Cir. 1980) (EPA's PCB standard was not supported by substantial evidence); National Lime Ass'n v. EPA, 627 F.2d 416, 455 (D.C. Cir. 1980) (EPA's regulations for particulate matter remanded for more adequate technical justification); Texas Indep. Ginners Ass'n v. Marshall, 630 F.2d 398, 409 (5th Cir. 1980) (OSHA cotton dust regulation invalid because OSHA's assumptions were without an "adequate evidentiary basis"); Asarco, Inc. v. EPA, 616 F.2d 1153, 1162 (9th Cir. 1980) (no "reasoned scientific basis" for EPA to require stack sampling facility in 1000 foot smelter).

176. Industrial Union Dep't v. American Petroleum Inst., 448 U.S. 607 (1980).

177. See Mendeloff, supra note 172, at 117.

178. *Industrial Union*, 448 U.S. at 653; but see id. at 655 ("[T]he requirement that a 'significant' risk be identified is not a mathematical straitjacket."); id. at 666 (Powell, J., concurring) (stressing that agency not precluded from setting standard when reasonable quantification cannot be accomplished by "known methods"). For an insightful critique of the *Benzene* opinion, see Howard A. Latin, The Feasibility of Occupational Health Standards: An Essay on Legal Decisionmaking Under Uncertainty, 78 Nw. U. L. Rev. 583, 583 (1983) (arguing that courts lack adequate conceptual framework for dealing with factual uncertainties).

179. McGarity, supra note 155, at 1403.

compelled to provide detailed technical explanations for their standard-setting decisions to avoid the outcome reached in *Benzene*.[180]

By correlating the survival rate of an agency standard with the extent of technical explanations garnered in its support,[181] the courts offer agencies strong and virtually inescapable incentives to conceal policy choices under the cover of scientific judgments and citations.[182] In extraordinary cases like *Benzene*, courts have invalidated standards because the agency has admitted that science could not fully justify the standard.[183] In the majority of cases, however, the courts simply require a

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180. See Graham et al., supra note 12, at 151 ("Since the Supreme Court's 1980 benzene decision, federal agencies have felt compelled to use such numerical risk estimates to support both priority-setting and standard-setting decisions."); Frank B. Cross, Beyond *Benzene*: Establishing Principles for a Significance Threshold on Regulatable Risks of Cancer, 35 Emory L.J. 1, 12–43 (1986) (arguing that judicial review forces agencies to provide detailed technical explanations for standards); Latin, supra note 35, at 132 ("[T]he Court's benzene decision has . . . induced federal agencies to conclude that they must provide quantitative risk estimates even if they lack confidence in the resulting judgments."); Richard J. Pierce, Jr., Two Problems in Administrative Law: Political Polarity on the District of Columbia Circuit and Judicial Deterrence of Agency Rulemaking, 1988 Duke L.J. 300, 311 (arguing that courts often require "that agencies 'find' unfindable facts and support those findings with unattainable evidence").

181. Even those scholars who insist that invalidation of agency rulemakings is rare seem to admit that the survival rate is correlated with "the artfulness of agency opinion writers, the skills of government lawyers, and the plausibility of agency claims of 'expertise.' " Stephen G. Breyer & Richard B. Stewart, Administrative Law and Regulatory Policy: Problems, Text, and Cases 361–62 (3d ed. 1992).

Interestingly, many scholars have praised the courts' insistence on detailed technical explanations for rulemakings. See, e.g., Pedersen, supra note 144, at 60 (arguing that judicial review of "the minute details of methodology, data sufficiency and test procedure" used by an agency in rulemakings is a "great tonic" for a regulatory program); William H. Rodgers, Jr., A Hard Look at *Vermont Yankee*: Environmental Law Under Close Scrutiny, 67 Geo. L.J. 699, 706 (1979) ("The hard look doctrine plays no favorites, it is advanced as enthusiastically by industry as it is by environmentalists."); Richard B. Stewart, The Development of Administrative and Quasi-Constitutional Law in Judicial Review of Environmental Decisionmaking: Lessons from the Clean Air Act, 62 Iowa L. Rev. 713, 766 (1977) ("[A]n occasional dose of rigorous scrutiny is salutary.").

182. See McGarity, supra note 14, at 750 ("[T]o the extent that a reviewing court is willing to defer to agency 'expertise' in choosing between the theories of equally respectable scientists, the court will simply force the agency to disguise policy decisions as factual determinations" and this will ultimately result in less stringent judicial review of agency policy choices). But see Ethyl Corp. v. EPA, 541 F.2d 1, 37–38 (D.C. Cir. 1976) (court readily recognized policy judgments inherent in science-based standard-setting and did not require agency to base standard on "a single dispositive study," but instead found that EPA's "decision may be fully supportable if it is based, as it is, on the inconclusive but suggestive results of numerous studies"). Many authors have previously noted that the effect of this rigorous judicial review of agency decisions is to discourage agency rulemaking altogether or to force ad hoc policy decisions on specific issues. See Mashaw & Harfst, supra note 135, at 225; Pierce, supra note 180, at 302–03.

183. Three years after the Supreme Court's *Benzene* decision, the Fifth Circuit invalidated the Consumer Product Safety Commission's (CPSC's) reliance on a single study to set a protective standard for urea-formaldehyde foam insulation. Seemingly ignoring the absence of scientific data and the real health risks presented by urea-

thorough, technical accounting of how the agency determined the standard,[184] with the implicit threat of remanding a rule if the agency's policy choices are discovered, and the court believes a better path could have been followed.[185]

Second, and paralleling this general demand for substantial justification, is the tendency of many courts to defer to the agency as expert when the issue is framed as scientific in nature.[186] In fact, if an agency can

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formaldehyde foam insulation, the court held that "it is not good science to rely on a single experiment . . . . To make precise estimates, precise data are required." Gulf South Insulation v. United States Consumer Prod. Safety Comm'n, 701 F.2d 1137, 1146 (5th Cir. 1983). "The agency did not respond to the court's remand, and in the eight years since the Fifth Circuit's decision, CPSC has not attempted to regulate a single additional toxic product." McGarity, supra note 155, at 1419. For a scientific critique of the *Gulf South* decision, see Ashford et al., supra note 26, at 363–68. The authors conclude that "the Fifth Circuit's analysis [is] . . . unpersuasive in its evaluation of CPSC's cancer risk assessment for formaldehyde." Id. at 368. For more general criticisms of the failure of the courts to recognize scientific uncertainty and the resultant need for intermittent policy choices, see Devra L. Davis, The "Shotgun Wedding" of Science and Law: Risk Assessment and Judicial Review, 10 Colum. J. Envtl. L. 67, 85 (1985); Latin, supra note 35, at 131; Howard Latin, Ideal Versus Real Regulatory Efficiency: Implementation of Uniform Standards and "Fine-Tuning" Regulatory Reforms, 37 Stan. L. Rev. 1267, 1329 (1985); Richard A. Merrill, The Legal System's Response to Scientific Uncertainty: The Role of Judicial Review, 4 Fundamental & Applied Toxicology S418, S424–25 (1984).

184. See, e.g., Natural Resources Defense Council, Inc. v. EPA, 824 F.2d 1258, 1289 (1st Cir. 1987) (remanding portion of high level radioactive waste regulations because of EPA's failure to explain limit of 1000 years for duration of individual protection against such wastes); Ohio v. EPA, 798 F.2d 880, 882 (6th Cir. 1986) (remanding emissions limitations because of use of diffusion model which was not tested at site); American Mining Congress v. Thomas, 772 F.2d 617, 638–39 (10th Cir. 1985) (remanding portion of EPA's regnlations governing cleanup and disposal of uranium mill tailings because of EPA's failure to adequately address surface and groundwater quality concerns), cert. denied, 476 U.S. 1158 (1986); PPG Indus., Inc. v. Costle, 630 F.2d 462, 465–66 (6th Cir. 1980) (remanding "nonattainment" designation for portion of county for sulfur dioxide because EPA failed to explain model analysis); American Petroleum Inst. v. OSHA, 581 F.2d 493, 506–08 (5th Cir. 1978) (setting aside dermal contact provision because of OSHA's failure to collect existing scientific information).

185. This threat is indeed quite damaging, see infra notes 192–195 and accompanying text.

186. Judge Bazelon has perhaps been the most outspoken jurist on the judiciary's reluctance to oversee an agency's scientific judgments:

> Socrates said that wisdom is the recognition of how much one does not know. I may be wise if that is wisdom, because I recognize that I do not know enough about dynamometer extrapolations, deterioration factor adjustments, and the like to decide whether or not the government's approach to these matters was statistically valid.

International Harvester Co. v. Ruckelshaus, 478 F.2d 615, 650–51 (D.C. Cir. 1973) (Bazelon, C.J., concurring) (footnote omitted); see also Central Ariz. Water Conservation Dist. v. EPA, 990 F.2d 1531, 1540 (9th Cir.) (noting that courts should defer to agency judgments when the case involves technical rulemaking decisions), cert. denied, 114 S. Ct. 94 (1993); Pennsylvania v. EPA, 932 F.2d 269, 272 (3d Cir. 1991) ("The complexities of accurate emission measurement and the highly technical knowledge needed in relating particular measurements to Clean Air Act standards render deference to the EPA's expertise particularly appropriate here."); Reynolds Metals Co. v. EPA, 760 F.2d 549, 560

represent to the court that its technical explanations for a toxic standard lie on the "frontiers of scientific inquiry,"[187] a term that could easily encompass trans-scientific issues, the agency decision is subject only to the most cursory review.[188] By insisting on technical justifications on the one hand, and pledging not to scrutinize the accuracy of the technical expla-

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(4th Cir. 1985) (court does not sit "as a scientific body minutely comparing competing research methods and results"); Connecticut Fund for the Env't v. EPA, 696 F.2d 169, 178 (2d Cir. 1982) (deferring to agency expertise regarding modeling analysis for sulfur pollution); United Steelworkers v. Marshall, 647 F.2d 1189, 1263 (D.C. Cir. 1980) (deferring to technical expertise of OSHA with regard to complex model relating air-lead concentrations to blood-lead), cert. denied, 453 U.S. 913 (1981).

Although not explicitly giving the agency greater deference, in some cases courts do admit that when there are conflicting scientific views it will not "second-guess" the agency, even if it finds contrary views are more persuasive. See, e.g., Sierra Club v. United States Dep't of Transp., 753 F.2d 120, 129 (D.C. Cir. 1985) (deferring to agency standard instead of considering conflicting proposals because there was no abuse of agency discretion); Avoyelles Sportsmen's League v. Marsh, 715 F.2d 897, 917 (5th Cir. 1983) (difference of opinion does not mean that agency's decision is arbitrary or capricious).

While not every court is willing to defer to the expertise of the agency, see, e.g., National Lime Ass'n v. EPA, 627 F.2d 416, 451–52 (D.C. Cir. 1980) (hard look used for agency science), the general trend appears to be deference when the science is not easily accessible. See Melnick, supra note 17, at 356 (concluding that judges have wisely realized their own limitations and overturned only those standards based on "glaring error"); see also Christopher F. Edley, Jr., Administrative Law: Rethinking Judicial Control of Bureaucracy 57, 100 (1990) (identifying the "problem of [limited] judicial oversight of science and expertise" and concluding that "the more the issue at hand looks amenable to technically expert bureaucratic decision making, the more likely the court is to conclude that it is a question of fact"); Yellin, supra note 35, at 1325 ("[D]espite the interplay of the technical and political, with some notable exceptions judicial reluctance to address technical issues remains strong.") (footnotes omitted).

187. See, e.g., *National Lime Ass'n*, 627 F.2d at 454 & n.143 ("frontiers of scientific inquiry" means "judgment predicated on limited evidence when additional evidence cannot be adduced or adduced in the near future").

188. While some judicial panels have recognized that agency decisionmaking on the "frontiers of scientific knowledge" will necessarily require policy judgments, see, e.g., Lead Indus. Ass'n v. EPA, 647 F.2d 1130, 1147 (D.C. Cir.), cert. denied, 449 U.S. 1042 (1980); Ethyl Corp. v. EPA, 541 F.2d 1, 27 (D.C. Cir.) (en banc), cert. denied, 426 U.S. 941 (1976), these panels did not require the policy judgments to be made explicit nor did they identify when an agency was reaching a policy judgment on the "frontiers of scientific knowledge" rather than a technical judgment. See, e.g., *Lead Indus. Ass'n*, 647 F.2d at 1163 (conceding that line between policy judgments made "on the frontiers of scientific knowledge" and technical judgments is not bright one and concluding that both must be based on whether decision "is reasonable when examined in light of the evidence in the record").

In many opinions, however, the courts do not even allude to the possibility that policy judgments play any role on the "frontiers of scientific knowledge," and instead defer to the agency as expert when the science appears controverted or complex. See, e.g., Baltimore Gas & Elec. Co. v. Natural Resources Defense Council, Inc., 462 U.S. 87, 103 (1983) ("When examining this kind of scientific determination [i.e., one at the "frontiers of scientific knowledge"], as opposed to simple findings of fact, a reviewing court must generally be at its most deferential."); Natural Resources Defense Council, Inc. v. EPA, 902 F.2d 962, 968 (D.C. Cir. 1990) (deferring to agency decisions on frontiers of scientific knowledge), vacated in part, appeal dismissed in part, 921 F.2d 326 (D.C. Cir. 1991).

nations on the other, the courts not only fail to prevent the science charade, they make it almost obligatory.[189]

Finally and most disturbing is the recent trend of reviewing courts to reverse agency policy decisions set forth explicitly in agency rulemakings[190] in what seems to be a random or "lottery" fashion.[191] In a study of the National Highway Traffic Safety Administration (NHTSA), Jerry Mashaw and David Harfst conclude that this judicial second-guessing of agency policy choices played a significant role in causing NHTSA to abandon efforts to set systematic policy and to resort instead to ad hoc recalls of automobile defects,[192] making " 'administrative policymaking' an oxymoron."[193] Richard Pierce similarly concludes that erratic judicial review of agency policy decisions may cause "rulemaking as a vehicle for making [explicit] policy decisions [to] . . . soon be relegated to a chapter in a

189. Although sporadic judicial review of agency science has occurred on a few occasions, see, e.g., *National Lime Ass'n*, 627 F.2d at 435 (remanding EPA's new source performance standards for lime manufacturing plants based on "doubts about the representativeness of data"); Cincinnati Gas & Elec. Co. v. EPA, 578 F.2d 660, 663–64 (6th Cir. 1978) (concluding that EPA's decision to ignore private studies and experts' conclusions was arbitrary and capricious), this review does not appear to counteract the strong incentives for agencies to provide comprehensive technical explanations for toxic standards. Rather, it seems to fuel the charade by compelling the agency to provide in-depth scientific explanations for its underlying policy choices in order to avoid the slight, but unbearable, threat of reversal. The agency's characterization of policy as science therefore remains unchallenged. See, e.g., Edley, supra note 186, at 64–66 (citing examples of judicial misidentification of decisionmaking paradigms as science rather than policy). But see id. at 85–86 (suggesting that court might also look to agency's political or legal basis for rulemaking in validating rule when under challenge for being nonscientific).

190. See Melnick, supra note 17, at 371 (discussing import of "judges' preconceptions of environmental issues and the regnlatory process" as affecting reversal of agency policy embedded in rulemakings); Stephen G. Breyer, Judicial Review of Questions of Law and Policy, 38 Admin. L. Rev. 363, 384 (1986) ("The langnage in several important cases decided in the last two decades suggests an increasingly less hesitant judiciary, courts that are more ready to overturn agency policy decisions that they consider unreasonable.").

191. See Pierce, supra note 180, at 301–02 (arguing that judges on D.C. Circuit in recent years may be substituting their own interpretations of ambignous statutes for agencies' and randomly reversing agency policymaking in rulemakings). Cf. Melnick, supra note 17, at 266 (discussing D.C. Circuit bias for overprotection in setting air toxics standards under Clean Air Act prior to 1990 Amendments and concluding that D.C. Circuit gives agencies the benefit of the doubt provided the standard errs on the side of overprotection). Justice Breyer points out the interesting anomaly this strict judicial scrutiny of agency policy decisions presents when compared to the far greater deference the courts typically provide agencies in interpreting the law. As Justice Breyer has argued, one would think this is "the exact opposite of a rational system." Breyer, supra note 190, at 397.

192. See Mashaw & Harfst, supra note 135, at 225 ("The result of judicial requirements for comprehensive rationality has been a general suppression of the use of rules."); Jerry L. Mashaw & David L. Harfst, Regulation and Legal Culture: The Case of Motor Vehicle Safety, 4 Yale J. on Reg. 257, 273–74, 303 (1987).

193. Mashaw & Harfst, supra note 135, at 227.

legal history book."[194] Technical conclusions that have no apparent connection to systematic policy are not subjected to this more random and intrusive form of judicial review.[195] As a result, agencies may have yet another judicially inspired reason to disguise their policy choices as politically neutral, scientific judgments.

4. *Science-Based Legislative Mandates.* — Legislative mandates that make science the basis for standard-setting[196] also provide legal incentives for agencies to engage in the science charade or at least indulge the agencies' inclination to overstate the scientific grounding of a proposed protective standard. For example, under section 109(b)(1) of the Clean Air Act, Congress directs EPA to set ambient air quality standards at a scientifically determined level sufficient "to protect the public health" with an "adequate margin of safety."[197] It would seem that such science-based mandates not only invite, but actually compel the science charade due to the threat of reversal if an agency frankly acknowledges the inherent scientific uncertainties and its requisite retreat to economic, technological, and other policy considerations in reaching a final, quantitative standard.

Closer examination of these legislative mandates, however, reveals that although they are undoubtedly providing further incentives for agencies to engage in the charade, they are unlikely to be determinative in causing the science charade except in a few limited instances. First, many of the science-based standard-setting provisions expressly require agencies to consider the economic costs or technological feasibility of proposed standards[198] or have been interpreted to allow the agency to con-

194. Pierce, supra note 180, at 313. Other examples also exist in the literature. In his study of the Department of Energy, Peter Schuck found that the procedural obstacles posed primarily by judicial review and executive order led the agency to abandon policymaking through rulemaking in favor of policymaking through individual adjudications by an office authorized to make special exceptions to existing rules. See Peter H. Schuck, When the Exception Becomes the Rule: Regulatory Equity and the Formulation of Energy Policy Through an Exceptions Process, 1984 Duke L.J. 163, 194–96.

195. See supra notes 186–188 and accompanying text; see also Edley, supra note 186, at 59 ("[I]t is not unusual for an agency to decide based substantially on political calculations but to explain the conclusion in apolitical terms in hopes of securing what under the circumstances appears to be a form of legitimacy more resistant to judicial intervention.").

196. See supra note 15.

197. 42 U.S.C. § 7409(b)(1) (1988).

198. In some statutes, Congress requires agencies to engage in a form of cost-benefit balancing by limiting regulation to the prevention of "unreasonable" risks, or those risks for which the costs in terms of adverse effects are not offset by their benefits to society. See, e.g., Federal Insecticide, Fungicide, and Rodenticide Act § 3(c)(5)(d), 7 U.S.C. § 136a(c)(5)(D) (1994) (registration of pesticide requires a showing that it "will not generally cause *unreasonable* adverse effects on the environment") (emphasis added); Toxic Substances Control Act § 4(a)(1)(A)(i), 15 U.S.C. § 2603(a)(1)(A)(i) (1994) (agency must require testing based on potential "*unreasonable* risk of injury to health or the environment") (emphasis added); id. § 2605(a) (regulatory restrictions will be imposed if "a chemical substance . . . presents or will present an *unreasonable* risk of injury to health or

sider the economic or technological factors if the agency deems those factors relevant to the inquiry.[199] Second, although a statutory mandate that appears to require standards to be based predominantly on science will provide still greater legitimacy to the agency's science charade, the agencies generally prefer to adopt the most flexible interpretation of such mandates in order to meet a vast array of regulatory needs and stave off unnecessary judicial challenges.[200] Only two legislative mandates have been interpreted by the courts to preclude the agencies from considering economic and technological feasibility in setting standards.[201] Thus,

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the environment") (emphasis added). In other statutes, Congress directs regulation to be based specifically on economic or technological feasibility. See, e.g., Occupational Safety and Health Act, 29 U.S.C. § 655(b)(5) (1988) (permanent standards should be set at level "which most adequately assures, *to the extent feasible*, . . . that no employee will suffer material impairment of health or functional capacity") (emphasis added). See generally Percival et al., supra note 166, at 438–39 fig. 4.1 (providing summary of federal statutes regulating toxic substances that require some consideration of cost or technological feasibility).

199. See American Textile Mfrs. Inst., Inc. v. Donovan, 452 U.S. 490, 509 (1981) (finding that although OSHA is not required to conduct cost-benefit analysis, OSHA is required to consider feasibility of standard); Natural Resources Defense Council v. EPA, 824 F.2d 1146, 1163, 1165 (D.C. Cir. 1987) (finding that the Administrator may consider cost and technological feasibility in setting emission standards under Section 112 of the Clear Air Act; initial determination of "safe," however, must be based solely on science).

200. For example, extended delays and regulatory paralysis experienced by EPA in setting air toxics standards under Section 112 of the Clean Air Act, 42 U.S.C. § 7412 (1988) (amended 1990), coupled with amended, strict statutory deadlines for the promulgation of toxic standards, led the agency to abandon science entirely and to base standards instead on levels capable of being achieved by the best technology. See Graham, supra note 64, at 130–37. The agency's courageous reading of its science-based mandate to permit an exclusive technology-basis for standard-setting was refuted by dicta, see Hercules, Inc. v. EPA, 598 F.2d 91, 112 (D.C. Cir. 1978) ("Congress enacted section 112 [of Clean Air Act] . . . without provision for considerations of feasibility."), and questioned by scholars. See, e.g., Graham, supra note 64, at 132, 134 n.225 ("The EPA's legal defense of the technology-based approach to standard setting is a remarkable exercise in statutory (re)interpretation.") (citations omitted). Yet the agency appeared to consider the benefits of a broad and arguably impermissible reading of its mandate to outweigh the risks of judicial review. When the agency was finally challenged, the court held that while the agency could consider economic and technological feasibility in setting standards, a pure technology-basis for the standards was unsupported by the statutory language and legislative history. See *Natural Resources Defense Council*, 824 F.2d at 1163–66 (EPA must first make a scientific determination of a "safe" level based solely upon risks to health; technology-based approach fails to take "safe" level into account). This is not the only time the agency has voluntarily adopted a technology basis for setting standards when its mandate clearly called for some scientific grounding. See supra note 7.

