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***1613 THE SCIENCE CHARADE IN TOXIC RISK REGULATION**

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***1618 I. The Science-Policy Nature of Toxic Risk Problems**

A. The Mixture of Science and Policy

. . . 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. [\[FN18\]](#) 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. [\[FN19\]](#)

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.” [\[FN20\]](#) 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, [\[FN21\]](#) trans-scientific***1620** questions are uncertain because scientists cannot even perform the experiments to test the hypotheses. [\[FN22\]](#) This can be due to a variety of technological,***1621** informational, and ethical constraints on experimentation. [\[FN23\]](#) 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. [\[FN24\]](#) 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. [\[FN25\]](#)

Since trans-scientific issues arise from a variety of practical and theoretical limitations on scientific experimentation, [\[FN26\]](#) the ability of science to ***1622** quantify adverse health effects of low levels of toxins can be quite limited. [\[FN27\]](#) To reach a final quantitative standard, policy considerations [\[FN28\]](#) must fill in the gaps that science cannot inform. [\[FN29\]](#) 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. [\[FN30\]](#)

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. [\[FN31\]](#) . . .

1623** 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. [\[FN32\]](#) 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, [\[FN33\]](#) the types of curves which are possible originate in scientific theory. [\[FN34\]](#) . . . As a result, the contributions1624** of science and policy, although generally separable, [\[FN35\]](#) are mixed in complicated ways.

1625** 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. . . . Typically, the best information available on carcinogenicity consists of laboratory studies in which animals have been exposed to high concentrations of the specified chemical. [\[FN36\]](#) 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 science1626** in selecting among the options is limited. [\[FN37\]](#) 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. [\[FN38\]](#) Although there are several scientifically plausible extrapolatory models, . . . the choice of one model over another cannot be resolved by science and thus must be determined by policy factors. [\[FN39\]](#) This policy choice will have significant implications for the level ultimately chosen as adequate to protect public health. [\[FN40\]](#) 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, [\[FN41\]](#) 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. [\[FN42\]](#) 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). [\[FN43\]](#) The absorption model ultimately selected will again be based on policy considerations.

***1627** 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. [\[FN45\]](#) 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. [\[FN46\]](#) 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. [\[FN47\]](#)

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. [\[FN48\]](#) 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. [\[FN49\]](#) *1628 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. [\[FN50\]](#)

Second, and equally important, if policy decisions are to receive appropriate public scrutiny, science-policy decisionmakers must be extremely forthright in distinguishing 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, [\[FN51\]](#) or in order to further the scientists' "pursuit of authority and material resources." [\[FN52\]](#) 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 *1629 experimentation. [\[FN53\]](#) 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. [\[FN54\]](#) Toxics standards promulgated under science-based mandates are covered -- from the preamble to the regulatory impact analysis -- with scientific explanations, judgments, and citations. [\[FN55\]](#) Major policy decisions that undergird a quantitative toxic risk ***1630** standard are at best acknowledged as “agency judgments” [\[FN56\]](#) or “health policies,” [\[FN57\]](#) terms that receive no elaboration in the often hundreds of pages of agency explanations given for a proposed or final toxic standard [\[FN58\]](#) and appear in a context that gives readers the impression they are ***1631** based on science. [\[FN59\]](#