201. Section 109 of the Clean Air Act, 42 U.S.C. § 7409 (1988), has been interpreted to prohibit the EPA from considering economic and technological feasibility in setting ambient air quality standards. See Lead Indus. Ass'n v. EPA, 647 F.2d 1130, 1148 (D.C. Cir.), cert. denied, 449 U.S. 1042 (1980). Prior to *Lead Industries*, EPA did consider the cost of alternative standards in its revision of the ambient air quality standard for ozone, although these nonscientific deliberations were not publicly acknowledged, due at least in part to EPA's interpretation of the statute as precluding considerations of cost. See supra notes 95–104 and accompanying text. McGarity reports that even after the D.C. Circuit prohibited the agency from considering various policy considerations in setting national

although science-based mandates provide an incentive for agencies to engage in the science charade, they appear to play a determinative role only in the exceptional cases where the courts have held that agencies are not permitted, under any circumstances, to take into consideration economic and technological feasibility.

C. *Institutional Incentives*

Individual decisionmakers are also inclined, for reasons which appear to relate primarily to career advancement, to exaggerate the role of science in setting standards.

1. *Nonscientists.* — Challenges to the official's authority to make policy arise from virtually all sectors of the government,[202] and thus agency officials who are assigned responsibility for standard-setting face numerous, deep-seated institutional incentives to cover policy judgments with scientific justifications.[203] As Thomas McGarity observes, "[I]f the [agency regulatory] analyst confronts the inherent uncertainties of her predictions and alerts the decision maker to her general lack of confidence, she risks rejection by decision makers who demand greater accu-

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ambient air quality standards in *Lead Industries*, the EPA still engaged in a full cost-benefit analysis of these standards, although the analyses are not read by the Administrator in determining whether to approve the recommended protective standard. See Thomas O. McGarity, Regulatory Analysis and Regulatory Reform, 65 Tex. L. Rev. 1243, 1320 (1987).

The Delaney Clause in the Food and Drug Act similarly prohibits agencies from considering economic and technological factors in deciding whether to list color or food additives as safe. See 21 U.S.C. §§ 348(c)(3)(A), 376(b)(5)(B) (1988) (stating that additive may not be listed as safe if it is "found . . . to induce cancer in man or animal"). In contrast to Section 109 of the Clean Air Act, however, Congress did provide much more definitive, risk averse policy for the agencies' determination of what constitutes protection of the public health, thus eliminating the need for the agency to form judgments for many trans-scientific junctures common to other protective standard-setting endeavors. In fact, the Delaney Clause has been heavily criticized precisely because of its policy inflexibility. See, e.g., Richard Merrill, FDA's Implementation of the Delaney Clause: Repudiation of Congressional Choice or Reasoned Adaptation to Scientific Progress?, 5 Yale J. on Reg. 1, 2–3 (1988). The most unclear aspect of the Delaney Clause from the perspective of the agency is whether it allows an exemption for additives which pose "de minimis" human health risks. This question was resolved for color additives by the D.C. Circuit, see Public Citizen v. Young, 831 F.2d 1108, 1122 (D.C. Cir. 1987), cert. denied, 485 U.S. 1006 (1988) (concluding that agency may not list a color additive as safe, even if the risks to human health are at best "de minimis"), and by the 9th Circuit for food additives, see Les v. Reilly, 968 F.2d 985, 990 (9th Cir. 1992) (finding that EPA's de minimis risk policy for food additives that induce cancer is contrary to provisions of Delaney Clause).

202. For example, the ultimate authority of EPA came under question early in its infancy when its creator, President Nixon, maintained a strong hand in all decisions produced by the agency. The agency only gained its independence from constant White House oversight when its Administrator, William Ruckelshaus, threatened to quit unless his authority was acknowledged. See George C. Eads & Michael Fix, Relief or Reform: Reagan's Regulatory Dilemma 49–50 (1984).

203. Cf. supra note 159.

racy. Thus, the analyst faces almost irresistible pressures to gloss over uncertainties in making quantitative predictions."[204]

The prospect of having one's decisions scrutinized in congressional investigations and hearings,[205] high-level White House meetings,[206] routine inter-agency reviews,[207] and even in extensive intra-agency "red border review"[208] can lead an official to run for the cover of science. Indeed, not only an individual official but an entire agency office will "prefer minimal external interference with its activities" and resent other organizations' participation in reviewing and clearing its proposed standards.[209] Camouflaging fundamental agency biases and policy judgments about health protection with citations to the scientific literature provides the official or agency office with considerable immunity from attacks by others who are otherwise willing to second-guess a standard whose development consumed much of the officials' time and energy.[210] While recourse to the science charade will not lessen the number of "decision

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204. McGarity, supra note 201, at 1290. See generally Anthony Downs, Inside Bureaucracy 77 (1967) (noting that "all types of officials tend to exaggerate data that reflect favorably on themselves and to minimize those that reveal their own shortcomings"); id. at 84 (listing as general motives of bureaucratic officials desire for power, prestige, convenience, and security).

205. See McGarity, supra note 155, at 1427 ("Although agencies are not much concerned about congressional review when they assemble the detailed technical support for rules, they must be constantly aware of probable congressional reaction to major policy decisions made during individual rulemakings."); cf. Erwin G. Krasnow & Lawrence D. Longley, The Politics of Broadcast Regulation 74–75 (1978) (describing important influence of congressional investigations on Federal Communications Commission).

206. See, e.g., Greenwood, supra note 14, at 174 (noting that "the political and organizational cost to the agencies of being criticized by the White House . . . was high enough to influence their policy choices").

207. Agency dread of extended and potentially devastating Office of Management and Budget (OMB) review is undoubtedly an important inducement for agencies to engage in the science charade. It is well established that "[m]ost agency officials are quite resentful of the lack of respect that OMB economists have for agency expertise, and they jealously guard agency prerogatives against OMB usurpation of decision-making authority." McGarity, supra note 155, at 1433. Robert Percival observed that OMB "[r]egulatory review . . . inspired EPA to increase its analytic capabilities, which has increased its ability to withstand pressure from the Executive Office." Percival, supra note 134, at 161 (also quoting one EPA official who observed that regulatory review under President Carter resulted in regulations that were "more scientifically aggressive").

208. See, e.g., Greenwood, supra note 14, at 140 (intra-agency reviews are frequent and often extensive).

209. See id.

210. Peter Schuck has perhaps stated this position most strongly: "[T]echnical rules promote agency autonomy. Being more opaque to the generalist institutions like Congress and the media that seek to influence it, such rules make agencies more difficult to control and help obscure their pursuit of controversial policies." Schuck, supra note 130, at 31 (footnote omitted); see also James Q. Wilson, Bureaucracy: What Government Agencies Do and Why They Do It 245–46 (1989) (discussing how regulatory agencies present "complex oversight problems" for Congress because of technical issues and reliance on "experts"); Kweit & Kweit, supra note 149, at 21 (arguing that "internal logic, quantification, and unfamiliarity [of the underlying analytic techniques] tend to create an

points" a toxic standard must pass through in the agency or the government as a whole,[211] lengthy and hypertechnical discussions which permeate a science-based rulemaking are likely to reduce dramatically the level of scrutiny at each stage of review.

At least one case study lends credence to the possibility that individual agency decisionmakers engage in the science charade in order to win their battles within the agency, within the executive branch, and against elected officials.[212] In defending his selection of an ozone standard against an attack by Congress,[213] for example, the EPA Administrator admitted that if he could obtain from scientists their idea of the right numbers, "it would ultimately lend more credibility to the decision."[214] Armed with the numbers, he could then go to Congress and defend his decision "by saying I not only reviewed the advice of EPA scientists on this but I went outside EPA and reviewed the advice of reputable independent scientists."[215]

2. *Scientists.* — Agency bureaucrats are not the only administrative class of characters who seem to benefit from the science charade: agency scientists and scientific panels are also rewarded when a problem is characterized as resolvable by science.[216] Philosophers, sociologists, and gen-

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aura of inviolability to policy proposals, thus helping bureaucrats to defend policy turf during periods of threat") (citation omitted).

Disguising policy judgments as scientifically ordained may also prevent the discovery of policy judgments that are dominated by one or more agency officials' private values or biases. Although there is no direct evidence that an agency official would deliberately engage in the science charade in order to further his or her own political agenda, there is general evidence that private values can dominate the public decisionmaking process, see John D. Steinbruner, The Cybernetic Theory of Decision: New Dimensions of Political Analysis 145–46 (1974), and that once like-minded officials agree on the appropriate values for a decision, they can become blinded to all evidence to the contrary. See id. at 121–22 (observing that organizational and political groupings which form in bureaucracy can result in reinforcement of shared judgments on policy matters and citing examples in history).

211. For a discussion of the potential importance of the number of decision points affecting agency deliberations, see Mashaw & Harfst, supra note 135, at 228.

212. In their examination of EPA's attempts to revise the ozone standard in the late 1970s, Landy et al. observed that "[b]ureaucratic combat . . . proved to be a poor way to illuminate difficult and interlinked technical policy choices. Too many agency participants seemed to view their responsibilities in terms of overcoming internal opponents rather than learning from them . . . ." See Landy et al., supra note 14, at 80. The authors concluded that the result of this internal battle was compromises and agreements that tended to confuse and possibly hide key policy choices. See id. at 80; see also id. at 285 (concluding that EPA attempted to "strengthen its own hand" within government by asserting that ozone standard was technical issue).

213. See supra notes 90–104 and accompanying text.

214. Landy et al., supra note 14, at 72 (quoting Interview with Douglas Costle, EPA Administrator, conducted by Marc Roberts, Cambridge, Mass. (July 31, 1981)).

215. Id.

216. See, e.g., Gieryn, supra note 22, at 792. Dr. Gieryn not only provides examples of scientists deliberately characterizing the bounds of science to suit their professional goals, but he also discusses instances in which scientists found themselves arguing opposing views

eral observers of science have noted that in situations when the field of science is likely to be advanced, scientists may categorize issues as within the province of science that under most other circumstances would be categorized as "nonscience."[217]

In the case of toxics regulation, the science charade confers several benefits on scientists. First, it allows them to control access to the resolution of all questions that include even the slightest component of science, and to do so generally with minimal interference from lawyers and governmental officials.[218] Philip Handler, former president of the National Academy of Sciences, has argued that "most members of the public usually don't know enough about any given complicated technical matter to make meaningful informal judgments," and thus science-policy decisions should be left to the "knowledgeable wise men [sic] [of science]."[219] Second, when problems concerning the regulation of toxics are character-

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on the delineation of science and nonscience in their "simultaneous pursuit of separate professional goals." Id. For example, "[f]or the NAS [National Academy of Sciences] Panel on scientific communication and national security, technological fruits are placed 'inside' science when the goal is justification of public support for science, but they are excluded when the goal is protection of the autonomy of scientists from government regulation." Id.

217. See id.; see also supra notes 51–52 and accompanying text.

218. See, e.g., Greenwood, supra note 14, at 191 ("[A] professional's influence within an agency often derives from the presumption of expertise in a particular field" which can cause agency experts to represent that conclusions are based on scientific knowledge or judgment, even if they are not.); Brooks, supra note 54, at viii ("[T]he first instinct of the scientists is to close ranks and produce a consensus that papers over their disagreements and the underlying uncertainties. This course of action is powerfully reinforced by regulators who need seemingly objective information."); Nelkin, supra note 149, at 36 (Scientists "have interpreted demands for [public] participation as an indication of antiscience attitudes. They fear that lay involvement would threaten their autonomy and bring external controls that would infringe on freedom of inquiry and virtually paralyze the research process.").

219. Philip Handler, In Science, "No Advances Without Risks," U.S. News & World Rep., Sept. 15, 1980, at 60. The lack of interest by scientists in the general public's views on science policy matters has been demonstrated empirically. In Jon Miller's study of the role of the public in formulating science policy, he found that most of the major science societies and professional associations focused "on their own membership, with little or no overt effort to identify and mobilize the 30 million [people who are attentive to science policy] in the broader population." Jon D. Miller, The American People and Science Policy: The Role of Public Attitudes in the Policy Process 132 (1983). Even when the need for research monies was high, there "were only a few efforts to reach out beyond the scientific community itself, and the results of the mobilization effort were correspondingly modest." Id. This marked separation between science policy leaders and the public at large led Miller to hypothesize that the science policy "leadership group [is] largely unskilled in mobilization" and the "attentive public" is "unaccustomed to being mobilized." Id. at 133. Part of the problem could be attributed to Miller's parallel finding that science policy leaders, who were predominantly comprised of scientists, had a lower estimate of the public's understanding of various scientific issues than the public's estimate of its own knowledge. Miller concludes that "[i]t is clear that science policy leaders have come to expect a relatively low level of public understanding and the leadership's perception of the public's knowledgeability has some empirical basis." Id. at 72.

ized as appropriate questions for science, their resolution is believed to depend upon scientific research. The science charade thus may actually increase the amount of funding dedicated to research or, at the very least, highlight the importance of scientific research and potentially elevate the role played by scientists in determining the future of toxics regulation.[220] Third, scientists may also enjoy the ability to participate actively in important national policy decisions without the inconvenient public accountability that attaches to most elected and appointed governmental officials.[221]

This is not to say that scientists will take the lead in the government's science charade by selfishly distorting the usefulness of science in resolving problems involving the regulation of toxics. The existence of such attractive incentives may, however, explain why scientists have failed to expose the charade in the past.[222]

IV. CONSEQUENCES OF THE SCIENCE CHARADE

The science charade is pervasive and deeply entrenched in administrative practice. In this Part, the effects of the charade on the advancement and ultimate success of three major goals of environmental rulemaking—public participation, efficient and effective protection of public health and the environment, and the optimal incorporation of science—are explored. The tendency of the charade to distance the public, and in some cases even elected or appointed policymakers, from major decisions affecting not only public health but also economic well-being is, in and of itself, a matter of considerable concern. The ramifications of the science charade extend well beyond intrusion into the democratic process, however: the science charade impairs the essential progress and prioritization of standard-setting by miring it in unresolvable scientific complexities. The quality of the science supporting the regulations is also impaired because the agency escapes not only review by the public, but scientific review due to its failure to divulge those questions it considered scientifically uncertain and the sources and range of error it considered in resolving them. In addition, because gaps in scientific knowledge are not highlighted, incentives for scientific research decline, and the

220. Daryl Chubin, an authority on science policy, provides an excellent example of the scientists' tendency to overpromise the capabilities of science in early 1970 cancer bills. Chubin concludes that the scientists did this "to ensure an allocation of research funds." Daryl Chubin, Research Missions and the Public: Over-Selling and Buying the U.S. War on Cancer, *in* Citizen Participation in Science Policy, supra note 149, at 109, 112; see also Rushefsky, supra note 14, at 183–84 ("[T]he scientist is a policy entrepreneur, science poses problems, politics uses science to justify policy actions or policy changes, scientific research receives public funding, and regulatory science comes into being.").

221. See supra note 73.

222. See, e.g., Graham et al., supra note 12, at 149 (suggesting scientists' awareness of large role played by personal judgment and intuition, particularly when policy questions are involved).

public's confidence in science erodes as scientific answers appear illusive and subject to debate.

A. *Barriers to Democratic Participation*

Mischaracterization of the entire standard-setting endeavor as resolvable by science results in significant obstacles to democratic participation.[223] Although some have questioned the benefit or cost-effectiveness of any public involvement in science-policy issues,[224] most commentators conclude that the wide range of public values implicated in these complex problems can and must be ascertained only with the general public's assistance.[225] Science-policy leaders working in isolation are likely to

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223. See Kweit & Kweit, supra note 149, at 19, 29 ("Technocratic methods are tools that seem to limit the role of public participation. Through sophistry, these tools can be used to justify and reify the wishes of a few."). But see id. ("On the other hand, these methods provide a means to aggregate the wishes of the many.").

224. One of the most troubling statements suggesting an incompatibility between technical issues and democratic participation is a report by the President's Commission for a National Agenda for the Eighties:

> During the decade of the eighties, our social needs to examine critically the relationship between scientific expertise and democratic policy making . . . [and] the management of increasing scientific and technological complexity poses a difficult challenge for public and private institutions, requiring flexibility and adjustment at all levels. . . . However, a nascent contradiction may exist between the requisites of science and the requisites of democracy.

President's Commission for a National Agenda for the Eighties, Science and Technology Promises and Dangers in the Eighties 3 (1980). Frank Cross has presented a series of impressive arguments for limiting the role of the public's perception of risk in developing national policy. See Frank B. Cross, The Public Role in Risk Control, 24 Envtl. L. 887, 949–55 (1994); see also Clayton P. Gillette & James E. Krier, Risk, Courts, and Agencies, 138 U. Pa. L. Rev. 1027, 1107–09 (1990) (positing that incremental approach to decisionmaking, which is almost always an inevitable consequence of active participation by the public, could prove "catastrophic" in managing public risks due in part to the latent nature of risks and the resulting inability to learn from trial and error.).

More mild and perhaps realistic concerns were expressed by Dr. Wildavsky on the general topic of public participation in science-policy decisions: "In order for citizens to participate in the operation of policy, they would have to understand what is in it for them, recognize the differences between small and large changes (so as to know whether and how much participation was worthwhile), and be involved continuously so that they could learn from experience." Aaron Wildavsky, Speaking Truth to Power: The Art and Craft of Policy Analysis 253 (1979); cf. supra notes 145–149 and accompanying text.

225. See Kweit & Kweit, supra note 149, at 29 ("[C]itizen participation has a role to play in common policy analytic techniques by supplying decision makers with more comprehensive information on the potential impacts of policies and the valuation of those impacts."); Yvette M. Barksdale, The Presidency and Administrative Value Selection, 42 Am. U. L. Rev. 273, 320–21 (1993) ("Without public participation in the process, administrators cannot even begin to ascertain society's consensus values.") (footnotes omitted); id. at 327 (arguing that contemporary models of administrative decisionmaking uniformly have "transcended the idea of the insular agency, holed up in back rooms, deciding policy questions solely through sterile technocratic judgments. Instead, both interest group participation and new public law models require that agency value selection be democratic.") (footnotes omitted); David Bazelon, Risk and Responsibility, 205 Science 277–80 (1979) (stating that public, not "disinterested expertise", is proper determinant for

overlook values which may prove to be of overriding import for the majority of the public.[226] If the values a regulator incorporates into a science-based standard do not correspond with the values of society, then the resulting standard will lack democratic legitimacy.[227] As Harvey Brooks notes, "The modern nation risks being no longer recognizable as a democracy, either representative or plebiscitary, if more and more policy areas are excluded from public participation because of the technical complexity."[228] Full participation is also essential if the citizenry is to benefit from and commit itself to continued implementation and enforcement of the regulatory targets.[229]

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level of technological risk); Brooks, supra note 23, at 46 (public participation is necessary to represent societal values to experts and clarify necessary choices that must be made); McGarity, supra note 150, at 103 (arguing that public participation is viewed as a theoretical necessity in health and safety regulation); Richard B. Stewart, The Reformation of American Administrative Law, 88 Harv. L. Rev. 1667, 1760–61 (1975) (judges and scholars generally agree on importance of public participation in agency rulemakings and adjudications).

226. In American policies for nuclear development and control, for example, public participation was of critical import in "bringing about a reexamination of the problem definitions undergirding American policies." Randy J. Rydell, Solving Political Problems of Nuclear Technology: The Role of Public Participation, *in* Citizen Participation in Science Policy, supra note 149, at 182, 193. In biomedical issues, greater involvement of citizens in decisionmaking "usually resulted in more comprehensive consideration of issues, greater attention to potential risks and possible alternatives, and a more realistic assessment of likely benefits." Diana Dutton, The Impact of Public Participation in Biomedical Policy: Evidence from Four Case Studies, *in* Citizen Participation in Science Policy, supra note 149, at 147, 171; see also Gillette & Krier, supra note 224, at 1100–01 (positing that fundamental prerequisite to risk regulation may be democratic resolution of "what risk is to mean").

227. See, e.g., The Federalist No. 10 (James Madison) (arguing that representative democracy is essential for sound government); Gillette & Krier, supra note 224, at 1103–05 (citing "growing body of literature" calling for greater public participation in management of public risks and concluding that participation may be necessary "to enhance the legitimacy of the decision making process" and to ensure that decisions regarding public risks comport with "what the public knows, values, and prefers"); John Rawls, The Domain of the Political and Overlapping Consensus, 64 N.Y.U. L. Rev. 233, 250 (1989) (observing that in order for public to support government choices, those choices must reflect public's "fundamental political and constitutional values"); see also Brooks, supra note 54, at viii ("[A]n artificial consensus among scientists is undemocratic in its implications. Only if they are completely honest about the extent of their ignorance are they playing a role appropriate to democratic polity.").

228. Brooks, supra note 23, at 46.

229. See, e.g., Barksdale, supra note 225, at 322 ("A lack of public participation is therefore likely to significantly weaken the public's overall faith in the legitimacy of administrative decisionmaking."); Brooks, supra note 23, at 46 ("Public participation . . . confers political legitimacy on the policy choices that are made and secures public acceptance and cooperation in the actual implementation of these choices."); Ellison Folk, Public Participation in the Superfund Cleanup Process, 18 Ecology L.Q. 173, 179–80 (1991) (argning that public participation may lend legitimacy to government decisions and citing as example import of public participation in understanding and supporting Superfund cleanup decisions); Susan Wiltshire, Public Participation in Department of Energy High-Level Waste Management Programs, 53 Tenn. L. Rev. 541, 552 (1986)

Once toxic standards are delegated to scientists for resolution, interested citizenry,[230] and often the government officials themselves,[231] are largely excluded from the decisionmaking or are forced to pay a high entry cost to discern at what point policy choices were made and what those choices were.[232] The National Research Council of the National Academy of Sciences has concluded: "EPA often does not adequately communicate to its own decisionmakers, to Congress, or to the public the variabilities that are and are not accounted for in any risk assessment and the implications for the conservatism and representativeness of the resulting risk numbers."[233] Judicially reviewable public comment procedures do little to involve interested parties in policy choices when those choices

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("[A]mong the benefits an agency can expect from effective public participation are improved decisionmaking, reduced uncertainty when planning is based on an accurate assessment of public concerns and possible opposition, increased credibility and legitimacy, and a final product that is more likely to be acceptable.").

230. The inaccessibility of risk assessments to public participation has been the subject of considerable concern. See generally Folk, supra note 229; McGarity, supra note 150; Public Must be Involved in Water Regulation, Industry Representative Says at Risk Conference, Env't Rep. (BNA) 1336 (Nov. 11, 1994) (member of water association argued that language of risk assessment must be simplified so that public, and not only experts, can participate in decisions).

A small percentage of the public who are well-educated and scientifically literate may not be fooled by the science charade. The involvement of only the scientific strata of the general population, however, discriminates among the general citizenry in an undemocratic way. Cf. Miller, supra note 219, at 126 (study revealed that public attentive to science policy is "somewhat better educated than other segments of population" and contains a higher proportion of males than females); id. at 128–29 (concluding that gender difference in attentiveness to science policy "should be addressed by science educators").

231. In his analysis of EPA's carcinogen risk assessment guidelines and benzene regulatory proceedings, Professor Latin concludes that it is unlikely "that EPA risk managers were aware of the inconsistent treatments of uncertainty, which were obscured by the presentation of precise quantitative risk estimates." Latin, supra note 35, at 125; see also Greenwood, supra note 14, at 140 (noting that a regulatory administrator's "staff may not include people who are competent to evaluate or question the scientific and engineering components of a draft regulatory document.").

232. In their discussion of the final Interagency Regulatory Liaison Group cancer policy, Landy et al. concluded that because of the agency's "failure explicitly to defend and explain its own assumptions" "a reader does not emerge from these twenty large and closely printed pages with a clarified and critical view of the issues and choices." Landy et al., supra note 14, at 198; see also Yellin, supra note 35, at 1328 (arguing that public participation is effectively precluded when administrators use "their discretion gradually to draw political decisions under the cloak of expertise"); cf. Jasanoff, supra note 69, at 188–89 (noting that relatively few public comments were received on EPA's proposed cancer guidelines in 1984 and that criticisms levied against guidelines were directed in part at EPA's failure to identify and explain underlying policy choices).

233. Science and Judgment, supra note 23, at 212; see also id. at 78 ("The general public often receives [as the basis for EPA's risk decision] . . . only the point estimate or range (without a description of the uncertainty)"); id. at 81 (by failing to identify existence and basis for default options, agency officials, public, and Congress are excluded from "judg[ing] the wisdom of the default options"); Case, supra note 79, at 279–80 ("[E]nvironmental decisions are often 'masked' by the numbers which embody the

have been disguised as issues of scientific judgment. For all practical purposes, then, all but the best-funded organizations are foreclosed from participating in the development of science policy through the administrative process.[234]

B. *Impediments to Protecting Public Health*

The agencies' standard-setting record under science-based statutory mandates has been dismal. Standards exist for only a small percentage of identified toxins, and the agencies typically default to a science-biased prioritization system in which substances that pose the greatest potential health threat are not necessarily regulated first. Since the task of determining levels of toxins that are "safe" is misidentified as one that must be answered by science, and is typically in the first instance assigned to agency scientists, it is not surprising that few answers come forward.[235] Although delays and the flawed prioritization system cannot be attributed entirely to the science charade, the misidentification of policy issues as resolvable by science surely bears some responsibility for the agencies' slow pace in setting toxic standards.[236]

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decision . . . [which in turn] affects the ability of the public to visualize and respond to the decisions.").

234. See supra note 152 and accompanying text. In her book on science advisory panels, Sheila Jasanoff notes that typically only industry has the resources to comment on advisory deliberations and that public interest groups rarely attend routine advisory committee meetings. See Jasanoff, supra note 69, at 247. But cf. id. at 250 (concluding that advisory process, which relies heavily on negotiations with agency, tends to result in trend towards societal mean).

235. See supra notes 67–70 and accompanying text. In his study of the extended regulatory delays associated with the listing and promulgation of science-based standards for hazardous air pollutants, John Graham concludes that scientific paralysis is an almost inevitable result:

> In the presence of scientific dispute about cancer risk assessment, and in the absence of legislative guidance, how is the EPA supposed to decide which airborne pollutants are 'hazardous' within the meaning of section 112? How can the EPA set national emission standards for nonthreshold pollutants at a level that protects the public health with an ample margin of safety? If the EPA is brave and lists a pollutant under section 112, how is it supposed to fulfill its nondiscretionary duty to propose emission controls for all stationary sources within six months and promulgate final standards within one year? Faced with these demands, it is hardly surprising that the EPA has behaved in a manner that can be criticized.
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> . . . In an effort to protect itself from scientific, judicial, and industrial criticism, the EPA has erected a formidable process of scientific review that allows only the most blatantly carcinogenic air pollutants to be listed under section 112.

Graham, supra note 64, at 148–49.

236. See, e.g., Graham, supra note 64, at 121, 142–43 (current agency policy requiring thorough scientific review prior to listing "takes anywhere from two to seven years and delays are often so long that a document requires updating before a first, unapproved draft has been completed"); Latin, supra note 67, at 1666 ("I believe EPA's virtual paralysis in the realm of harm-based toxic controls was a joint product of its reluctance to act without a credible scientific basis and its reluctance to create significant

1. *Inaction and Delay.* — The strong correlation between agency inaction and science-based mandates is striking,[237] with delays extending evenly across all administrations, regardless of political ideology.[238] The most notable standard-setting delays occurred in the Hazardous Air Pollutant program under the Clean Air Act.[239] In two decades EPA was able to promulgate standards for only seven of at least 189 total hazardous air pollutants identified by Congress.[240] Progress under other science-based mandates has been similarly limited.[241] Even for substances that are ulti-

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economic dislocation."); McGarity, supra note 155, at 1407–10 (1992) (citing scientific review requirements as one of several causes of slowing pace of informal rulemakings).

237. See, e.g., Flournoy, supra note 14, at 329 (arguing that scientific uncertainty encountered in implementing science-based mandates has caused agency action to fall "far short of stated congressional intent" under authorizing statutes); Sanford E. Gaines, Science, Politics, and the Management of Toxic Risks Through Law, 30 Jurimetrics J. 271, 282 (1990) ("Given the paucity, the softness, and the incompleteness of the scientific data in the context of public administrative decision making . . . it should be no surprise that administrators . . . rarely propose concrete decisions.").

238. If one examined only the number of protective, science-based standards promulgated under the four years of the Carter Administration and the first four years of the Reagan Administration, it would appear that President Reagan was as concerned about promulgating these standards as President Carter. See Frank B. Cross, Environmentally Induced Cancer and the Law: Risks, Regulation, and Victim Compensation 101–03 (1989) (noting similar number of standards promulgated under OSHA during Reagan and Carter years); id. at 107 (noting similar number of standards promulgated under Clean Air Act during same period); id. at 119 (noting similar number of standards promulgated under Food, Drug, and Cosmetic, Act during same period). In theory, however, Reagan's express de-regulatory policy should have resulted in the promulgation of far fewer protective standards. See Eads & Fix, supra note 202, at 1–2; Jeffrey A. Eisenach, A White House Strategy for Deregulation, *in* Mandate for Leadership III: Policy Strategies for the 1990s at 87, 88 (Charles L. Heatherly & Burton Y. Pines eds., 1989) ("[T]he 1980 platform . . . stated that 'The Republican Party declares war on government overregulation.' ").

239. 42 U.S.C. § 7412(a)(1) (1988) (amended 1990).

240. From the date of listing to the date of the promulgation of final standards, EPA averaged almost four years each for six of the seven toxic air standards. Four of the six standards were promulgated under legal pressure. See OTA Paper, supra note 4, at 106 (discussing seven air toxic standards promulgated by EPA and extraordinary delays associated with them); see also Comptroller General, supra note 69, at i–ii (noting that four of 37 hazardous substances identified for possible regulation between 1977 and 1982 had been regulated by 1983). For a general discussion of regulatory failure in the promulgation of science-based air toxic standards, see Cross, supra note 238, at 104–07; Graham, supra note 64, at 115; Phillip D. Reed, The Trial of Hazardous Air Pollution Regulation, 16 Envtl. L. Rep. (Envtl. L. Inst.) 10,066 (Mar. 1986).

The small number of standards actually promulgated stands in stark contrast to the number of substances that were identified by the government in need of regulation. By 1976, EPA had identified 43 toxic air pollutants in need of regulation under the Clean Air Act. See Cross, supra note 238, at 105. By 1990, Congress had legislatively identified at least 189 toxins that required such standards and ultimately abandoned science and resorted to technology-based standards. See 42 U.S.C. § 7412(b) (1988 & Supp. V 1993).

241. In the first 13 years under the Safe Drinking Water Act, EPA promulgated only eight final standards. See OTA Paper, supra note 4, at 116. Impatient with the delays, Congress identified in 1986 83 toxins which were in need of regulation in drinking water supplies and set tight deadlines for their promulgation. See 42 U.S.C. § 300g-1(b) (1988). Two years after the statutory deadline had expired, EPA had not issued standards for 40

mately regulated, delays in the final promulgation of standards are extraordinarily lengthy: on average, promulgation of a science-based standard takes from twenty months to six years per substance.[242]

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percent of the identified toxins. See Michael Weisskopf, EPA Falls Far Short in Enforcing Drinking Water Laws, Wash. Post, May 20, 1991, at A1, A4.

Close behind this abysmal record was the EPA's pace in setting toxic water quality standards under the Clean Water Act. After promulgating approximately two standards per year for several years, pressure from both industry and public interest groups led the agency to adopt a judicially approved technology-basis for regulating toxic pollutant discharges into surface waters. See supra note 7 and accompanying text.

Under the Federal Insecticide, Fungicide, and Rodenticide Act, EPA by 1987 had restricted or cancelled the registration for only 18 out of 81 pre-existing pesticides EPA had identified as carcinogenic. See OTA Paper, supra note 4, at 118–19. Moreover, EPA completed reregistration of less than 12 out of 600 active ingredients scheduled for review during the first seven years of FIFRA. See Mendeloff, supra note 172, at 2.

By 1988, "[o]f forty-one existing chemicals that EPA ha[d] identified as carcinogens subject to [the Toxic Substances Control Act], only four ha[d] been listed as siguificant risks under section 4(f). Of these four, EPA ha[d] yet to issue any TSCA regulations." Cross, supra note 238, at 111.

Finally, in its first ten years, the Occupational Safety and Health Administration issued only eight final rules to reduce exposures to specific carcinogens. See OTA Paper, supra note 4, at 84. One of the eight was immediately invalidated by the Fifth Circuit. See American Petroleum Inst. v. OSHA, 581 F.2d 493, 510 (5th Cir. 1978), aff'd Industrial Union Dep't v. American Petroleum Inst., 448 U.S. 607 (1980). By 1988 OSHA had promulgated standards for 21 substances (two were later invalidated by the courts), which constituted less than one-third of the substances recommended for regulation by the National Institute for Occupational Safety and Health (NIOSH), a parallel research agency also created under the Occupational Safety and Health Act of 1970. See OTA Paper, supra note 4, at 82.

242. For example, from 1970 to 1980, OSHA averaged 32 months per standard. From 1980 to 1986, OSHA's pace slowed to 60 months per standard. See OTA Paper, supra note 4, at 84–85; see also McGarity, supra note 155, at 1387–88 (noting increasing delays in OSHA's promulgation of protective standards which ranged from six months per standard in 1972 to an average of three-and-one-half years per standard in the late 1970s to more than five years per standard in the 1990s). EPA did not even begin its slow pace of regulation of existing products under Section 4(f) of TSCA until six years after passage of the Act. See Cross, supra note 238, at 110. Although progress is generally more rapid in setting carcinogen standards for food additives under the Food, Drug, and Cosmetic Act, the PCB standard took 45 months to promulgate. See id. at 117. After spending slightly less than two years per standard under the Safe Drinking Water Act, EPA set standards for eight additional volatile organic compounds in one rulemaking—a process which consumed 63 months from the start to the time of final promulgation. See id. at 112. EPA's efforts to regulate ethylene dibromide under FIFRA took approximately seven years from the identification of its carcinogenic effects to the promulgation of a final regulation. At least four of these years were spent debating the risk posed by the substance. See id. at 114.

Some substances which remain unregulated have been under intermittent regulatory consideration by an agency for decades. See, e.g., id. at 117 (Food and Drug Administration has intermittently considered proposed 15 ppb aflatoxin standard for 14 years); id. at 111 ("The struggle to list formaldehyde under section 4(f) of TSCA took fifty-five months, and even this listing did not invoke regulation. EPA still has not imposed actual restrictions on exposure to formaldehyde under TSCA's authority.").

It is possible that the delays encountered in the promulgation of science-based standards are nothing unusual given the widespread plague of regulatory ossification, see,

The agencies' slow progress in setting standards based on science stands in stark contrast to their record for setting parallel technology-based standards.[243] Faced with pressure from the same interest groups, tight deadlines, and a monumental information-collection task requiring an engineer's grasp of the technical operations of regulated industries,[244] the agencies nevertheless promulgated three to ten times more technology-based standards in the same period of time than they did science-based standards.[245]

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e.g., McGarity, supra 155, at 1389 & n.22, 1390 (noting delay of five and one-third years for Federal Trade Commission industry-wide rules which do not require science for their promulgation), but the literature generally suggests that the extraordinary delays associated with science-based regulations are among the worst and occur uniformly across several agencies with science-based mandates. See supra notes 2–4 and accompanying text.

243. Although some science is necessary in technology-based standard-setting in order to identify the substances in need of regulation (e.g., those which are carcinogenic), this involves far fewer assumptions and studies than later stages of risk assessment when "safe" doses must be determined. See supra Part I; see also OTA Paper, supra note 4, at 27 (noting that two most important aspects of risk assessment occur after hazard identification in determining appropriate levels protective of health and environment).

244. See Houck, supra note 7, at 10,537 (describing development of technology standards as "the most Herculean task ever imposed on an environmental agency" which requires EPA to "master the economics, engineering, and technology of every industrial process in the most industrialized and fastest-growing economy in world history").

245. For example, after modifications to the Clean Water Act which substituted technology-based standards for prior, science-based standards, the agency's standard-setting pace for toxic water pollutants shot from approximately two per year to seven or eight standards per year. See Houck, supra note 7, at 10,538 ("By early 1983 [seven years after the Clean Water Act settlement], most of EPA's proposals for regulation of the [65] priority pollutants of the consent decree industries had been developed in at least draft form."). Within 10 years after settling on a technology basis for reducing toxins in industrial effluent, EPA had issued regulations for 26 of the 28 industrial groups, with standards covering all 126 toxic substances identified by the agency, and later by Congress, in need of regulation. See OTA Paper, supra note 4, at 110–11; see also Staff of Subcomm. on Investigations and Review, House Comm. on Pub. Works and Transp., 95th Cong., 1st Sess., Implementation of the Federal Water Pollution Control Act: Summary of Hearings on the Regulation and Monitoring of Toxic and Hazardous Chemicals 28 (Comm. Print 1977) (EPA Administrator Costle referred to regulatory paralysis occurring under prior science-based mandate of Clean Water Act and testified that EPA's experience with "technology-based limitations . . . leave us firmly convinced that for the bulk of known or suspected toxics of concern, technology-based standards established on an industry-by-industry basis are by far the most feasible to implement and administer."); Gaines, supra note 237, at 300 ("[U]niform application of 'best' technology has achieved relatively rapid installation of treatment systems with the design capacity to control toxic discharges."); Latin, supra note 183, at 1332 ("[S]ociety's real choice may be to rely either on crude [technology-based] regulation or no regulation."). According to EPA, implementation of these effluent standards that are technology-based has resulted in improved water quality. See EPA, Report to Congress: Water Quality Improvement Study at v (1989). But see infra notes 309–313 and accompanying text for significant limitations of technology-based standards.

The best general discussion of the expedient implementation of technology-based standards in relation to their science-based counterparts is presented in Thomas O. McGarity, Media-Quality, Technology, and Cost-Benefit Balancing Strategies for Health and Environmental Regulation, Law & Contemp. Probs., Summer 1983, at 159, 203–24.

The social costs that result from these delays in science-based regulations are profound.[246] The public remains unprotected against recognized hazardous substances,[247] industries face limited or no incentives to reduce their use of these toxic substances,[248] and the toxins become increasingly dispersed into the environment, making cleanup extraordinarily costly, if not impossible.[249]

2. *A Skewed Prioritization System.* — Many observers of toxics regulation believe that the agencies assign priority to the worst risks first.[250] A careful examination of the standard-setting record reveals, however, that this is not the case. Rather, the agencies tend to be "science-biased" in selecting the toxic substances to regulate:[251] instead of developing a reg-

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246. See, e.g., William J. Nicholson & Philip J. Landrigan, Quantitative Assessment of Lives Lost Due to Delay in the Regulation of Occupational Exposure to Benzene, 82 Envtl. Health Persp. 185, 185 (1989) (reporting results of study that from 1978 to 1987 between 30 to 490 excess leukemia deaths occurred from occupational exposure to benzene concentrations of greater than one ppm).

247. See supra notes 240–241; see also OTA Paper, supra note 4, at 194 fig. 5.1 (presenting the number of substances regulated in relation to the number of substances not regulated under each statute).

Underregulation is also counter-productive to the purpose of the regulatory program. Ostensibly Congress mandated the agency to set protective standards to fill in the voids created by tort law, which generally requires a high level of evidence, almost universally human evidence, to establish causation, and which generally provides only after-the-fact compensation, without prevention. Cf. Steven Sbavell, Liability for Harm Versus Regulation of Safety, 13 J. Legal Stud. 357, 368–69 (1984) (arguing that "it is desirable that society resort to safety regulation where it generally does" in part because "liability alone would not adequately reduce risks"). If the agency, like the tort courts, delays action until a statistically significant number of people have been seriously injured or have died, then the protective function of the regulatory system is illusory.

248. See infra note 279 and accompanying text.

249. The costs encountered under the Superfund program, see 42 U.S.C. §§ 9601–9675 (1988 & Supp. V 1993), which targets only the worst sites, see § 9605, provides an apt illustration of the exorbitant costs of cleanup after-the-fact. See, e.g., Jan P. Acton, Understanding Superfund: A Progress Report at vii (1989) (observing that EPA paid $2.6 billion for Superfund cleanups). Furthermore, in some cases such as widely contaminated aquifers, existing technology is not capable of cleaning the environment to "safe" levels. See Pbilip H. Abelson, Inefficient Remediation of Ground-Water Pollution, 250 Science 733, 733 (1990) (concluding that continuous pumping and treating of contaminated groundwater has had very limited success in reducing pollution levels).

250. See, e.g., Fiscal Year 1992 EPA Research and Development Budget: Hearings Before the Subcomm. on Environment of the House Comm. on Science, Space, and Technology, 102d Cong., 1st Sess. 21 (1991) (proposing EPA budget for "worst environmental risk first"). For a discussion of what the "worst first" *should* mean in a regulatory setting, see Applegate, supra note 12, at 304–28.

251. See 56 Fed. Reg. 1470, 1471 (1991) (EPA selects contaminants for regnlation under Safe Drinking Water Act based in large part on "[a]vailability of sufficient information on the substance"); Science and Judgment, supra note 23, at 253 ("In the past, EPA has often appeared to base its priorities on the ease of obtaining data on a particular chemical."); Latin, supra note 35, at 141 ("In practice, agencies seldom commence regulatory proceedings until considerable evidence has accumulated that a substance may be hazardous."); Richard Wilson et al., Uncertainty in Risk Assessment, *in* Risk Quantitation and Regulatory Policy, supra note 76, at 133, 136 (describing how

ulatory system that prioritizes substances based on the risks they present to health and the environment, the agencies appear to default to an ad hoc system[252] in which the substances with more scientifically established health effects are selected over less-studied substances, many of which are believed to present greater risks at lower concentrations.[253]

Perhaps the clearest example of science bias is the agencies' preference for regulating substances for which evidence of toxicity has been demonstrated on humans, whether through clinical trials or epidemiological studies.[254] Since this type of evidence exists for only a very small number of toxic substances,[255] the agencies' bias in this regard is not

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Carcinogen Assessment Group of EPA calculates risks for chemicals that have been tested on animals, but often neglects all other chemicals which haven't been similarly tested, "even when other information suggests that risks from them may be large enough to be important").

252. See NRC Risk Assessment, supra note 14, at 38 ("In general, agency risk assessments for priority-setting have been more informal, less systematic, and less visible than those for establishing regulatory controls."). The Consumer Product Safety Commission has also had a "strange" and "clumsy" history of prioritizing substances for regulation, a system that appears to have no systematic basis. "[T]he Commission's risk management decisions have been haphazard, with little analysis of costs or benefits." Cross, supra note 238, at 122; see also Greenwood, supra note 14, at 234 (in air toxics program where EPA did attempt systematic priority system, agency discovered that discretion was still exercised in ad hoc manner and EPA ultimately "found its criteria so unhelpful in practice that it essentially abandoned the effort to set priorities systematically").

253. The reviewing courts' insistence on complete scientific evidence for each stage of the standard-setting process has been identified as one of the major culprits for the agency's fastidiousness. See Melnick, supra note 17, at 241.

254. This trend is supported best by reference to the standards promulgated under two statutes. First, all but one of the toxic standards ultimately promulgated by EPA under Section 112 of the Clean Air Act (prior to the 1990 Amendments) were supported by definitive studies on humans. See OTA Paper, supra note 4, at 107 tbl. 3-8; Graham, supra note 64, at 143 ("EPA has yet to list a pollutant [as a hazardous air pollutant] primarily or solely on the basis of animal experiments, even though a policy of waiting for positive human data is inconsistent with the precautionary purposes of section 112."). Second, 50 percent of the standards promulgated under the Occupational Safety and Health Act were supported by studies on humans. See OTA Paper, supra note 4, at 85. Interestingly, all of the standards based exclusively on animal evidence were promulgated early in OSHA's history—in 1974. See id. All of the eight subsequent standards promulgated by OSHA were based on "at least some evidence of human carcinogenicity." Id. Although the Clean Air Act and OSHA provide the clearest examples, standards promulgated under many of the other statutes also appear to have been selected with some discernible science-bias. See generally id. at 87 tbl. 3-3, 89–96 tbl. 3-4, 104 tbl. 3-7, 113 tbl. 3-11; see also Mendeloff, supra note 172, at 121 (observing that "hazards were more likely to be addressed [by regulators] if there was evidence of human illness").

255. The National Toxicology Program of the U.S. Department of Health and Human Services has listed only 24 substances or groups of substances as " 'known carcinogens,' " which are "those substances for which the evidence from human studies indicates that there is a causal relationship between exposure to the substance and human cancer." National Toxicology Program, U.S. Department of Health and Human Services, Seventh Annual Report on Carcinogens at iv, viii (1994). This constitutes approximately 17 percent of carcinogens listed as " 'reasonably anticipated to be carcinogens' . . . for which there is a

inconsequential. Left behind are a number of toxins, such as dioxin, that are believed to pose even greater risks to humans at very low concentrations, although the toxic effects have not been demonstrated in epidemiological studies.[256]

EPA's long awaited carcinogen guidelines,[257] promulgated after sixteen years of administrative effort, reaffirm the agencies' practice of waiting for "good (generally equivalent to complete) science" before undertaking regulatory action on a particular substance, even though toxic substances that are less studied may be considered by scientists to present a greater threat to human health and the environment.[258] The dangers of withholding regulation until a quantitative standard is supported by the "weight of evidence"[259] is compounded by the unfortunate reality that information deficiencies on potential carcinogens are corrected at an extraordinarily slow pace, potentially extending the delay to several decades for each toxic substance.[260]

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limited evidence of carcinogenicity in humans or sufficient evidence of carcinogenicity in experimental animals," id. at iv–viii, and less than 0.04 percent of the " 'select universe' " of 65,725 substances generated by the National Research Council as "of possible concern to the National Toxicology Program (NTP) because of their potential for human exposure." See National Research Council, Toxicity Testing: Strategies to Determine Needs and Priorities 1 (1984).

256. Dioxin (specifically the compound 2,3,7,8-TCDD) has been identified by EPA as "by far the most potent carcinogen evaluated to date by the Agency" and "also the most potent reproductive toxin yet evaluated by EPA." EPA, Integrated Risk Assessment for Dioxins and Furans from Chlorine Bleaching in Pulp and Paper Mills 1 (1990); cf. Draft Reassessment Critique Approved Pending Changes by Executive Committee, 26 Env't Rep. (BNA) 986, 986–87 (Sept. 29, 1995) (reporting on Science Advisory Board's review of EPA's draft reassessment of dioxin and projecting that final reassessment document will be complete in fall of 1996). There are many other substances that have not been studied in sufficient detail to even identify whether they are carcinogenic to animals. By 1985, long-term bioassays on animals had been performed on only about 1000 of the estimated 60,000 chemicals used in commerce, not to mention the six million recorded by the Chemical Abstracts Service. See Wilson et al., supra note 251, at 140; see also infra note 280.

257. EPA Carcinogen Guidelines, 51 Fed. Reg. 33,992 (1986).

258. See Latin, supra note 35, at 127 ("The Agency decision [in the carcinogen guidelines] to wait until regulators can meet the particularized evidentiary requirements of the guidelines is equally a decision to stress scientific validity rather than safety after an indeterminate toxic hazard has been qualitatively identified."); see also Cranor, supra note 1, at 137 (recommending that because of the large number of "possible unidentified toxins and known but unassessed carcinogens," OSHA should "not wait for scientifically certain information" before promulgating safety regulations).

259. "Weight of evidence" is a term used by Latin to describe EPA's approach in recent regulatory efforts to base risk assessment on " 'the most scientifically appropriate interpretation.' " See Latin, supra note 35, at 97–98 (quoting EPA Carcinogen Guidelines, 51 Fed. Reg. 33,992 (1986)).

260. For a description of the extended delays currently encountered in the study of carcinogens, see infra notes 280–281 and accompanying text. Agencies appear to take action more rapidly on toxic substances under certain limited circumstances, however, even when the available scientific information is less than complete. For example, the agencies have on several occasions promulgated numerous science-based standards (e.g., ambient water quality criteria under the Clean Water Act) which are only advisory in

Potentially exacerbating this science-bias, at least with respect to EPA's standard-setting efforts, is EPA's simultaneous tendency to adopt uniformly risk averse assumptions in its risk assessments of those substances it does ultimately regulate.[261] This tendency may make it difficult, if not impossible, for the agency to justify similarly stringent standards for substances where the scientific information supporting toxicity is limited to a few studies, and yet the agency may find itself unable to rationalize departing from conservative policy choices simply because the scientific information is sparse. The net result may not only be an increase in the cost of regulation due to the overregulation of certain substances, but may also be an increase in total risk due to the additional impediments to the regulation of less-studied but potentially hazardous substances.[262]

3. *Transaction Costs.* — When the standard-setting problem is mischaracterized as predominantly a scientific problem, considerable resources are diverted unnecessarily to debates over competing scientific theories that contribute little or nothing to resolution of underlying controverted policy choices.[263] Given the already large expense associated

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nature and are thus not subject to the notice and comment and judicial review procedures of the APA. See 5 U.S.C. §§ 553(c), 706(2) (1994). Standard-setting progress under these largely unreviewed circumstances is impressive. See, e.g., OTA Paper, supra note 4, at 111 ("As of 1986, EPA had issued water quality criteria for 65 classes of priority toxic pollutants.").

Science-based standards also seem to be determined more quickly when the economic repercussions are local rather than national in character as evidenced by the cleanup decisions for Superfund sites. See, e.g., EPA Superfund Records of Decisions, available in Westlaw, EDR-ROD Database (providing comprehensive file of cleanup decisions, including in many cases the identification of cleanup standards, for Superfund sites). Although national non-reviewable guidelines have been published by EPA to assist with site risk assessments, in the first instance levels of "safe" are to be determined by reference to applicable state and national standards which have already been promulgated. See 42 U.S.C. § 9621(d)(1)–(d)(2)(A) (1988 & Supp. V 1993). Since the opponents are local and diffused, the agency appears to be generally successful in the identification of case-by-case science-based standards for site cleanups.

261. See Nichols & Zeckhauser, supra note 44, at 18 (arguing that EPA typically bases quantitative standards on a long series of upper-bound assumptions which present "a substantial exaggeration of the overall risk"). But see Adam M. Finkel, Is Risk Assessment Really Too Conservative?: Revising the Revisionists, 14 Colum. J. of Envtl. L. 427, 429 (1989) (arguing that it is not clear that there exists systematic conservatism in risk assessments).

262. See Nichols & Zeckhauser, supra note 44, at 17–18.

263. See Collingridge & Reeve, supra note 69, at 158 (concluding that when policy issues are disguised as scientific problems "[h]uge resources are wasted . . . [and] the real questions at issue remain[ ] undebated and hidden while arguments go on between a handful of qualified experts over minute technical points"); David Schoenbrod, Goals Statutes or Rules Statutes: The Case of the Clean Air Act, 30 UCLA L. Rev. 740, 743 (1983) (discussing high transaction costs associated with science-based standards under Clean Air Act). For an illustration of such unnecessary "good science" debates, see the discussion of the Alar controversy, supra notes 160–171 and accompanying text.

Focusing agency resources largely, if not exclusively, on the science undergirding a toxic standard may also cause the agency to dedicate far too little time to economic

with typical rulemakings,[264] the added cost of finalizing a rulemaking that has been deliberately shrouded in science is alarming. After agency scientists dedicate several years to the development of a toxic standard and its multiple page justification,[265] the standard has approximately an eighty percent chance of being delayed in litigation and a thirty percent chance of being significantly revised as a result of litigation.[266] Since the standard is steeped in scientific justifications, the litigation is particularly costly: experts must be called on for affidavits, consultations, and clarifications, and the debates over scientific evidence are likely to slow the pace of litigation to a veritable crawl through the courts.[267]

C. *Adverse Impacts on Science*

The science charade also has adverse effects on science itself. When areas of scientific uncertainty are unspecified, critical agency science judgments, as well as policy judgments, may go unreviewed; significant gaps in scientific knowledge regarding toxic substances, which could be cured with research, fail to be highlighted; and the public's confidence in

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research and analysis. Regulatory analysis requirements that require agencies to consider the costs and benefits of a rulemaking, see infra Part V.A.2, have appeared to result in regulations that are more cost-effective. See, e.g., Percival, supra note 134, at 185 (observing that regulatory review requirements from Nixon through Reagan "stimulated more rigorous regulatory analysis by EPA . . . [and may have caused] 'a more rigorous internal review' [to develop within EPA]") (quoting Erik D. Olson, The Quiet Shift of Power: Office of Management and Budget Supervision of Environmental Protection Agency Rulemaking Under Executive Order 12,291, 4 Va. J. Nat. Resources L. 1, 49 (1984)); Paul R. Portney, The Benefits and Costs of Regulatory Analysis, *in* Environmental Policy Under Reagan's Executive Order 226, 238 (V. Kerry Smith ed., 1984) (concluding that regulatory analysis and oversight will "cover its cost, if not return it several times over" due to increased scrutiny of regulatory alternatives, including economic incentives or other innovative approaches to source-by-source regulation).

264. See, e.g., McGarity, supra note 155, at 1389–90 & n.22 (observing that it has taken Federal Trade Commission an average of five and one-third years per rulemaking promulgated since 1974). The considerable agency resources dedicated to more commonplace regulations lead to an inescapable inference that toxic risk regulations must be costing the government, and hence the taxpayers, a great deal. See, e.g., Mendeloff, supra note 172, at 54 (estimating in 1988 that cost to government to develop a single protective standard under OSHA was on average $1 to $2 million).

265. See supra note 242 and accompanying text and infra note 281 and accompanying text.

266. See Lawrence Susskind & Gerard McMahon, The Theory and Practice of Negotiated Rulemaking, 3 Yale J. on Reg. 133, 134 (1985) (citing William Ruckelshaus, Environmental Negotiation: A New Way of Winning, Address to the Conservation Foundation's Second National Conference on Environmental Dispute Resolution 3 (Oct. 1, 1984) (on file with the Yale Journal on Regulation)); see also Breyer & Stewart, supra note 181, at 607 (on average, for major rules it takes EPA three and one-half years from internal preparation of proposal to final rule; "there is an 85 percent chance of subsequent court litigation").

267. Cf. Barton C. Legum, Note, Increased Risk of Cancer as an Actionable Injury, 18 Ga. L. Rev. 563, 574–75 (1984) (citing as one of the problems encountered in litigating cancer claims the expense associated with "scientific tests and expert testimony").

science declines as scientists debate what appear to the lay observer to be "scientific truths" regarding toxic risks.

1. *Incomplete or Inaccurate Science.* — Ironically, while the agency goes to great lengths to make protective standards appear scientifically determined, some of the most important information for the purposes of scientific review—the identification and explanation of scientific uncertainties and sources and ranges of error—are not disclosed. An agency's lack of explicitness regarding the areas of scientific uncertainty thus not only prevents policymakers and the public from reviewing the agency's policy judgments, but also poses substantial barriers to scientific review in instances where science could be of assistance, for example by providing scientifically plausible "default options" at the trans-scientific junctures.[268]

In its recent report *Science and Judgment*,[269] the National Research Council identified a number of scientific deficiencies in EPA's risk assessments, which it attributed in significant part to the agency's tendency to understate scientific uncertainties and the scientific support for its assumptions, as well as the agency's corresponding inclination to overstate "point estimates."[270] When "[t]he predictive accuracy and uncertainty of the methods and models used for risk assessment are not clearly understood or fully disclosed" by EPA,[271] the agency evades critical but necessary scientific review both from within and outside the agency.[272] The NRC concluded that EPA's failure to make science and policy choices explicit in its cryptic preambulatory explanations may not only prevent the agency from making "intelligent and consistent" policy decisions,[273] but could "undercut the scientific credibility of the agency's risk assessments."[274] The resulting possibility that EPA will base quantitative standards on outdated or inaccurate scientific information thus may lend

268. See supra notes 32–34 and accompanying text.

269. See Science and Judgment, supra note 23.

270. See supra notes 80–81 and accompanying text; see also Science and Judgment, supra note 23, at 158 (recommending that EPA should better identify and "explain the analytical and measurement methods it uses for ambient outdoor exposures, including the errors, precision, accuracy, detection limits, etc., of all methods that it uses for risk-assessment purposes."); id. at 184 (noting that EPA's use of single point estimates suppresses important scientific information undergirding EPA's assumptions and EPA should instead clarify that such numbers are "the product of a consideration of both the estimate of risk and its uncertainties, [and do] not appear out of nowhere from a formulaic process").

271. Science and Judgment, supra note 23, at 137.

272. The NRC has suggested that the failure of EPA to articulate criteria for departure from "standard" default options in a particular risk assessment undercuts the scientific credibility of that assessment. See id. at 90–91.

273. See id. at 81.

274. Id. at 105.

credence to those who charge the agency with scientific incompetence.[275]

2. *Disincentives for Research.* — A less obvious but nevertheless important consequence of the agencies' science charade is the failure to provide proper direction or incentives for scientific research. The NRC has noted that little effort has been made to use risk assessments to "systematically elucidate[ ] scientific uncertainties" and thereby "provide valuable guidance to research scientists."[276] Although in some cases the uncertainties can only be resolved with policy choices because of the current limitations of scientific knowledge, in other cases uncertainties may be capable of being resolved by scientific studies.[277] When government researchers are not alerted to easily-remedied research gaps in a systematic way, however, they will be unnecessarily forestalled from conducting relatively straightforward and inexpensive tests on a chemical that could result in invaluable information regarding the risk it may pose to human health.

Even after remediable gaps in scientific knowledge are identified, however, the science charade may create disincentives for private research. The agencies' science-bias in prioritizing substances for regulation virtually guarantees that greater regulation will ultimately follow advancements in scientific information and knowledge.[278] A rational manufacturer with fiduciary obligations to shareholders rather than to the public is thus unlikely to undertake research voluntarily on the potential carcinogenicity or mutagenicity of a substance it produces if more aggressive regulation is likely to result.[279] While these substances may ultimately be studied by the federal government, the primary research institution, the National Cancer Institute/National Toxicology Program

275. See, e.g., Greenwood, supra note 14, at 15 ("[T]he charge has frequently been made that agencies have low scientific competence.").

276. Science and Judgment, supra note 23, at 27–28. The courts' general insistence on detailed scientific explanations for quantitative standards, see supra Part III.B.3, is likely one of the leading causes of the agencies' tendency to refrain from expressly identifying informational gaps in the science supporting protective standards. See, e.g., Proposed Use of Short-Term Toxicity Studies to Predict Carcinogenicity Draws FDA Criticism, Env't Rep. (BNA) 450, 450–51 (July 1, 1994) (proposal by National Toxicology Program to use short-term toxicology study results for preliminary regulatory decisions bas sparked criticism from agencies like Food and Drug Administration and EPA due to likely legal challenges which could be filed against them for failing to regulate carcinogens identified through this short-term process).

277. See Science and Judgment, supra note 23, at 253 (recommending that "[a]t a minimum, [EPA assemble] an inventory of the relevant chemical, toxicologic, clinical, and epidemiologic literature" for listed chemicals, which will highlight relative risks and identify research gaps).

278. See supra Part IV.B.2.

279. Cf. Mary L. Lyndon, Information Economic and Chemical Toxicity: Designing Laws to Produce and Use Data, 87 Mich. L. Rev. 1795, 1814 (1989) ("[A]s long as the information market [on the toxicity of chemicals] remains undeveloped, ignorance of toxicity may be an advantage to a product. New or unstudied chemicals will do better in relation to chemicals that have been shown to have some indication of toxicity.").

(NCI/NTP), has been able to conduct tests on less than one-third of the substances on its ever growing list of substances to be evaluated.[280] The NCI/NTP takes approximately six to eight years to study each substance,[281] and its annual budget for publicly funded research is far from stable, much less expanding.[282]

3. *Public Alienation from Science.* — Failure of the agencies to set more than a handful of science-based standards may also result in a loss of public confidence in science itself.[283] As scientists debate what appear to the public to be fundamental scientific issues at the heart of risk assessment, the public may become increasingly skeptical about the ability of scientists to answer any question definitively.[284] Since disagreements among scientists over toxic risk standards are often heated and highly publicized, the public is likely to misperceive science as adversarial rather than truth-seeking. Even though the public continues to have great respect for science,[285] the fact that public confidence in scientific experts has been declining gradually over the past two decades lends credence to this theory.[286]

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280. See OTA Paper, supra note 4, at 160, 175 (by 1986, NCI/NTP had conducted one or more tests on only 308 substances out of over 942 which were nominated for all types of testing); see also National Research Council, supra note 255, at 5, 11–12 (concluding that no toxicity information was available on approximately 38,000 (or 80%) of chemicals in general commercial use).

281. See OTA Paper, supra note 4, at 167 ("Developing protocols, awarding contracts, and performing chemical disposition and prechronic and chronic tests takes at least 5 years; the evaluation of organs and microscopic sections adds at least an additional year; and preparation of the report, review, and publication add still more time.").

282. See, e.g., Lyndon, supra note 279, at 1805–06 ("In fiscal year 1987, the federal government allocated $210 million for toxicological research, but in real dollars, the budget for chemical testing was smaller than the 1980 budget."); cf. William J. Broad, Science Research Would Be Hit Hard in Budget Cutting, N.Y. Times, May 22, 1995, at A1 (reporting Republican proposals to cut government funding of basic science by one-third to one-half).

283. See Brooks, supra note 54, at ix ("The dangers . . . [of science-policy which is made to look as if it is grounded primarily in science] is that the public will lose confidence in science. . . .").

284. See Science and Judgment, supra note 23, at 1 ("[P]ublic skepticism about the reliability of scientific predictions concerning possible threats to human health . . . has arisen in part because scientists disagree."). Despite its growing skepticism, however, the public does appear to continue to place science generally in high regard, at least in relation to other professions or institutions. See generally supra note 142 and infra notes 339–341 and accompanying text.

285. See supra note 142 and infra notes 339–341 and accompanying text.

286. See Miller, supra note 219, at 71 (citing 1981 studies demonstrating that while majority of science policy leaders and attentive public rejected idea of growing public distrust in science, "a substantial minority of both groups . . . did express concern about public distrust of science"); DeSario & Langton, supra note 148, at 11 (stating that "[w]hile many people still retain a naive faith in experts and technological process, a growing proportion of Americans has become more skeptical of technology and its elite"). Scientists also appear to be recognizing this growing distrust by the public. Cf. Malcolm W. Browne, Scientists Deplore Flight from Reason, N.Y. Times, June 6, 1995, at C1 (reporting on convention attended by scientists concerned about public's growing fascination with

V. REFORM

Over the last fifteen years, a number of regulatory reforms have been implemented specifically to combat regulatory delays, increase public participation, and prevent the incomplete or inaccurate incorporation of science into health and environmental regulations. These reform efforts, while offering some improvement for certain facets of science-based rulemakings, do nothing to cure the science charade and may have the unintended effect of exacerbating rather than combatting the general regulatory malaise. Recognition of the science charade and the pervasive political, legal, and institutional forces that support it is essential to designing a successful reform.[287] In this Part, contemporary reforms are considered and ultimately rejected precisely because of their symptomatic rather than systemic approach to rectifying regulatory failure. Although current reforms generally achieve the one specific goal they are designed to address—whether it be speedier rule promulgation, enhanced public participation, or better incorporation of science into protective standards—because the reforms fail to target one or more of the causes of the charade, they either have no beneficial effect or may actually exacerbate current regulatory failure with respect to the other two remaining goals.[288] In the final subpart of this section, new reforms are proposed that directly confront the science charade and thus offer improved approaches for setting protective standards.

A. *The Inadequacy of Current Reforms*

Contemporary regulatory reforms fall into three general categories that parallel the three major goals of environmental rulemaking: 1) reforms designed to speed the promulgation of regulations; 2) reforms designed to enhance public participation in complex rulemakings; and 3) reforms designed to incorporate science into regulations in a more complete and accurate way.

1. *Reforms to Speed Promulgation of Regulations.* — While many recent reforms have been implemented with the specific goal of shortening reg-

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faith healing and astrology and public's loss of trust in scientific tools such as statistical analysis and controlled laboratory experiments).

287. Attempts to counteract regulatory delays have targeted at best only generic causes of regulatory ossification which appear to occur, albeit not evenly, across all agencies and agency mandates. See McGarity, supra note 155, at 1397–98 (identifying four general causes of regulatory ossification). Far less attention has been dedicated, however, to exploring the characteristics of delay for science-based regulation which may present uniquely difficult problems. Although anecdotal observations of the charade have been noted in the literature for several decades, it has not been formally isolated or analyzed as an impediment to science-based rulemaking. See supra notes 128–129 and accompanying text. For limited discussions of the causes of delay for science-based standard setting, see Flournoy, supra note 14, at 353–69; Gaines, supra note 237, at 276–91; Latin, supra note 183, at 1307–09, 1324–31.

288. See generally supra Part IV.

ulatory delays,[289] only a few are of particular significance to science-based rulemakings. Perhaps the most notable and far-reaching is negotiated rulemaking,[290] which attempts to cut through the complexity and adversarial nature of rulemakings in order to arrive at regulatory outcomes in an expeditious fashion.[291] In negotiated rulemaking, the agency identifies the major interested parties and convenes them to negotiate a proposed rule. Negotiated rulemaking is touted as being most advantageous when a small group of interested parties are involved and administrative delays are expected to be substantial under the traditional informal rulemaking process.[292] If the parties are able to reach agreement, the public is provided an opportunity to comment on the proposed negotiated regulation and can seek judicial review of the final rule as is done in traditional rulemakings.[293]

Although negotiated rulemaking has been used in a variety of standard-setting projects to speed the promulgation of regulations[294] and

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289. In fact, the most popular goal of contemporary regulatory reform, by a significant margin, is to design reforms which speed the regulatory process. See, e.g., McGarity, supra note 155, at 1386 ("[M]any observers from across the political spectrum agree with [E. Don Elliott of Yale Law School] . . . that [ossification of the regulatory process] . . . is one of the most serious problems currently facing regulatory agencies."). Delays are not only costly with regard to the numerous administrative and judicial transactions that they typically engender, see, e.g., id. at 1386, but also delays often impede the very purpose of the statute that mandated the regulations, such as expeditious protection of the public health and environment. See id. at 1392. The inevitability of delays may also cause agencies to seek other, less participatory mechanisms for setting policy, see id. at 1386, and may reduce incentives for agencies to revise protective standards as the relevant science changes. See id. at 1392.

290. See Negotiated Rulemaking Act of 1990, 5 U.S.C. §§ 561–570 (1994); Procedures for Negotiating Proposed Regnlations (ACUS Recommendation No. 82-4), 1 C.F.R. § 305.82-4 (1995) (encouraging agencies to use negotiated rulemaking). See generally Philip J. Harter, Negotiating Regulations: A Cure for Malaise, 71 Geo. L.J. 1, 7 (1982) (proposing negotiated rulemaking as alternative to adversarial system which has arisen from formalized rulemaking procedures).

291. See generally McGarity, supra note 155, at 1438 ("In recent years, regulatory reformers have heralded regulatory negotiation as an attractive vehicle for avoiding many of the costs and delays of the ossified informal rulemaking process."); Patricia M. Wald, Regulation at Risk: Are Courts Part of the Solution or Most of the Problem?, 67 S. Cal. L. Rev. 621, 652 (1994) (noting that a primary advantage of negotiated rulemaking is that it usually takes no more than six months to develop proposed regulation). Peter Schuck bas noted that negotiated rulemaking can also be used to circumvent complexity by allowing interested parties to contractually agree "to substitute and be bound by a new, simpler regime." Schuck, supra note 130, at 40–41.

292. See, e.g., Susskind & McMahon, supra note 266, at 138–40 (listing hypothetical preconditions for success of negotiated rulemaking which include incentives to negotiate in first place and limited number of parties with "rough practical limit" of 15).

293. See 5 U.S.C. § 561, 570 (1994).

294. See, e.g., William Funk, When Smoke Gets in Your Eyes: Regulatory Negotiation and the Public Interest—EPA's Woodstove Standards, 18 Envtl. L. 55, 61–63, 88–89 (1987) (describing how new source performance standards for emissions from woodstoves were promulgated using negotiated rulemaking; although standards are technology-based, some scientific issues did enter negotiations); James T. Harrington, The Importance of

although it has resulted in a miraculously low record of judicial challenges,[295] negotiated rulemaking does little to counteract the science charade and may actually aggravate it. Experience with negotiated rulemaking has shown that science and policy are not separated before, during, or after negotiations, but instead are incorporated into a proposed rule in a mysterious way, leaving careful observers wondering whether and in what way science was considered in reaching the final, negotiated result.[296] Philip Harter, one of the creators of negotiated rulemaking, admits that the parties are free to negotiate the "facts," even when those facts have not been fully researched,[297] and does not exclude the possibility that such negotiated facts might include scientific assumptions, models, and scientific studies deemed by the parties to be applicable to the problem.[298] Still more troubling is the fact that many of the negotiators have little scientific expertise, raising the possibility that negotiated outcomes will contain erroneous scientific findings and the possibility that some of the negotiators will mistakenly identify critical policy

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Negotiations in Illinois Environmental Rulemaking and Overview of the Illinois Environmental Regulatory Process, 13 N. Ill. U. L. Rev. 531, 543 (1993) (noting that negotiated rulemaking was used by State of Illinois to develop standards for particulates less than 10 microns in size); cf. Agency to Pursue 'Negotiated' Rule-Making Despite Changes in Senate Bill, Official Says, 25 Env't Rep. (BNA) 414, 414 (June 24, 1994) (EPA favors using negotiated rulemaking process for development of national cleanup standards and risk assessment protocols).

295. There appears to have heen only one judicial challenge of any of the negotiated rules. See Derek R. McDonald, Note, Judicial Review of Negotiated Rulemaking, 12 Rev. Litig. 467, 486 (1993).

296. In his case study of the negotiated woodstove standards promulgated by EPA, William Funk notes the appearance of "negotiated science" in the final rule, with explanations which attempt to make negotiated numbers appear fact-based rather than the result of compromise. See Funk, supra note 294, at 88–89 (observing that while explanation for standard "consumes a full page in the Federal Register, with the impression given that the rates were derived through a neutral, scientific process," numerical limit undergirding standard was actually negotiated, and reviewing public was "left not knowing what role the data and methodology played, if any"). Judge Wald has also expressed concern regarding the consensual nature of the rulemaking and the after-the-fact nature of the agency's explanation for a proposed regulation: "The consensus could also be pure political logrolling . . . rather than rational decisionmaking." Patricia M. Wald, Negotiation of Environmental Disputes: A New Role for the Courts?, 10 Colum. J. Envtl. L. 1, 22 (1985). Finally, in indicating their interest in negotiated rulemaking as a possible reform for toxic standard-setting, Graham et al. caution that negotiations should be only over policy, not science, and that negotiators should "understand the sources of technical disagreements about a chemical's risk . . . even if this awareness complicates negotiations." Graham et al., supra note 12, at 217.

297. Harter states: "It would be inappropriate to require the negotiating group and the agency to conduct research similar to that required in the hybrid [informal rulemaking] process because a negotiated regulation is generated not through development of enormous factual material, but through the agreement of the parties on the relevant facts and issues." Harter, supra note 290, at 106.

298. See id. at 89–91.

issues as scientific in nature.[299] Despite these potential scientific inaccuracies, the scientific appearance of the negotiated standards will continue to limit public participation and impose high entry costs on those concerned with the policy implications of standard-setting.[300] For these reasons and also because even the originators of negotiated rulemaking admit that it may fail to produce a consensus when the issues being negotiated are controversial,[301] as they often are in protective standard-setting,[302] negotiated rulemaking does not appear to provide a remedy for the science charade and may actually create further impediments to effective public participation and the optimal incorporation of science into environmental rulemakings.

A second reform that has been instituted to speed the rulemaking pace is the adoption of a technology-basis for setting protective standards. Rather than basing standards on science, standards are based instead on

299. See Susskind & McMahon, supra note 266, at 141 (asserting that "the negotiated rule should take account of the best scientific and technical information" because scientific inaccuracies will be caught during the notice and comment process). If scientific uncertainties and assumptions are not clearly identified, however, it is likely that scientific, as well as the lay public's, review will be impaired. See supra Part IV.C.1.

300. See Funk, supra note 294, at 88–89 (discussing adverse impact on public participation resulting specifically from negotiation of scientific information and methodology). In fact, the literature on negotiated rulemaking suggests that there is a consistently low number of comments filed on negotiated rules. See, e.g., Susskind & McMahon, supra note 266, at 146 (noting that only 13 comments were received on a proposed EPA nontechnical rule governing Clean Air Act penalties). While this fact could suggest that most of the interested parties were present at the table or that the regulation was noncontroversial, low public participation could also be attributable, at least in part, to the difficulties the public faces in commenting on the negotiated rule.

For more general concerns with regard to the public accessibility of negotiated rulemakings, see Funk, supra note 294, at 79 (expressing concern over EPA's preamble being an "after-the-fact rationale attempting to justify decisions made by the negotiating committee for reasons we can never know"); McDonald, supra note 295, at 477–78 (discussing concern that public is not adequately included in negotiated rulemakings).

301. See Harter, supra note 290, at 49–50 (asserting that negotiated rulemaking is inappropriate if the "disputed issue concerns fundamental values" and citing as example unlikelihood of OSHA, unions, and industry being able to agree on occupational health standards). In fact, many negotiated rulemaking efforts attempted by EPA failed to produce consensus. In 1991, the EPA reported that only 12 of the 60 regulatory negotiation efforts undertaken by EPA had resulted in regulations. See Matthew L. Wald, U.S. Agencies Use Negotiations to Pre-Empt Lawsuits over Rules, N.Y. Times, Sept. 23, 1991, at A1. Even once consensus has been reached, negotiated rulemaking participants may nevertheless seek to unravel the agreement. See, e.g., Air Pollution: Future of Reg Neg Process Questioned as Ethanol Proposal Overturns Agreement, 1992 Daily Env't Rep. (BNA) 192 d23 (Oct. 2, 1992), available in Westlaw, BNA-DEN Database ("The future of the regulatory negotiating process . . . was called into question by industry and regulators . . . [when] ethanol proponents broke from the [reg neg] agreement they had sigued . . . and put pressure on the White House to grant them concessions they were not able to gain [through] . . . the negotiated rulemaking.").

302. See supra notes 132–133 and accompanying text.

achieving technologically practicable reductions in toxins.[303] The reform, which has been implemented by Congress in critical sections of the Clean Water Act[304] and the Clean Air Act,[305] and by EPA in the Resource Conservation and Recovery Act,[306] has resulted in the promulgation of a

303. See, e.g., 33 U.S.C.A. § 1311(b)(2)(A) (West 1986 & Supp. 1995) (national standards for water toxics are to be based on best or available technology rather than ambient water quality); 42 U.S.C. § 7412(d) (Supp. V 1993) (national standards for air toxics are to be based on best technology rather than ambient air quality). See generally Gaines, supra note 237, at 291–303 (discussing paradigmatic models for science-based and technology-based standards in toxics regulation).

In abandoning science as a method by which to achieve enforceable controls on point sources of water pollutants, the Senate Conferees admitted that regulation based on science appeared to portend regulatory paralysis. See S. Rep. No. 414, 92d Cong., 2d Sess. 8 (1972), reprinted in 1972 U.S.C.C.A.N. 3668, 3675 ("Water quality standards often cannot be translated into effluent limitations—defendable in court tests, because of the imprecision of models for water quality and the effects of effluents in most water."). Similar statements were made by Congress in resorting to a technology-basis for the control of air toxics in the 1990 Amendments to the Clean Air Act: "This new approach is desperately needed to overcome the inertia that plagued the health-based standards in current law." 136 Cong. Rec. S17,234 (daily ed. Oct. 26, 1990) (statement of Sen. Baucus). For further discussions of this evolution away from science-based standards in air and water pollution control, see Brennan, supra note 12, at 27–35; Hall, supra note 7, at 316–17; Houck, supra note 7, at 10,529–39.

Despite widespread recognition of the substantial delays that plague science-based standard setting, Congress has established a science-based "back-up" system under several environmental statutes. See supra note 13. In theory, under the Clean Air and Clean Water Acts, the agency or state must promulgate a science-based standard when it appears that a technology-based standard is not sufficiently protective of health or the environment. See, e.g., 42 U.S.C. § 7412(f)(2) (Supp. V 1993) (requiring EPA to promulgate more stringent emission standards for hazardous air pollutants if necessary "to protect public health" or to "prevent . . . an adverse environmental effect"). In practice, however, because of the discretion given to agencies to define key terms, it will be very difficult to force agencies to promulgate these more rigorous standards. See 33 U.S.C. § 1314(l) (1988) (requiring EPA to review state individual control strategies to assure protection of health and environment under Clean Water Act, but ambient water quality standards and calculations from ambient standards to effluent limits are unspecified and may be determined by states with wide latitude of discretion); 42 U.S.C. § 7412(f)(2)(A) (Supp. V 1993) (requiring agency to promulgate science-based standards under Clean Air Act only if agency determines such standards are necessary based on a series of vague factors, including cancer risk to "most exposed" individual, a term not defined by Congress).

304. 33 U.S.C.A. § 1311(b)(2)(A) (West 1986 & Supp. 1995).

305. 42 U.S.C. § 7412(d) (Supp. V 1993). Congress has also adopted a technology-basis for setting some standards under the Safe Drinking Water Act, although regulatory expediency was not the reason for adopting this approach. See 42 U.S.C. § 300g-1(b)(4) (1988) ("Each national primary drinking water regulation . . . shall specify a maximum level for such contaminant which is as close to the maximum contaminant level goal as is feasible.").

306. 42 U.S.C. 6924(m) (1988). See Hazardous Waste Management System: Land Disposal Restrictions, 55 Fed. Reg. 6640, 6642 (1990) (explaining technology basis for standards for hazardous waste land disposal is preferable "until [agency] . . . develops acceptably certain threshold concentration levels."); see also Hazardous Waste Treatment Council v. EPA, 886 F.2d 355, 363 (D.C. Cir. 1989) (affirming EPA's ability under RCRA to convert science-based mandate into technology-based mandate).

far greater number of standards in less time.[307] This approach thus appears to overcome much of the regulatory paralysis that plagues science-based rulemakings.

Despite the benefits of more expeditious regulation promulgation, the technology-based approach fails to produce a regulatory outcome that is justified by science or cost as is its science-based counterpart. Technology-based standards, by design, will produce either an under- or overprotectiveness in the proper level of health and environmental protection that varies from substance to substance.[308] If the technology has not advanced sufficiently, some technology-based standards will not be protective enough. In his comprehensive analysis of regulation and residual risk, Troyen Brennan concludes that a technology-based approach to health and environmental protection will leave "toxic hot spots" and thus allow "[s]ome discrete communities . . . [to] continue to be exposed to hazardous pollutants."[309] Conversely, if a technology-based standard provides more protection of the environment and public health than is scientifically necessary simply because the agency has determined that the added protection is technologically feasible, tremendous cost inefficiencies, which have been projected to reach billions of dollars annually, will result.[310]

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307. See supra note 245 and accompanying text.

308. Howard Latin has succinctly summarized the general deficits of technology-based standards:

> Technology-based standards normally impose end-of-the-pipe controls that may not promote pollution prevention and cannot ensure that any given level of ecological purity will be maintained. Technology-based regulations are complicated, expensive, and often fail to achieve benefits that justify the high regulatory costs. Technology-based standards may stifle technical innovation and would allow high levels of emissions to continue from relatively unprofitable dischargers.

Latin, supra note 67, at 1661.

309. Brennan, supra note 12, at 35; see also id. at 28–29 (noting that uncertain status of water quality as result of technology-based standards caused Congress to amend Clean Water Act in 1987 to require states to implement additional protections where technology standards proved ineffective). While Congress' attempt to include a science-based prophylactic for technology-based standards, see supra note 13, should in theory correct the underprotectiveness problem, there is little hope that useful standards will be promulgated in the near term. See supra note 303; see also Brennan, supra note 12, at 34 & n.104 (outlining some of the limitations to the residual risk provision of the Clean Air Act).

310. See Bruce A. Ackerman & Richard B. Stewart, Reforming Environmental Law: The Democratic Case for Market Incentives, 13 Colum. J. Envtl. L. 171, 173 ("Uniform BAT requirements waste many billions of dollars annually by ignoring variations among plants and industries in the costs of reducing pollution and by iguoring geographic variations in pollution effects."); OMB Position on Use of Risk Assessment, Cost-Effectiveness Analysis, Benefit-Cost Review in Setting Standards for Toxic Air Pollutants, 14 Env't Rep. (BNA) 1593, 1593 (Dec. 8, 1983) (concluding that under technology-based standards, public health gains per dollar of expenditure vary across sources by factor of 2000).

Technology-based standards may also create substantial disincentives for further research. First, technology-based standards do not provide "strong incentives for the development of new, environmentally superior strategies and may actually discourage their development."[311] Second, since the effects of varying concentrations of a toxic substance on health and the environment are largely irrelevant in setting technology-based standards, once a substance is selected for regulation, the incentives and potentially the funding for additional research on the adverse effects and environmental pervasiveness of the substance might be reduced.[312]

It is also not clear that a technology-based approach overcomes current obstacles to effective public participation. Although technology-based standards may enhance public participation by relying on technological and economic feasibility to dictate the selection of an ultimate standard, it is equally possible that the agency may find the technical details of alternative technologies equally effective cover from searching public comment and judicial review.[313]

2. *Reforms to Enhance Public Participation.* — Although most reforms have focused on reducing regulatory delays,[314] there has been at least one significant effort to assist the public in understanding and commenting on complex rulemakings. In 1981 President Reagan signed Executive Order 12,291,[315] which required administrative agencies to conduct a Regulatory Impact Analysis (RIA)[316] on all major rulemakings[317] in order

311. Ackerman & Stewart, supra note 310, at 173–74.

312. See, e.g., William F. Pedersen, Jr., Turning the Tide on Water Quality, 15 Ecology L.Q. 69, 85 (1988) (concluding that by making water quality irrelevant, technology-based approach of Clean Water Act eliminates "incentives to implementing agencies to ascertain trends in water quality" with natural result being alarming paucity of water quality statistics against which to measure success of program).

313. Cf. McGarity, supra note 201, at 1328 (noting that fear of judicial reversal can cause agencies to gloss over uncertainties in economic assessments and give appearance that selected rule is based on greater factual clarity than is warranted).

314. In fact, efforts to reduce regulatory delays are often at odds with attempts to enhance public participation. Thomas McGarity, for example, has noted the tradeoff between "increased regulatory flexibility [decreased oversight and delays] and bureaucratic accountability." McGarity, supra note 155, at 1398; see also McGarity, supra note 150, at 112 (noting that public participation is not an "unalloyed good" since it can drain agency resources and is time consuming).

315. 3 C.F.R. 127 (1981) (revoked by Exec. Order 12,866 § 11, 3 C.F.R. 638, 649 (1993)).

316. The Impact Statement included a description of the benefits of the rule, including non-quantifiable benefits; a description of the potential costs of the rule, including any adverse effects that could not be quantified; a description of net benefits of the rule; and a description and economic analysis of alternative approaches that could achieve the same regulatory goal at lower cost. See Exec. Order No. 12,291 § 3(d), supra note 315, at 129.

317. A rulemaking was "major" if it was likely to result in: an annual effect on the economy of $100 million; a major increase in costs or prices of particular goods; or significant adverse effects on competition, employment, investment, productivity, or innovation. See id. § 1(b), 3 C.F.R. at 127–28.

to determine the economic impact of the regulations.[318] The Executive Order, which has since been replaced by the Clinton Administration with

318. An even more aggressive cost-benefit requirement for major rulemakings has been proposed legislatively and passed the House "by wide margins of support" in the spring of 1995. See Bob Benenson, House Easily Passes Bills To Limit Regulations, 53 Cong. Q. Wkly. Rep. 679, 679 (1995). If enacted into law, H.R. 9 would require agencies to conduct cost-benefit analyses of all major rulemakings and to promulgate regulations only if the agency is able to demonstrate that the benefits of the regulation "justify, and . . . [are] reasonably related to" the cost of implementing and complying with the regulation. See H.R. 9, 104th Cong., 1st Sess. § 422(a)(2) (1995). In fact, under H.R. 9, the agency must not only justify the costs of a proposed regulation, but must establish that there is no better way to achieve the identified benefits at lower cost. See id. § 324(i)(4)(D). Although unquantifiable costs and benefits may be specified qualitatively, see id. § 324(i)(4)(A), (C), the justification requirement appears to necessitate, as did Executive Order 12,291, that the costs and benefits be monetized in order to determine whether the regulation strikes the appropriate balance between protection of the public health and the economy. This monetization requirement may in turn cause the agency to engage in a economic charade that rivals the science charade: agencies may not only be permitted, but may be mandated to disguise qualitative agency judgments as monetary projections or other quantitative figures derived from complex economic models. In fact, the judicial review requirements set forth in H.R. 9, which allow any party to seek procedural review of a regulation if the agency has not "substantially compl[ied]" with the cost-benefit requirements, see id. § 441, or if the agency is not able to support with "substantial evidence" its conclusion that a rule is justified, see id. § 422(b)(2), could dramatically reinforce the agency's tendency to monetize costs and benefits and to disguise or explain away underlying uncertainties.

Equally troubling are the excessive delays which will almost definitely, and perhaps intentionally, result from H.R. 9. See Benenson, supra, at 681–82 (Benenson quotes Republican Rules Committee Chairman Gerald Solomon as stating that "[f]or years, business and industry have been forced to jump through hoops to satisfy regulators in the bureaucracy. Well, if this legislation becomes law, we are going to turn that around."). First, the extensive procedural requirements of H.R. 9 appear capable of slowing the current standard-setting pace to a virtual halt, see, e.g., Gregory S. Wetstone, And Now, Regulatory Reform, N.Y. Times, Feb. 23, 1995, at A15 (diagramming procedural maze required under H.R. 9), and at the very least may exceed the months of rulemaking delays experienced under the much more modest procedural requirements of Executive Order 12,291. See infra note 325 and accompanying text. Second, under H.R. 9 the agency is also required to conduct additional substantive analyses in its risk assessments which will further deplete limited agency time and resources. See H.R. 9 § 414(b)(1) (agency must include discussion of conflicts in existing studies and data); § 414(b)(2) (agency must present list of plausible assumptions, inferences, and models, and explain bases for policy judgments); § 415(1)(B) (agency must provide statement of reasonable range of scientific uncertainties); § 415(3) (agency must compare the risk in question to similar risks, such as skiing and driving a car); § 415(4) (agency must include analyses of substitute risks—risks of products that could be substituted for the risk at issue). Finally, the peer review requirements incorporated into H.R. 9 for major agency risk assessments should add still more delays to the standard-setting process for each standard. See id. § 431(b); infra note 338 and accompanying text (identifying delays associated with peer review panels). Interestingly, the bill also permits the formation of peer review panels comprised of scientists with admitted institutional allegiances. See id. § 431(a)(3). While this may enhance the range of scientific opinions expressed during peer review, it might also make it difficult for the panel to reach agreement about a standard in a timely fashion. The absence of clear procedures for selection of the peer review panel may also lead to peer review committees with distinct biases.

a less formal requirement,[319] surpassed all previous presidential efforts to force agencies to publicly account for the cost-effectiveness of regulatory programs,[320] and in theory[321] substantially enhanced public participation

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Despite its disadvantages, however, H.R. 9 does present some marked improvements over Executive Order 12,291 with regard to the science charade. See id. §§ 414(b)(2), 415(1)(B). See generally infra note 355.

319. See Exec. Order No. 12,866, 3 C.F.R. 638 (1993), reprinted in 5 U.S.C. § 601 (1994). While the new Executive Order still requires an agency to weigh the costs and benefits of a proposed regulation which the agency considers "significant" for purposes of White House review, see id. § 6(a)(3)(C), 3 C.F.R. at 645–46, the requirement appears to be much less formal since many of the procedural restrictions of the prior Executive Order, most importantly close oversight and enforcement by the Office of Management and Budget, have been eliminated. See infra note 321 and accompanying text. Absent strong internal enforcement, agencies are likely to minimize the effort devoted to ensuring that the economic consequences of rulemakings are clear and accessible to the public. See supra Part III; see also McGarity, supra note 201, at 1311 (noting agency resistance to Executive Order 12,291 and hypothesizing that it was in part due to fact that technical staff "feels threatened by analysis because it directly challenges the status quo approaches to regulatory problem solving that the technical staff historically has dominated").

The Clinton Administration's OMB also recently released a draft risk assessment principles document which encourages agencies to make the assumptions and uncertainties embedded in their risk assessments explicit. See, e.g., Risk Assessment: OMB Draft Principles Document Spurs Some Misgivings From Interested Groups, Chem. Reg. Daily (BNA) 165 d12 (Sept. 7, 1994), available in LEXIS, Nexis Library, Curnws File. The document is criticized, however, as being "too general and not enforceable." Id.

320. See, e.g, McGarity, supra note 201, at 1247–49 (noting that agencies have been formally required to identify regulatory impacts since Nixon and Carter Administrations and that Reagan Executive Order 12,291 added to these prior requirements by "elaborat[ing] on the threshold requirements for regulatory analysis preparation, specif[ying] a cost-benefit format for the analysis, and expand[ing] OMB's role in overseeing and monitoring the regulatory impact assessment process").

321. In practice, certain procedural requirements of Executive Order 12,291 may have actually led to reduced public participation. Perhaps the most notorious was the requirement for a proposed rule to be reviewed by OMB prior to publication in the Federal Register:

> By directing OMB to conduct its review prior to publication of proposed regulations, the executive order deprived the public of an opportunity to learn the unfiltered views of the agency . . . . [U]nder the Reagan program documents reflecting OMB's reviews were not incorporated into the public record, even in rulemakings under the Clean Air Act where Congress had explicitly required it.

Percival, supra note 134, at 151 (footnote omitted). In fact, Percival notes that some critics of regulatory review maintain that public participation was not even one of "the principal aims of regulatory review, particularly during the Reagan Administration." Id. at 180; see also Harold H. Bruff, Presidential Management of Agency Rulemaking, 57 Geo. Wash. L. Rev. 533, 550 (1989) ("The section 2 principles [of Executive Order 12,291] are . . . expressly intended to require agencies to weight competing values in a particular way, and to be prepared to justify regulatory decisions according to a generally prescribed form of analysis. In this sense, section 2 is not neutrally 'procedural.' ").

Other criticisms of Executive Order 12,291 which had some bearing on public participation were the extensive delays caused by the OMB review process and the tendency of OMB officials to iguore or manipulate the agencies' policy and scientific justifications in order to reach a different, less economically burdensome regulation. See Olson, supra note 263, at 40–49. Robert Percival maintains that rather than focusing on maximizing net benefits to society, the Reagan Administration " 'principally used the

by providing the public with a clearer picture of the economic impact of an agency's selected standard.[322]

While a step in the right direction, this cost/benefit approach to enhancing public participation in rulemakings did little or nothing to remedy the science charade: agencies were still not required to disclose the scientific uncertainties or the wide range of error associated with a single standard.[323] In fact, economic analyses, which rival risk assessments both with regard to their complexity and their underlying informational deficiencies and modeling uncertainties, may present many of the same dangers as the science charade by providing incentives for agencies to overstate the dependability of economic calculations in order to justify a selected standard.[324] In addition to doubtful benefits for public participation, regulatory analyses are also likely to increase regulatory delays

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system of OMB review created by the executive orders to implement a myopic vision of the regulatory process which places the elimination of cost to industry above all other considerations.' " Percival, supra note 134, at 187 (citing Alan B. Morrison, OMB Interference with Agency Rulemaking: The Wrong Way to Write a Regulation, 99 Harv. L. Rev. 1059, 1065 (1986)).

322. See McGarity, supra note 203, at 1269 ("Regulatory analysis documents also can enhance public accountability by informing affected persons and encouraging them to participate effectively in the public rule-making process.") (footnotes omitted); id. at 1309–10 ("Many regulatory analysts believe one of the most important benefits of regulatory analysis is that it enhances the quality of public participation in the rule-making process."). In fact one of the express purposes of Executive Order 12,291 was to "increase agency accountability for regulatory actions . . . and insure well-reasoned regulations." Exec. Order No. 12,291 pmbl., supra note 315, at 127. Economic analysis may also "correct communication deficiencies" by alerting appointed officials and congresspersons to the policy consequences of a protective standard, consequences which might otherwise be lost in the agency's science charade. See McGarity, supra note 201, at 1267, 1267–70; Portney, supra note 263, at 236–37 (discussing benefits (including improved cost-effectiveness of regulations) which could result from improved understanding of economic implications of federal regulations).

323. Economic assessments of alternative standards are not required unless the alternative standards "substantially achieve the same regulatory goal at lower cost." Exec. Order No. 12,291 § 3(d)(4), supra note 315, at 129. But see Office of Management and Budget, Executive Office of the President, Interim Regulatory Impact Analysis Guidance (1981), reprinted in 12 Env't Rep. (BNA) 258, 258 (June 19, 1981) (recommending that agencies consider alternative levels of stringency in RIAs). For a proposed reform that does require the agencies to disclose scientific uncertainties under the threat of judicial review, see infra Part V.B.3.

324. OMB-issued guidance under Executive Order 12,291 actually directed the agencies to attempt to quantify all costs and benefits, instructing that uncertainties be listed only after monetary comparisons had been made. Uncertainties thus were residual considerations which were apparently not factored into the determination of whether a regulation's costs were justified by the benefits. See Office of Management and Budget, supra note 323, at 259; see also McGarity, supra note 201, at 1288 ("Too often . . . the regulatory analysis document merely identifies a model without explaining its critical assumptions."); id. at 1328 ("[F]ear of reversal in reviewing courts can induce regulatory analysts and agency attorneys to gloss over uncertainties [in economic assessments] and represent the selected alternative as more attractive than the facts warrant."); supra note 321.

substantially due to the additional time[325] and resources[326] they require. As a result, at least one and possibly two of the goals of environmental rulemaking—expeditious regulation promulgation and enhanced public participation—are adversely affected by such a reform.

3. *Reforms for Optimal Incorporation of Science.* — Efforts to infuse "better science" into the science-based standard-setting process consist primarily of expanded peer review,[327] which is achieved through a greater reliance on science advisory panels to assist the agency in standard-setting.[328] While an advisory panel's comments on a proposed stan-

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325. See McGarity, supra note 201, at 1302–03 (discussing delays resulting from Executive Order 12,291); Percival, supra note 134, at 157–58 (tallying delays resulting from OMB review under Executive Order 12,291, and observing that average OMB delays in 1984 and 1985 for EPA rules was between 50 and 100 days).

326. The cost of conducting one regulatory analysis under Exec. Order No. 12,291 during the early 1980s was on average $100,000 and typically required one or more person-years of agency staff time. See McGarity, supra note 155, at 1406. Although costs decreased as preparation of RIAs became routine, delays and costs were still not insignificant. See McGarity, supra note 201, at 1304–07. The total cost of regnlatory impact analyses on an annual basis was estimated to be from $17 to $25 million. See Portney, supra note 263, at 231.

327. See, e.g., EPA, Safeguarding the Future: Credible Science, Credible Decisions 5–7 (1992) (recommending that EPA can strengthen its scientific capabilities with expanded peer review and better incentives for staff scientists). For an insightful discussion of the unique posture of peer review in regulatory science, see Jasanoff, supra note 69, at 61–83.

328. A Science Advisory Board was legislatively created to assist EPA in its research initiatives and science-based regulatory determinations. See 42 U.S.C. § 4365 (1988). EPA's Science Advisory Board has become increasingly active in assisting the agency with regnlatory decisions over the past decade. See Jasanoff, supra note 69, at 89–91. Although EPA can call on its Science Advisory Board voluntarily, under limited circumstances EPA is legislatively required to submit its regulatory proposals to formal scientific review. See, e.g., 7 U.S.C. § 136w(d)–(e) (1994) (scientific advisory panel established under FIFRA is required to review scientific basis for major regulatory proposals concerning pesticides and to adopt peer review procedures for scientific studies carried out pursuant to FIFRA); 42 U.S.C. § 7409(d)(2)(B)–(C) (1988) (Clean Air Scientific Advisory Committee established to review EPA's ambient air quality standards).

The Food and Drug Administration (FDA) is required to seek the assistance of scientific advisory panels only for medical devices, but FDA also tends to rely heavily on a variety of science panels to review many of its regulatory decisions. See Jasanoff, supra note 69, at 34. OSHA may rely on its technical arm, the National Institute for Occupational Safety and Health, for scientific advice, but traditionally has not sought NIOSH review of its scientific decisions. See id. at 34–35. Finally, the science-based deliberations of the Consumer Product Safety Commission are subject to mandatory peer review by the legislatively created Chronic Hazard Advisory Panels. See 15 U.S.C. § 2080(b) (1994). See generally Jasanoff, supra note 69, at 35 (concluding that legislative provisions dealing with scientific advice display remarkably little consistency of philosophy or approach, but for most part they do leave agencies with considerable discretion in deciding how or whether to use scientific review panels).

The Clinton Administration is also considering reconstituting an existing national scientific advisory board in order to improve the quality of scientific advice available to agencies engaged in science-based rulemakings. See Office of Vice President, supra note 88, at 7–9.

dard is typically not binding on the agency,[329] it can be afforded considerable weight in court.[330]

Extensive peer review does little to counteract the science charade, however, and may even lend it added legitimacy by implicitly classifying protective standard-setting as largely, if not exclusively, a scientific enterprise[331] and by placing important social decisions in the hands of groups of scientists who may have numerous reasons to exploit their authority.[332] Advisory panels, comprised predominantly, if not entirely, of scientists who are "[p]rotected by the umbrella of expertise," often find themselves "free to serve in widely divergent professional capacities" including that of "policy advocates."[333] These panels can therefore function to resolve not only scientific or technical issues, but also political conflicts.[334] Although the resulting peer reviewed standards generally do succeed in incorporating science in the fullest and most accurate way,[335] embedded policy judgments can be even more difficult to discern or evaluate in the final regulatory justification supporting a standard,[336] and the lay public is likely to find the standards less, rather than more, accessible. Furthermore, the standards created in proceedings led by scientists on these advi-

329. See Jasanoff, supra note 69, at 35.

330. See id. at 249 ("[C]ourts may have considerable difficulty discerning when a committee has strayed over the indeterminate border between science and policy . . . . [Thus] when a smoothly functioning advisory process is in place, as in EPA's air pollution control program, the rationale for judicial intervention on substantive issues will be weak at best.").

331. See, e.g., id. at 229 ("There is growing awareness in both [EPA and FDA] . . . that timely consultation with outside experts can prevent controversy or, at the very least, protect effectively against challenge.").

332. See generally supra Part III.C.2.

333. Jasanoff, supra note 69, at 237.

334. See id.

335. Since scientists often play a significant role in developing the standards in the course of peer review, problems resulting from the agencies' failure to disclose scientific uncertainties and sources of error, see supra Part IV.C.1, are generally overcome. See, e.g., Greenwood, supra note 14, at 126–30 (concluding that scientific advisory committees generally enhance scientific accuracy of regulations and regulatory agencies); Jasanoff, supra note 69, at 241 (noting that conscientious scientific review by advisory panels certifies that the agency's scientific approach is balanced and rational and that its conclusions are sufficiently supported by the evidence).

336. See, e.g., Jasanoff, supra note 69, at 229 ("[Science a]dvisory committees, we know from experience, rarely restrict their deliberations to purely technical issues. In fact, the experts themselves seem at times painfully aware that what they are doing is not 'science' in any ordinary sense, but a hybrid activity that combines elements of scientific evidence and reasoning with large doses of social and political judgment."); id. at 122 (describing policy role played by EPA's Clean Air Science Advisory Committee); id. at 178 (describing policy role played by FDA's scientific advisors and concluding that "[t]he ambiguity of the boundary between science and policy is also strategically useful to FDA, permitting the agency to harness the authority of science in support of its own policy preferences"); see also McGarity, supra note 155, at 1398 (concluding that scientific advisory process has "divested agencies of a certain degree of discretion to press the process forward toward particular policy-dominated outcomes").

sory boards "lack many of the safeguards of classic administrative decisionmaking," making it difficult for the public to effectively participate or voice their concerns in the process.[337] Regulatory delays are also typically increased when science advisory boards are involved since they add yet an additional layer to the cumbersome administrative process.[338] Thus, this reform again leaves two of the three environmental rulemaking goals unfulfilled, and may even exacerbate the problem of the science charade.

B. *Proposed Reforms*

Current reforms fall short of providing a permanent remedy to the science charade. At least two explanations may be offered to account for this failure. Proponents of the first, more gloomy explanation posit that the science charade results because an inadequately educated public has too much confidence in science. A number of social scientists have observed that despite some growing skepticism,[339] the general public continues to entrust important social decisions to scientists[340] who may not

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337. See Jasanoff, supra note 69, at 229 (further observing that "[p]articipation by lay interests is limited and often one-sided, cross-examination is almost unknown, and committee recommendations, however much weight they carry, are seldom accompanied by detailed explanations or consideration of alternatives"); id. at 247 ("[S]ignificant policy decisions, particularly decisions not to act, may be reached after advisory deliberations that effectively engaged only one set of interests [i.e., industry].").

338. See McGarity, supra note 155, at 1409–10 (documenting how use of scientific advisory boards often slows the pace of rulemakings); see also supra note 69.

339. The public has only recently begun to call into question the motives and capabilities of scientists. See supra Part IV.C.3. Despite this slight decline in public confidence, the general public continues to place great trust in the scientific community. The public also appears to have somewhat contradictory opinions about scientific information. In a recent survey, 76 percent of the respondents generally agreed with the statement that "you can find a scientific study that proves just about anything you want to prove," yet 86 percent admitted that references to a scientific study increased the credibility of a story. See Cynthia Crossen, Tainted Truth: The Manipulation of Fact in America 36 (1994).

340. In a public opinion survey conducted in three California cities, lay subjects were asked to gauge the reliability and preferred authority of eight sources of information, which included government officials, industry officials, and knowledgeable acquaintances, concerning technological risk. Of the eight sources, "university expert" was considered the most reliable. "University experts" also ranked at the top as the preferred source of influence on decisionmaking. (Interestingly, the subjects perceived "politics" as the largest influence on risk decisions.) The authors concluded that "[i]t is likely . . . that the reputation of the independent expert is one that will prove useful to the political process and that university scientists will be called on more often to help allay public fears." Marc Pilisuk et al., Public Perception of Technological Risk, 24 Soc. Sci. J. 403, 407–411 (1987); see also National Science Board, Science & Engineering Indicators 203 (1993) (reporting a General Social Survey which revealed that "the leadership of medical and scientific communities has been among the most trusted in the nation—more so, for example, than the leadership of the Supreme Court"); id. at 484 tbl. 7-13 (since 1983 over 80 percent of public agree that "science and technology are making our lives healthier, easier and more comfortable").

The illusion of a complete science-basis for toxics regulation is so strong that 92 percent of the attentive lay public interviewed in a study by Jon Miller stated that scientists

always be forthright about their restricted abilities and may be willing to function as a wise and powerful elite.[341] Much of this naivete can be attributed to the distressing fact that approximately eighty percent of the American public lacks a working knowledge of basic science, which in turn prevents the public from understanding the dramatic limitations of the scientific method.[342] Deficiencies in scientific and risk education also appear to have caused the public to demand a risk-free world and to expect science to be able to provide it.[343] Faced with public insistence on the elimination of toxic risks, public officials use the cover of science to disguise the fact that unpleasant tradeoffs are needed. By doing so they avoid the unpopularity that revealing "the truth" may bring.[344] If the proponents of this first explanation are correct, the science charade is so deep-seated that it can only be abated by vastly improving the scientific education of lay persons or by abandoning our democratic form of government because, as Plato feared, the public cannot be trusted with making decisions on issues which surpass their competency.[345]

A second and more optimistic explanation for the failure of past reforms is that they fail to counteract any of the incentives that currently lead regulators to frame policy choices as based on scientific research. Past reforms outlined in Part V.A have been designed and implemented without considering the science charade, and hence they tend to exacerbate some symptoms of the charade—such as impaired public participa-

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and engineers should set standards for food additives. See Miller, supra note 219, at 92. The second most preferred group for standard setting was a federal regulatory agency, selected by 59 percent of the attentive public. See id. at 93; see also Marcus E. Ethridge, Procedures for Citizen Involvement in Environmental Policy: An Assessment of Policy Effects, *in* Citizen Participation in Public Decision Making, supra note 148, at 115, 123 (noting that citizen participation fell far short of expectations despite EPA's "vigorous" efforts, with eight out of every ten participants generally being government officials or government consultants).

341. See David S. Landes, The Disenchantment of Success *in* Fear of Science—Trust in Science 71, 82 (Andrei S. Markovits & Karl W. Deutsch eds., 1980) (observing general population's view of scientists as a "new kind of priesthood"); Kristina Petkova & Pepka Boyadjieva, The Image of the Scientist and its Functions, 3 Pub. Understanding Sci. 215, 215 (1994) ("Many leading sociologists of science have pointed out that the scientist is portrayed by society as an almost mythological figure."). See generally supra notes 51–52 and accompanying text.

342. See National Science Board, supra note 340, at 200 (approximately 10 percent of the U.S. population "display a high level of interest" in science, "believe that they are well-informed about it," and "display a pattern of current information consumption"); id. at 209 (results of 1992 study on public attitudes towards science "point to substantial gaps in the public understanding of environmental science concepts" despite "a high level of public concern about the environment"); id. at 210 (two recent studies on public knowledge of scientific method reveal that only "about one in five American adults was able to provide an acceptable definition of a scientific study" and "not more than a third of American adults have a minimal understanding of scientific processes").

343. See supra notes 137–139 and accompanying text.

344. See supra notes 140–143 and accompanying text.

345. See Plato, The Republic 133 (G.M.A. Grube trans., 1974) (arguing that philosopher class should govern).

tion and the complete and accurate incorporation of science—in the course of correcting other problems, such as regulatory delays. If a reform of protective standard-setting is to be successful, it must go beyond superficial attempts to ensure more rapid regulation promulgation, more quantitative information upon which the public can comment, or better scientific accuracy in resulting standards, and directly combat one or more of the incentives that make the science charade so pervasive.

Although the pessimists may be correct in positing the first explanation and predicting the perpetuation of the charade irrespective of aggressive governmental reforms, until conclusive evidence is produced demonstrating that the science charade cannot be overcome except by extensive education programs, the more responsible course is to continue attempts at counteracting the charade through incremental reforms of governmental processes.[346] The reforms proposed in this final subpart follow this course and are designed to combat one or more of the causes of the science charade. While none of these reforms is perfect, particularly with regard to satisfying all three regulatory goals simultaneously, hopefully they will initiate a dialogue that may eventually work toward ending the science charade.

1. *Congress.* — In theory, the most democratic and comprehensive way to stop the science charade is to remove from agencies the authority to make significant policy decisions. Congress, rather than unaccountable bureaucrats, would legislate all policy decisions and state those choices explicitly in the text of the legislation.[347] Administrative agencies would be left to resolve only the remaining technical details.

One would expect that by transferring to Congress the responsibility for making all policy decisions, serious deficiencies in the current system would be corrected. Public participation would be enhanced as the need for scientific expertise is reduced, entry costs are lowered, and authority for policymaking is placed on elected officials.[348] Administrative delays

346. An improved scientific education should remain a high priority in the United States and would undoubtedly succeed in eliminating, or greatly reducing, the significance of the science charade. The reforms proposed in this final subpart are by no means meant to be a substitute for better scientific training, but are premised on the realistic assumption that educational programs will take at least several decades before the general public is able to contribute meaningful comments on protective standards that are obscured by the science charade.

347. The legislature would first need to establish an overarching public policy goal, for example, that no more than one in one million cancers be tolerated from exposure to a substance. The legislature could then direct in a generic fashion that "middle range" or "risk averse" assumptions be used at each stage of decisionmaking. The legislature could also direct the agency to adopt more specific assumptions unless better evidence is available, such as the use of a linear curve for all extrapolations; the inclusion of all tumors, not just malignant tumors, in counting; and the use of animal studies for extrapolation to humans.

348. See David Schoenbrod, Power Without Responsibility: How Congress Abuses the People Through Delegation 119–21, 129–31 (1993) (concluding that "agency expertise" justification for delegation is flawed and that public participation in and commitment to

and skewed prioritization schemes would be eliminated, since the legislature would resolve all regulatory decisions in a single piece of legislation challengeable only with regard to its constitutionality, not its reasonableness. Finally, congressional hearings on the relevant science and its limitations should ensure that the proper contributions of science are identified and debated prior to legislative codification of quantitative standards or risk assessment guidelines.

Upon reflection, however, it becomes evident that a complete reliance on Congress to end the charade is likely to lead to disappointment. First and most obvious are the practical barriers to implementation. It is highly probable, given the controversial nature of the issues, that Congress has deliberately delegated policy decisions regarding the appropriate level of toxic risk to the executive branch precisely in order to avoid making the decisions itself.[349] If this is the case, it is difficult to do anything about it. Nondelegation doctrine challenges, which assert that legislative decisions have been unconstitutionally delegated to an administrative agency, have proved uniformly unsuccessful for several decades.[350] Even if Congress decided—either voluntarily or through a successful

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environmental policy choices would be greatly enhanced if policy choices were made by Congress rather than agency).

349. As discussed in supra Part III.A, any toxic standard which requires striking a balance between protection of health and the environment on the one hand and the economy on the other will draw opposition from sectors in every congressional district. For Congress, potential unpopularity is avoided by passing these damaging decisions on to the agencies, where the President must bear ultimate responsibility for the political hot potato. See Melnick, supra note 17, at 253 (speculating that in Clean Air Act, Congress may have provided broad mandate precisely in order to be relieved of "the burden of resolving difficult controversies"); Percival, supra note 134, at 194 ("One of the reasons Congress has delegated such significant responsibility to EPA is Congress's own reluctance to determine precisely who the winners and losers should be in allocating the burden of environmental regnlation."); see also Peter H. Aranson et al., A Theory of Legislative Delegation, 68 Cornell L. Rev. 1, 64–67 (1982) (calling for renewed nondelegation doctrine so that legislature can no longer shift political responsibility through regulation); cf. Jerry L. Mashaw, Prodelegation: Why Administrators Should Make Political Decisions, 1 J.L. Econ. & Organization 81 (1985) (arguing that vague mandates of policy authority to agencies are better than no action).

In fact, in H.R. 9, supra note 318, Congress appears to be doing exactly that: the agencies are reprimanded for conducting inadequate risk assessments in the past and mandated in a reform of agency risk assessment to conduct even more analyses in the future. The agencies, rather than Congress, will be held accountable if policy decisions are made unwisely. See id. § 402(4) (Congress finds that in risk assessments agencies should do better job collecting, organizing, and evaluating scientific and other data); Benenson, supra note 318, at 681–82 (quoting Republican Rohert Walker who touts H.R. 9 as legislation designed to ensure that "good science" determines appropriate level of regulation). See generally supra note 318 for discussion of H.R. 9.

350. See, e.g., Touby v. United States, 500 U.S. 160, 165 (1991) ("So long as Congress 'lay[s] down by legislative act an intelligible principle to which the person or body authorized to [act] is directed to conform, such legislative action is not a forbidden delegation of legislative power.' ") (questioning J.W. Hampton, Jr., & Co. v. United States, 276 U.S. 394, 409 (1928)); Schoenbrod, supra note 348, at 41–45 (noting that nondelegation challenges have generally not succeeded in courts).

nondelegation doctrine challenge—that policy decisions should be made at the legislative level, however, there is no guarantee that explicit agreement on policy would be reached. Years of legislative inaction and the resulting underprotection of public health and the environment, which equal or exceed current administrative delays, could result if the regulation of toxics were suspended until Congress agreed on how to resolve these highly contentious environmental problems.[351] Even after a decision was ultimately reached on one or more science-policy issues, however, developments in science might require Congress to revisit these complex statutory programs frequently, a task which might prove impracticable, if not impossible.

Second, political incentives that cause agencies to engage in the science charade would seem to apply with even greater force to Congress. In fact, Congress may have already engaged in its own legislative science charade in recent environmental legislation, enacting quantitative standards and technical goals that appear to be based on science, but which in truth are the result of invisible, political compromise.[352] A science

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Even if the nondelegation doctrine could be reinvigorated, see, e.g., id. at 180–91 (proposing how the nondelegation doctrine could be reformed and brought back to life); Harold J. Krent, Delegation and Its Discontents, 94 Colum. L. Rev. 710, 710 (1994) (reviewing Schoenbrod, supra note 349) (presenting penetrating critique of Schoenbrod's reform and less revolutionary counter-reform), however, it would be difficult for courts to enforce the claim in the case of toxic standards. Particularly problematic would be the complexities involved in identifying the nature and extent of policy decisions when they are located intermittently between scientific issues, when they generally appear scientific, and when they are cumulatively significant but less important individually. If a nondelegation doctrine challenge were successful in the future, however, it could provide a superb hammer to force Congress to take responsibility for the various policy choices and reverse the science charade. But see infra notes 351–354 and accompanying text.

351. See Mashaw, supra note 349, at 95–99; Daniel B. Rodriguez, Management, Control, and the Dilemmas of Presidential Leadership in the Modern Administrative State, 43 Duke L.J. 1180, 1184 (1994) ("The assertion that because legislators develop their own agendas and interests it is difficult to mobilize 535 of them in the direction of comprehensive reform is, all things considered, rather modest."). But see Schoenbrod, supra note 348, at 121–22 (arguing that Congress may be more expedient in finalizing rules legislatively than agencies because of regulatory ossification).

352. In the Clean Air Act Amendments of 1990, for example, very specific quantitative standards for pollutant levels in a variety of fuels were legislated, see, e.g., 42 U.S.C. § 7545(k) (Supp. V 1993), but the scientific basis for these numbers cannot be traced in the sparse legislative history. Congress has also delayed resolution of environmental problems by characterizing an issue as completely resolvable by science. In the case of acid rain, for example, Congress relegated resolution of the problem to scientists until the scientific uncertainties had become inescapable. Only after a decade of policy paralysis, while a congressionally-funded scientific panel struggled with the impossible task of quantifying the damage done by acid rain and tracing the damage back to specific sources, see Leslie Roberts, Learning from an Acid Rain Program, 251 Science 1302, 1302 (1991) (describing extraordinary time and expense associated with National Acid Precipitation Assessment Program (NAPAP)), was Congress able to recoguize the scientific limitations and reach agreement on a 10-million ton reduction target for electric utility sulfur dioxide emissions which had no basis in science. See id. at 1305 ("NAPAP's final integrated assessment, evaluating likely emission reduction scenarios, was released in draft form last

charade at the legislative level may actually pose more dangers both to democracy and to the optimal incorporation of science than the administrative science charade because there is no possibility of oversight by the courts[353] and because there is no opportunity for the public to comment in a direct or systematic way to ensure that legislated science-policy is accurate.[354] In fact, many congresspersons themselves may be unaware of the policy ramifications of quantitative standards and goals embedded in legislation when those provisions are presented by more scientifically sophisticated colleagues (or their staff persons) as based on noncontroversial scientific principles.

2. *The Agencies.* — Since a reform of Congress leaves considerable room for improvement, it seems logical to consider whether the science charade can be combatted by a reform directed at the agencies. Both a moderate and a revolutionary proposal for agency reform are offered.

The more modest reform would require agencies to disclose the rough magnitude of policy decisions made in selecting each toxic regulatory standard. Specifically, agencies would be instructed, preferably through an Executive Order,[355] to calculate the economic conse-

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September, almost at the moment Congress was passing a bill mandating a 10-million ton reduction in sulfur emissions."); Edward S. Rubin, Global Warming Research: Learning from Past Mistakes, USA Today, Sept. 1993, at 64, 65 (in Clean Air Act decision regarding extent of sulfur emissions reductions "was decided with virtually no input from NAPAP [National Acid Precipitation Assessment Program]" and it is still unclear whether reductions will provide too much or too little protection). It is unclear whether this delayed outcome was deliberate (to stall acid rain controls) or unintentional (Congress lacked the scientific expertise to ask focused and "answerable" scientific questions and to oversee the scientific panel) or both.

Ongoing research which will form the basis for a subsequent article on "Legislated Science" indicates that Congress' approach to reaching scientific conclusions appears to be haphazard at best. Preliminary interviews with congressional staff reveal that in some cases scientific findings are gathered by individual congresspersons or staff members. In other instances certain quantitative limits and other scientific findings codified into law have been reached through compromise, despite the fact that they appear scientifically ordained. In either case, however, the resulting decisions would seem to be inaccessible to most congresspersons and to the public at large.

353. Even though judicial review of agency standard-setting is currently far from optimal with regard to ensuring honest science-policy delineations, it does appear to cause agencies to go to great effort to ensure that their factual details are correct. See, e.g., supra notes 172, and 181–185 and accompanying text.

354. Cf. Krent, supra note 350, at 723 ("[D]elegation should be beneficial from a policy standpoint whenever the potential for rent-seeking or abuse in Congress is greater than in agencies.").

355. Included in the recently passed bill, H.R. 9, is the requirement that agencies provide a reasonable range of scientific uncertainties in each risk assessment, such as low- and high-end estimates of risk using scientifically plausible conservative and risk tolerant assumptions, respectively. See H.R. 9, supra note 318, § 415(1)(B). Under H.R. 9 agency estimates may be scrutinized and ultimately remanded by reviewing courts, however, see id. § 441, and hence this legislative proposal will almost surely add substantial additional delays and costs to the standard-setting process as compared to an unreviewable Executive Order mandate. See generally supra note 318.

quences[356] resulting from two scientifically plausible quantitative standards, which in one case incorporate uniformly risk tolerant assumptions[357] and in the other case adopt risk averse assumptions.[358] Although this disclosure will reveal little about the number, identification, or significance of the individual trans-scientific junctures at which policy choices have been made, it will call attention to the cumulative scientific uncertainties associated with science-based standard setting.[359] All regulatory participants, including the public, courts, and Congress, would be enlightened as to the extent of policy consequences emerging from a science-based standard and might begin to question the absence of policy discussions in regulatory preambles.[360] Agencies might respond to this

356. Because of the limitations of information and the substantial resource demands required for economic analyses, the scope of these estimates should be limited to readily available information, with uncertainties and unverifiable assumptions clearly expressed in the agencies' published analyses. See infra note 382.

357. Risk tolerant assumptions are those that would be the least risk averse. For example, in selecting a high to low dose extrapolatory curve, the threshold model would be selected, see Figure 2, because it predicts no risk below a relatively high dosage and is thus the most risk tolerant of the extrapolatory curves.

358. Risk averse assumptions are those that adopt the worst case scenario. In selecting the most risk averse high to low dose extrapolatory curve, the supra-linear model would be selected. See Figure 2. Of the available models, this curve predicts the greatest risk at the lowest concentrations. An alternate term for "risk averse" used more commonly in the risk assessment literature is "conservative." See, e.g., NRC Risk Assessment, supra note 14, at 37 ("A risk assessor, in the absence of a clear indication based on science, could choose a particular approach (e.g., the use of an extrapolation model) solely on the basis of the degree to which it is conservative, . . . a desire to err on the side of overprotection of public health . . . .").

359. The range of policy implications arising from the identification of a risk averse and risk tolerant standard should be considerable. See Nichols & Zeckhauser, supra note 44, at 18 (describing 35,000x difference between two estimates of risk for perchloroethylene). Due to the obvious difficulties confronting policymakers when presented with two estimates which can vary so widely in policy implications, Nichols and Zeckhauser have suggested that an additional, "expected-value" estimate should be made which would enable policymakers to base a standard on the weighted average of all risk estimates with the weight for each estimate based on the subjective probability that it is correct. See id. at 21. The authors admit, however, that their "expected-value" approach incorporates some assumptions about risk that runs counter to public attitudes, see id. at 22–24 (public's lower tolerance of catastrophic risks would be iguored since all deaths would be viewed as same in "expected-value" model), and that their proposal cannot be implemented at the current time given the many scientific uncertainties which plague risk assessments. See id. at 24 ("At several critical steps in risk assessment, such as extrapolating from high-dose to low-dose risks . . . , our knowledge is so meager that there is no way to judge objectively the probability that alternative risk estimates are correct."). Based on the inescapable limitations of their more progressive "expected-value" approach, Nichols and Zeckhauser ultimately retreat to a reform recommendation which amounts to the one proposed here. See id. at 24 ("[S]cienists should begin to present policy officials with a broader range of risk estimates.").

360. See id. at 24 (concluding implementation of this reform may not be perfect, but even though "policy makers may continue to take refuge in upper-bound estimates, at least the uncertainties involved, and the degree of exaggeration built into conventional estimates, would be clear to them and to the public. Moderation in regulatory decisions

heightened scrutiny by questioning the prominent role played by scientists in the standard-setting process. Congress might also be persuaded to alter those mandates that require protective standards to be based exclusively on science.[361] Such a simple reform would also appear to have a straightforward implementation.[362]

While this modest reform should be effective in counteracting the unintentional charade, which results primarily from agency officials' mistaken impression that protective standard-setting is largely a scientific endeavor, it may not be strong enough to overcome the many incentives that lead officials to engage in the charade deliberately.[363] Since the reform will equip the public and courts only with the knowledge that policy choices are embedded somewhere in the standard-setting process and that the economic ramifications of these policy choices are far-reaching, it may not improve the ability of the public or the courts to recognize or challenge the agencies' concealment of specific policy decisions as scientifically determined.[364] Absent these more sophisticated inquiries from a better informed public and judiciary, an agency with multiple incentives to engage in the charade is unlikely to volunteer individual policy decisions. At best, the agency may only admit to some overarching policy biases, such as the tendency to adopt worst-case assumptions in order to ensure that public health is adequately protected. The courts would then be left with the dilemma of determining whether these general statements are sufficient to support the agencies' conclusions.

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would be a likely result."); see also Cranor, supra note 1, at 134 (concluding that in order to democratize standard-setting, uncertainties must be identified in publicly accessible way).

361. See supra Part III.B.4.

362. Execution of Executive Orders is relatively unencumbered with process, see, e.g., Rodriguez, supra note 351, at 1194–95 ("Not plagued by the difficulties associated with collective decisionmaking, the presidency is an institution of action, capable of responding [with regulatory reforms] . . . ."), and the President is likely to reap political benefits by revealing the extent of the policy decisions delegated by Congress, even though the Order might make the agencies' regulatory writing process more formidable.

363. Although this reform would not seem to assist in meeting the other two regulatory goals of expeditious regulation promulgation and the optimal incorporation of science, it should not make them markedly worse, as other reforms appear to do. For example, in contrast to H.R. 9, supra note 318, this proposal should not pose a significant drain on agency resources. Since the courts will not have the authority to review agencies' compliance with the requirements of this Executive Order, there should be no added delays resulting from additional litigation, and thus the agency will be less concerned with quantitative precision in providing rough upper and lower bound estimates. Some additional agency resources may be necessary to prepare the estimates, but they should not prove too onerous since only two crude estimates are required.

364. It is possible that the realization of the siguificant policy judgments incorporated into the standard-setting process may encourage the public and courts to educate themselves with regard to both the science and the trans-science in risk assessments. In this sense, the modest reform could act as a catalyst to improve public understanding of the contributions of science and policy in setting a protective standard.

A much more revolutionary reform of agency standard-setting, which is modeled partly on the European system,[365] would provide a carefully selected administrative task force with carte blanche authority to set a quantitative standard.[366] The task force would be comprised of several "neutral" research scientists from academia or government, several appointed or high level agency officials, and one scientist and one policymaker from each group having a major stake in the standard. Selection of the private members of the task force would be governed by detailed procedural protections equivalent to APA notice and comment and subject to judicial review.[367] Under the current proposal, however, the task force, once formed, would not be required to solicit or respond to public participation in developing a standard,[368] and the final standard would not be capable of being challenged in court.[369] Implementation of this

365. In Great Britain and Germany, the governments give almost unlimited power to several standing committees comprised of a mix of industry, public interest, and government representatives. These committees "review nearly all agency programs and proposals, typically enjoy the power of initiation and unrestricted purview, and almost always see their recommendations adopted by their official sponsors." Ronald Brickman et al., Controlling Chemicals: The Politics of Regulation in Europe and the United States 162–65 (1985) (describing ACTS (Advisory Committee on Toxic Substances) in Great Britain and AGA (Committee on Hazardous Substances in the Workplace) in Germany). The resulting regulatory actions taken by the ACTS standing committee in Great Britain appeared to parallel roughly the actions taken by EPA and OSHA in the United States. See id. at 330–36 tbl. A2 (of 36 Group 1 carcinogens, Great Britain had banned four, while the U.S. had banned three by 1985). Since judicial review of administrative actions is quite restricted in both Britain and Germany, see generally id. at 100–19 (identifying limited scope of review of agency actions in Europe and comparing to more aggressive posture of U.S. courts), the possibility of judicial review of the activities of these European standing committees is effectively nonexistent.

366. Bert Black, in comments on a draft of this Article, suggested this reform as a possible approach to combatting the science charade. Mr. Black, in turn, credits Bruce Ackerman as the originator of the idea, although it was not developed in connection with the science charade.

367. Although the agency is currently required to notify the public before convening an advisory panel under the Federal Advisory Committee Act, 5 U.S.C. app. § 9(a)(2) (1994), the public is not involved in the selection of committee members. Thus, under the current proposal, the public would actively participate in the development of such task forces.

368. Even though the task force's ultimate acceptance or rejection of public comments would not be subject to judicial review, it might still be beneficial to open all task force meetings to the public, to provide the public with access to transcripts of all task force meetings, and to provide the public with an opportunity to comment on task force deliberations. Cf. 5 U.S.C. app. §§ 10–11 (1994) (all advisory committee meetings are open to public and transcripts of all meetings must be made available to public).

369. While the revolutionary reform has theoretical similarities to negotiated rulemaking where interested parties serve as participants rather than as advocates, the inability of the public to formally comment on or challenge the task force's selected standard diverges dramatically from the adherence to standard notice, comment, and judicial review of rules emerging from negotiated rulemakings. See supra note 293 and accompanying text. In addition, unlike negotiated rulemaking, the selection of task force members in the revolutionary reform would involve extensive public participation in order to ensure that the selected members fully represent diverse public views.

reform, then, would be contingent on the enactment of specific authorizing legislation.[370]

Delegating full responsibility for standard-setting to an administrative task force completely bypasses several of the major incentives that currently fuel the science charade, such as the public comment process, judicial review, and various political forces.[371] Delegating protective standard-setting to an administrative task force should also succeed in meeting at least two of the three goals of environmental rulemaking. Administrative delays would be significantly shortened, assuming consensus could be reached, since the task force would not be burdened with soliciting and responding to public comments, compiling administrative records, or withstanding lengthy and expensive judicial challenges. Scientific accuracy would also be assured since a number of carefully selected scientists with different institutional biases would be contributing to the selection of a final standard.[372]

While this more revolutionary reform would seem to go quite far in ending the charade, it does so largely at the expense of the third goal of environmental rulemaking, public participation. The extensive public comment in selecting task force members provides important participatory protections. Nevertheless, it is unlikely that the few interest groups, industries, and agency officials that make up the task force will be capable of adequately representing the diverse values of the public even if consensus could be reached on their selection.[373] The dangers of relying on task force members as representatives of the public is even more pre-

370. The statute would need to prohibit judicial review of the final agency standard embodied in the task force's recommendation. See Abbott Lab. v. Gardner, 387 U.S. 136, 141 (1967) (stating that Congress must be clear in its intent to preclude judicial review of certain agency actions). Since constitutional issues are presumably not implicated in the promulgation of protective standards, see Pierce et al., supra note 151, at 118, Congress is free to eliminate legislatively the right to judicial review for such matters. See id. at 118 ("A party attempting to obtain judicial review of an agency action must find a right to judicial review either in a statute governing the action or in the Constitution."). Congress might also wish to specify the general procedures an agency must follow in convening a task force, particularly with regard to the selection of committee members.

371. While scientists within the task force may continue to face incentives that cause them to categorize embedded policy issues as scientific in nature, the purpose of the task force (to counteract the science charade) coupled with the presumed sophistication of those persons skilled in policy analysis should diminish the possibility of a scientist-dominated outcome. Interest groups might also be less apt to use science to disguise their underlying policy disputes since they will be operating in a less adversarial setting.

372. In fact the scientific expertise in the proposed task force would rival that present in most science advisory boards which are created specifically to ensure that the agency's science is current and accurate. See supra Part V.A.3.

373. See, e.g., Susan Rose-Ackerman, Controlling Environmental Policy: The Limits of Public Law in Germany and the United States 106 (1995) (concluding that German efforts to use negotiations to develop environmental regulations do not and possibly cannot "fulfill the conditions required to produce a legitimate policy choice" because some parties "who will be affected by the deliberations are not at the table" and even citizen groups which are present "cannot make strong claims to represent the general public").

carious in light of the fact that task force members will not be accountable once they have been chosen and confirmed. The American public's dedication to full participation in administrative matters, which appears to be more entrenched than in Europe,[374] thus makes it unlikely that the public would support the legislative amendments necessary to implement this radical reform.

3. *The Courts.* — While the modest agency reform discussed previously may counteract at least some aspects of the charade, a more formal reform of administrative rulemaking that entrusts the courts with review of an agency's science-policy delineations may be the most effective and practical mechanism for bringing the charade to an end. In order to correct the courts' current inclination to interpret the APA to require more, rather than less, quantitative and technical justifications,[375] an amendment to that statute is essential. The amendment should expressly require the agencies to separate science from policy[376] and task the courts with the responsibility for ensuring that the agency does so in an accurate and accessible way. The amendment should also specify that once the court has taken a "hard look" to ensure that the agency has adequately separated science from policy,[377] the court should accord the

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374. Brickman et al. found that legislative oversight and judicial review of administrative agencies were much more extensive in the United States than in England, France, and Germany. See Brickman et al., supra note 365, at 93 (U.S. Congress is most zealous in supervising exercise of power of executive branch); id. at 100 (challenges of administrative decisions regarding regulation of toxic chemicals are litigated much more extensively in U.S.).

375. See supra notes 173–185 and accompanying text.

376. Many of the leading science-policy scholars have concluded that some type of separation of science and policy is necessary to improve the rulemaking process. See, e.g., NRC Risk Assessment, supra note 14, at 7 (explicit separation of science from risk assessment policy is necessary to keep policy decisions from being disguised as scientific conclusions); Science and Judgment, supra note 23, at 8 (recommending that "EPA . . . explicitly identify each use of a default option in risk assessments . . . [and] should clearly state the scientific and policy basis for each default option"); Graham et al., supra note 12, at 203–05 (concluding that agency officials should work closely with agency scientists to identify in a rough way the true extent of the scientific uncertainty with regard to a particular quantitative standard); Latin, supra note 35, at 142–43 (urging regulators to "emphasize the policy-oriented bases of their decisions"); Roberts et al., supra note 26, at 116, 120–21 (recommending "deep mapping" in developing a standard, which would require disputants to explore nature and sources of scientific disagreement). But see Jasanoff, supra note 69, at 230–31 (concluding that science and policy cannot be separated nor is the attempt at "rigid" separation well-advised). These scholars uniformly propose reforms which are voluntary in nature, however, and hence overlook the numerous incentives which lead the agencies to engage in the science charade. See, e.g., Graham et al., supra note 12, at 218 (suggesting that because of difficulties of separating science and policy completely, voluntary efforts should be made by agency to effect more honest separation); Latin, supra note 35, at 142–43 (recommending that regulators "preemptively acknowledge their inability to provide dispositive scientific answers to many important questions").

377. This generally would require the agency to provide in its proposed and final rulemaking preambles: 1) a list of each trans-scientific juncture encountered in the

content of the policy and science decisions great deference[378] provided the agency has given some nonarbitrary basis for its conclusions. For example, a subsection (2)(G) could be added to Section 706 of the APA[379] directing the courts to set aside agency action, findings, and conclusions found to be: "(G) based on facts or policy judgments which are not clearly identified or which are not clearly explained using existing and readily accessible qualitative and quantitative information. The court should, however, afford great deference to agency conclusions of fact and policy once identified, and should not substitute its judgments for those of the agency."[380]

A reform which places more direct responsibility on the courts to restrain agencies from engaging in the charade should eliminate many, if not all, of the incentives for the charade. First and most importantly, agencies should find the judiciary more forgiving and hence will be more likely to divulge administrative policy choices once the courts have been specifically instructed by Congress to give these agency judgments added deference. Agencies should similarly be freed from the pressure to envelop regulatory preambles in unnecessary hypertechnical explanations

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specific standard-setting project, similar to the list published by the National Research Council, see Appendix; 2) the policy choice and scientific assumptions adopted at each trans-scientific juncture; and 3) the basis for each policy choice and scientific assumption. The public thus will be specifically invited to comment not only on the agency's resolution of the separated policy and scientific components, but also on the agency's initial characterization of the portions of the problem actually resolvable or guided by science.

378. See, e.g., Pierce, supra note 180, at 326–28 (noting that it is a " 'long accepted' principle" that courts must defer to agency policy choices, but concluding that additional Supreme Court precedent reaffirming this principle might be helpful).

379. 5 U.S.C. § 706 (1994).

380. Although it is possible that Congress might ultimately resist such an amendment if it believes that its delegation of significant policy questions would be revealed and that such a revelation would have adverse political repercussions, the passing of H.R. 9 by the House in the spring of 1995 would suggest that at least half of Congress is willing to require the agencies to divulge policy choices. See supra note 318. In fact, adjustments to the 50 year-old APA are long overdue. The APA, passed in the 1940s, was designed primarily to provide public input into the government's regulation of firms using monopoly positions to charge excessive prices or reduce services. This single-minded purpose of the APA may be insufficient for these new, more complex regulatory problems. See Yellin, supra note 35, at 1301–05 (arguing that agency responsibilities under current statutes go well beyond duties of agency experts during New Deal). Public health regulation, for example, requires an entirely different set of administrative tools and involves more numerous and siguificant policy determinations. See Melnick, supra note 17, at 6.

Congress could also be more specific in legislation or in legislative history that risk assessments based solely on positive animal data provide sufficient science and policy information for the promulgation of science-based standards. See Graham, supra note 64, at 150 ("By stating clearly that positive animal data on carcinogenicity are sufficient to justify listings, Congress would accelerate the listing process."). This will further offset the tendency of the agency to develop standards only for those substances that have the most extensive and definitive scientific studies regarding their toxicity, see supra Part IV.B.2, in order to survive, among other things, aggressive judicial review.

in order to survive judicial review.[381] Indeed, if this added deference were not given to agency fact or policy judgments, the proposed judicial reform would likely exacerbate the charade by drawing in economic analysis as well.[382]

Second, an amendment that requires agencies under the threat of judicial review to separate science from policy in standard-setting provides an additional avenue for public comment and judicial challenge. Interest groups, which have the sophistication but currently have little reason to monitor the extent to which agencies exaggerate science when setting standards,[383] may be motivated by the possibility of obtaining a rule reversal based on a procedural claim that does not require proof of unreasonable or arbitrary policy choices. Reliance on these already highly trained interest groups as gatekeepers who will challenge inade-

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381. H.R. 9, supra note 318, which was passed by the House in the spring of 1995, also requires agencies to make policy judgments explicit subject to judicial review, see id. §§ 414(b)(2), 441, but unfortunately the bill does not direct the courts to give great deference to these policy judgments once they are disclosed. As a result, the legislation would at best provide only minimal incentives for an agency to admit to underlying policy choices given the judiciary's propensity for second-guessing policy decisions and its corresponding tendency to defer almost completely to an agency's scientific findings. See supra Part III.B.3. At worst, H.R. 9 threatens to grind all rulemakings to a halt, see supra notes 318 and 355, and will make the science charade more pervasive and deeply entrenched in agency rulemakings due to the heavy emphasis on more detailed risk assessments, economic quantifications of costs and benefits, and additional peer review by scientific panels. For a general discussion of H.R. 9, see supra note 318.

382. See National Academy of Sciences, Decision Making for Regulating Chemicals in the Environment 44 (1975) (recommending against "formalized methods of benefit-cost analysis . . . for making decisions about regulating chemicals in the environment," but acknowledging that the "benefit-cost and decision frameworks . . . can be useful in organizing and summarizing relevant data on regulatory alternatives which the decision maker must review"); McGarity, supra note 201, at 1330 ("Stringent judicial review of regulatory analysis will only encourage agencies to hide behind a cloak of expertise, and thereby stifle policy debate."). In order to provide added protection against an "economic charade," monetization of the benefits of a protective standard and cost-benefit comparisons should also be discouraged, if not prohibited, by law due to the host of economic difficulties associated with quantification of health and environmental benefits. See id. at 1281–83. The NRC gives an example of how EPA could substantially improve its identification of the policy and scientific assumptions undergirding the selection of a default option without going so far as to require an economic analysis. Rather than characterizing a risk selection obliquely as "The risk number R is a plausible upper bound," EPA could instead characterize the risk by acknowledging the scientific and policy assumptions. For example, EPA could say: "The person we are modeling is assumed to be of average susceptibility, but eats F grams per day of food grown in his backyard; the latter assumption is quite conservative, compared with the average." Science and Judgment, supra note 23, at 212. Where possible, the bases for the policy choice should also include distributional consequences. For example, a regulation may impact a particular industry or locality rather than having a more diffuse, national impact. See, e.g., Jeffrey H. Howard & Linda E. Benfield, Rulemaking in the Shadows: The Rise of OMB and Cost-Benefit Analysis in Environmental Decisionmaking, 16 Colum. J. Envtl. L. 143, 170 (1991) (noting the importance of considering distributional consequences in regulatory analyses).

383. See supra notes 154–159 and accompanying text.

quate agency science-policy delineations should also leave the public with a much clearer picture of which issues in the standard-setting process were resolved with policy and the basis for those decisions, without requiring the public to become scientifically adept in order to participate effectively.

Third, the threat of a remand should direct agency attention to the importance of accurately separating science and policy in science-based standard-setting[384] and counteract many of the institutional and political rewards that currently lead agency officials either deliberately or inadvertently to characterize policy choices as scientifically determined. Finally, forcing agencies to characterize honestly the role of science and policy in setting a standard will expose the extent to which Congress has delegated policy decisions to the agencies and may cause Congress to address some of the policy issues legislatively or at least acknowledge their import in future statutory mandates.

Delineating the roles science and policy play in developing standards should also provide dramatic improvements in meeting two of the three goals of environmental rulemaking—public participation and the optimal incorporation of science. Once policy choices have been identified and explained, lay persons can participate readily and effectively through existing notice and comment procedures. Frank agency explanations of policy choices incorporated into protective standards should educate the public as to the nature and extent of uncertainties in risk assessments and the extraordinary expense of demands for absolute safety.[385] This en-

384. Some scholars have argued that policymaking is incapable of being made in such a formal fashion, and that at best decisionmakers are able only to "muddle through the decision-making process . . . relying heavily upon intuition and back-of-the-envelope predictions, and depending on rapid feedback to meet limited short-term goals." McGarity, supra note 201, at 1272 & n.148 (citing Raymond Bauer and Charles Lindblom). While citing the views of these scholars, McGarity actually suggests that the agencies have engaged in, and can in the future engage in, rational analysis of rulemakings. He cites as examples of rational success stories EPA's lead phasedown regulations and EPA's revision of the National Ambient Air Quality Standard for particulates. See id. at 1272 & n.151. Even if these doomsday observations are accurate, however, it is possible that the agency has "muddled through" in part because the science charade has permitted it to disguise successfully its "back-of-the-envelop" calculations. If the agency is required to divulge significant steps in its decisionmaking process (such as its separation of science and policy issues), its dubious "intuition" may be replaced with findings and conclusions that are based more heavily on meaningful public comments. In any case, until it becomes evident that agencies simply cannot adapt to more formal decisionmaking processes, regulatory reform efforts should proceed; a significant amount of administrative tinkering is unlikely to do much damage to the already dysfunctional regnlatory system.

385. Jon Miller, who has conducted extensive research on the scientific literacy of the American public, concludes that there are millions of adults in the U.S. with a strong interest in science-policy issues who are "seeking to better understand those concepts and the issues to which they relate. It is important to continue programs designed to meet the informal science learning needs of these citizens." Jon D. Miller, The Public Understanding of Science and Technology in the United States, 1990: A Report to the National Science Foundation 138 (Feb. 1, 1991) (on file with the *Columbia Law Review*). It

lightenment may even cause the public to recognize their unrealistic expectations from science[386] as well as some of the biases in their perception of risk.[387] A more informed public will also become less "alienated" from science and from the regulation of toxic chemicals,[388] and ultimately public values, rather than the biases of an agency or individual staff member, will dictate the selection of protective standards.[389] The quality of the science embodied in the final standard should also be improved since the courts and interest group overseers would no longer allow the agency merely to gloss over scientific uncertainties and scientific assumptions.[390]

The effects of this proposal on the third, but equally important, goal of expedient regulation is less certain. The increased comments and judicial challenges that would result from the proposed amendment to the APA, and which in any case typically accompany enhanced public participation,[391] could very likely produce the familiar side effect of increasing regulatory delays.[392] It is also possible, however, that once the science

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is evident that the public is not receiving this supplemental education with regard to toxic risk regulation, however. In the controversy over Alar, for example, see supra notes 160–171 and accompanying text, the press coverage which was most illuminating and which revealed that the dispute was essentially over underlying policy choices was in the journal "Science." See supra note 162. The rest of the media, such as "60 Minutes," managed only to confuse and mislead the public, rather than enlighten them as to the true choices at issue. See supra note 164 and accompanying text. The tendency of the press to exacerbate deficiencies in the public's understanding of risk and, more generally, science, has been well documented by Dorothy Nelkin. See Dorothy Nelkin, Selling Science: How the Press Covers Science and Technology 15 (1987).

386. See supra note 340 and accompanying text.

387. See supra notes 137–139 and accompanying text.

388. See Gillette & Krier, supra note 224, at 1103 (arguing that "the public's sense of alienation is at the core of the public risk problem").

389. See supra notes 225–227 and accompanying text.

390. As discussed above, see supra Part IV.C.1, currently the agency is not only unclear about when and on what basis policy decisions should be made, but it is also unclear about when "in the course of this evolutionary development [of science] the evidence has become strong enough to justify overriding or supplementing an existing default assumption [trans-scientific juncture]." Science and Judgment, supra note 23, at 255. In fact, the bureaucratic tendency to allow "considerations of consistency to override good scientific judgment" has led to considerable criticism of agency science as well as its ability to communicate that science and its uncertainties effectively. See id. at 259.

391. See, e.g., McGarity, supra note 64, at 112–13 ("[P]ublic participation undeniably slows down the governmental wheels."). In fact, in attempting to speed up the regulatory process, the Council on Competitiveness, chaired by then-Vice-President Dan Quayle, allegedly resorted to reducing public and inter-governmental participation in regulatory programs as a means of accomplishing this goal. See George Miller, Keeping Public Policy Public, The Envtl. Forum, Sept.–Oct. 1992, at 35, 35 ("One of the council's objectives has been to speed up the regulatory process by cutting back on the public's right to comment."); see also supra notes 145, 260, and 314.

392. Increased delays may result from added procedural challenges to the adequacy of the agency's science-policy delineations and from the agency's resulting need to support its policy choices, many of which were previously disguised as issues of scientific judgment, with at least crude estimates of the economic and social ramifications of a standard. Some

has been stripped away from the policy decisions, and the courts are legislatively instructed to give agency science and policy judgments great deference, the rulemaking process may proceed more quickly.[393] Expensive and counterproductive "good science" debates, like the one over Alar,[394] will give way to honest and open public discourse about how best to strike a balance between public health and environmental protection on the one hand and chemical products that make life easier and the economy more stable on the other hand. While this discourse could prove to be time-consuming, it is not clear that its resolution in the form of a protective standard will exceed the current delays associated with additional scientific research, extended scientific peer review, convoluted public comments that blur science and policy, and slow and costly legal challenges, all of which are characteristic of the science charade. In any case, it is quite conceivable that the social costs associated with some additional regulatory delays would be offset by the benefits derived from a high quality public exchange over how best to resolve these social problems.[395] Finally, if courts are expressly directed to give agency science and policy judgments great deference, agencies will know what to expect from reviewing courts, and they will no longer need to dedicate precious time and resources to preparing defensive regulatory preambles in a brief-like fashion. Many prominent scholars of administrative behavior concur that more predictable judicial review would have a net positive impact on the pace of agency rulemakings.[396]

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of these delays may be avoided, however, if both scientific and policy analyses proceeded simultaneously, rather than consecutively, as is commonly the case. See McGarity, supra note 201, at 1303 ("Most timing problems probably occur because the services of the regulatory analysts usually are not requested until after much of the technical work on the rule is complete.").

393. See supra Part IV.B.3.

394. See supra notes 160–171 and accompanying text.

395. See supra notes 225–229 and accompanying text.

396. Thomas McGarity has suggested as a cure to regulatory ossification convincing the courts to exercise self-restraint in their substantive review of agency rulemaking and, if that fails, to reduce the stringency of judicial review by amending the APA to change the scope of review for informal rulemaking. See McGarity, supra note 155, at 1453–54; see also Pierce, supra note 180, at 327–28 (proposing as reform of inconsistent and overreaching judicial review strong Supreme Court precedent reminding reviewing courts to give agency policy judgments deference and urging courts to exercise judicial self-restraint in second-guessing agency policy choices). The Administrative Conference of the United States (ACUS) has also recommended that in order to make informal rulemakings more efficient and effective, courts should adopt a clearer, more consistent standard of review. Specifically, ACUS recommends searching review only of the range of an agency's legally permissible choices (statutory, policy, and factual) and deference to the agency if its ultimate justification falls somewhere within this range of permissible choices. See Administrative Conference of the United States, Recommendation 93-4, Improving the Environment for Agency Rulemaking 4, 8 (Dec. 9, 1993), excerpted in 59 Fed. Reg. 4669 app. at 4669 (1994). For a discussion of how judicial review exacerbates the problem of science charade and regulatory delay, see supra Part III.B.3.

Clarification of what Congress expects from the courts in reviewing agency policy judgments and factual findings once it has ensured that the two have been separated

Ultimately, only implementation of the reform will reveal the extent to which this proposal will further speed or slow regulation promulgations. If damaging regulatory delays do result, a choice may need to be made between expeditious regulation on the one hand, such as that proposed above as a radical agency reform, and enhanced public participation on the other. Considering the high value that American society places on public participation in matters of such great import as toxic risk regulation,[397] and the tendency of many regulatory reform efforts to further distance an already alienated public from these decisions,[398] both practical and theoretical considerations point in the direction of reforms such as the one proposed here that first educates, and then includes the public in toxic risk decisionmaking. Indeed, even those most skeptical of the ability of lay persons to contribute meaningfully to science-policy decisions will concede that much of these participatory deficiencies result from inadequate scientific education of the public and that at least some of these deficiencies can be addressed by clearer and more accessible discussions in administrative rulemakings.[399]

The primary obstacle to successful implementation of the judicial review reform lies with the capabilities of the judiciary itself, since a certain level of scientific expertise is necessary in distinguishing between transscientific and scientific questions.[400] Although a few notable judges have fearlessly plunged into a review of the most esoteric scientific details of agency rulemakings,[401] most judges openly denounce such searching review[402] and admit to their own scientific incompetence if such a review were necessary.[403] If the courts are not capable of reviewing the accuracy of an agency's separation of policy and science in a rigorous or consistent way, the effects on the efficiency and expeditiousness of regulation promulgation could be devastating.

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would also be welcomed by the judiciary. Judge Wald of the D.C. Circuit strongly suggests that Congress be clearer in identifying the desired level of judicial review for agency rulemakings. See Wald, supra note 291, at 654 ("Congress might think about making its wishes clearer as to what kind of judicial review it does want. I have always been puzzled over why Congress has delegated such an important power as defining the scope and even the presumption of judicial review to the courts themselves.").

397. See supra notes 225–29 and accompanying text.

398. See supra notes 219 and 388.

399. More accessible and informative regulatory preambles will not only educate interested lay readers, but should also educate and hence improve media coverage of toxic risk decisionmaking. See supra note 385.

400. See supra Part I.B.

401. See, e.g., National Lime Ass'n v. EPA, 627 F.2d 416, 451–53 (D.C. Cir. 1980) (Wald, J.) (validity of agency science should receive "hard look" from reviewing court).

402. See cases cited in first two paragraphs of supra note 186.

403. See, e.g., International Harvester Co. v. Ruckelshaus, 478 F.2d 615, 651 (Bazelon, J., concurring) ("I recognize that I do not know enough about dynamometer extrapolations, deterioration factor adjustments, and the like to decide whether or not the government's approach to these matters was statistically valid.") (footnote omitted).

While the scientific competency of the judiciary is a significant obstacle to implementation of the reform, particularly in light of its current tendency to encourage rather than discourage the science charade, it should not immediately be assumed to be an insuperable one. First, there are features of the reform that may make the resulting protective standards more amenable to judicial review than current rulemakings that are burdened with the over-technical baggage of the science charade. In contrast to the substantive review of agency science, courts might find considerably more guidance for their adjudications of agency science-policy delineations.[404] In fact, much of the judicial frustration with reviewing highly technical regulations may stem from the fact that many challenges to standards are framed by the litigants in scientific terms without acknowledging the underlying importance of nonscientific factors in selecting among equally plausible models, curves, and methodologies. Second, concerns over the competency of the judiciary to enact the proposed reform may be tempered by legislatively requiring training courses for federal appellate judges[405] or by restricting all adjudications of these issues to the D.C. Circuit[406] where only a handful of judges[407] will need to develop the scientific expertise to master review of agencies' separation of science and policy in protective standard-setting.[408] Once trained, judges could be expected to conduct reviews in an evenhanded and consistent manner since the separation of policy from science is

404. The relatively uniform series of scientific and trans-scientific questions encountered in a risk assessment is outlined in several National Academy of Science studies, see for example Appendix. See generally NRC Risk Assessment, supra note 14; Science and Judgment, supra note 23. Although these comprehensive works do not provide a perfect template for determining whether an agency has accurately separated science from policy, they provide considerably more authoritative and uniform guidance than the courts receive for most other technical issues.

These adjudications might also prove to be more repetitious than factual disputes since there are typically only several dozen trans-scientific questions that arise in a standard risk assessment, see Appendix. Thus, in contrast to challenges to agency fact-finding, a court may see greater factual similarities between cases that involve challenges to the accuracy of an agency's separation of policy and science.

405. Training could be disseminated by videotaped presentations and science-policy delineation manuals. Given its extensive studies in the past on science-policy separations, the National Academy of Sciences would seem to be a superb candidate to develop the training program and materials.

406. Congress has already restricted the venue for certain rulemaking challenges. See, e.g., 42 U.S.C. § 6976(a)(1) (1988) (petition for review of regulations promulgated under Resource Conservation and Recovery Act may be filed only in District of Columbia U.S. Court of Appeals).

407. As of June 1995, there were only eleven judges appointed to the D.C. Circuit. See Judges of the United States Courts of Appeals, 53 F.3d at vii (1995).

408. The disadvantage of lay persons assigued the task of distinguishing trans-scientific questions from scientific ones outlined in supra Part I.B is substantial, but is likely not so onerous as to prevent a handful of judges with one or more graduate degrees and impressive credentials from being educated within a reasonable amount of time to distinguish scientific from trans-scientific questions.

largely value-neutral and should not be affected by a judge's potential personal or political biases.

In sum, an amendment to the APA that directs courts to review the agencies' delineation of science and policy in standard-setting and to provide agency science and policy judgments great deference should counteract most of the incentives currently at work in the science charade and attain at least two of the three major goals of environmental rulemaking. Although the capability of the judiciary to review science-policy delineations is the limiting factor to success of the reform, it is conceivable that this obstacle can be overcome. Given the importance of counteracting the charade and the added dysfunction it brings to environmental rulemakings, such a reform, as well as others discussed above, or even those not yet proposed, are worthy of further discussion in the effort to end the science charade.

CONCLUSION

Toxic regulatory problems typically involve policy questions of great magnitude. That they also depend on science for their best resolution has been used by decisionmakers to divert attention away from the controversial policy choices and exaggerate the scientific justification for toxic standards in order to survive a number of legal, institutional, and political hurdles. Such behavior, however, presents serious consequences for democratic participation, leads to substantial delays in the regulation of toxics, and wastes judicial, administrative, and scientific resources. In order to offset the multiple, uniform incentives that cause this science charade, reforms that target the specific causes of the charade must be implemented. Although the reforms proposed in this Article may not provide the definitive means for overcoming the pervasive charade, they begin what is hoped to be an extended discussion on how best to redirect regulation towards a more efficient, democratic, and scientifically honest approach to protecting the public health and environment from unreasonable toxic risks.

APPENDIX: NATIONAL RESEARCH COUNCIL'S IDENTIFICATION OF TRANS-SCIENTIFIC JUNCTURES IN CARCINOGENICITY RISK ASSESSMENTS†

Hazard Identification

Epidemiological Data

* What relative weights should be given to studies with differing results? For example, should positive results outweigh negative results if the studies that yield them are comparable? Should a study be weighted in accord with its statistical power?
* What relative weights should be given to results of different types of epidemiologic studies? For example, should the findings of a prospective study supersede those of a case-control study, or those of a case-control study those of an ecologic study?
* What statistical significance should be required for results to be considered positive?
* Does a study have special characteristics (such as the questionable appropriateness of the control group) that lead one to question the validity of its results?
* What is the significance of a positive finding in a study in which the route of exposure is different from that of a population at potential risk?
* Should evidence on different types of responses be weighted or combined (e.g., data on different tumor sites and data on benign versus malignant tumors)?

Animal-Bioassay Data

* What degree of confirmation of positive results should be necessary? Is a positive result from a single animal study sufficient, or should positive results from two or more animal studies be required? Should negative results be disregarded or given less weight?
* Should a study be weighted according to its quality and statistical power?
* How should evidence of different metabolic pathways or vastly different metabolic rates between animals and humans be factored into a risk assessment?
* How should the occurrence of rare tumors be treated? Should the appearance of rare tumors in a treated group be considered evidence of carcinogenicity even if the finding is not statistically significant?

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† Committee on the Institutional Means for Assessment of Risks to Public Health, National Research Council, Risk Assessment in the Federal Government: Managing the Process 29–33 (1983) (footnote omitted).

The National Research Council cautions that this "list is not exhaustive or comprehensive." The existence of specific trans-scientific questions in a particular risk assessment "depends on a number of factors, including the types and extent of the data." Id. at 28–29.

* How should experimental-animal data be used when the exposure routes in experimental animals and humans are different?
* Should a dose-related increase in tumors be discounted when the tumors in question have high or extremely variable spontaneous rates?
* What statistical significance should be required for results to be considered positive?
* Does an experiment have special characteristics (e.g., the presence of carcinogenic contaminants in test substance) that lead one to question the validity of its results?
* How should findings of tissue damage or other toxic effects be used in the interpretation of tumor data? Should evidence that tumors may have resulted from these effects be taken to mean that they would not be expected to occur at lower doses?
* Should benign and malignant lesions be counted equally?
* Into what categories should tumors be grouped for statistical purposes?
* Should only increases in the numbers of tumors be considered, or should a decrease in the latent period for tumor occurrence also be used as evidence of carcinogenicity?

Short-Term Test Data

* How much weight should be placed on the results of various short-term tests?
* What degree of confidence do short-term tests add to the results of animal bioassays in the evaluation of carcinogenic risks for humans?
* Should in vitro transformation tests be accorded more weight than bacterial mutagenicity tests in seeking evidence of a possible carcinogenic effect?
* What statistical significance should be required for results to be considered positive?
* How should different results of comparable tests be weighted? Should positive results be accorded greater weight than negative results?

Structural Similarity to Known Carcinogens

* What additional weight does structural similarity add to the results of animal bioassays in the evaluation of carcinogenic risks for humans?

General

* What is the overall weight of the evidence of carcinogenicity? (This determination must include judgment of the *quality* of the data presented in the preceding sections.)

Dose-Response Assessment

Epidemiologic Data

* What dose-response models should be used to extrapolate from observed doses to relevant doses?
* Should dose-response relations be extrapolated according to best estimates or according to upper confidence limits?
* How should risk estimates be adjusted to account for a comparatively short follow-up period in an epidemiologic study?
* For what range of health effects should responses be tabulated? For example, should risk estimates be made only for specific types of cancer that are unequivocally related to exposure, or should they apply to all types of cancers?
* How should exposures to other carcinogens, such as cigarette smoke, be taken into consideration?
* How should one deal with different temporal exposure patterns in the study population and in the population for which risk estimates are required? For example, should one assume that lifetime risk is only a function of total dose, irrespective of whether the dose was received in early childhood or in old age? Should recent doses be weighted less than earlier doses?
* How should physiologic characteristics be factored into the dose-response relation? For example, is there something about the study group that distinguishes its response from that of the general population?

Animal-Bioassay Data

* What mathematical models should be used to extrapolate from experimental doses to human exposures?
* Should dose-response relations be extrapolated according to best estimates or according to upper confidence limits? If the latter, what confidence limits should be used?
* What factor should be used for interspecies conversion of dose from animals to humans?
* How should information on comparative metabolic processes and rates in experimental animals and humans be used?
* If data are available on more than one nonhuman species or genetic strain, how should they be used? Should only data on the most sensitive species or strain be used to derive a dose-response function, or should the data be combined? If data on different species and strains are to be combined, how should this be accomplished?
* How should data on different types of tumors in a single study be combined? Should the assessment be based on the tumor type that was affected the most (in some sense) by the exposure? Should data on all tumor types that exhibit a statistically siguificant dose-related increase be used? If so, how? What interpretation should be given to statistically significant *decreases* in tumor incidence at specific sites?

Exposure Assessment

* How should one extrapolate exposure measurements from a small segment of a population to the entire population?
* How should one predict dispersion of air pollutants into the atmosphere due to convection, wind currents, etc., or predict seepage rates of toxic chemicals into soils and groundwater?
* How should dietary habits and other variations in lifestyle, hobbies, and other human activity patterns be taken into account?
* Should point estimates or a distribution be used?
* How should differences in timing, duration, and age at first exposure be estimated?
* What is the proper unit of dose?
* How should one estimate the size and nature of the populations likely to be exposed?
* How should exposures of special risk groups, such as pregnant women and young children, be estimated?

Risk Characterization

* What are the statistical uncertainties in estimating the extent of health effects? How are these uncertainties to be computed and presented?
* What are the biologic uncertainties in estimating the extent of health effects? What is their origin? How will they be estimated? What effect do they have on quantitative estimates? How will the uncertainties be described to agency decision-makers?
* Which dose-response assessments and exposure assessments should be used?
* Which population groups should be the primary targets for protection, and which provide the most meaningful expression of the health risk?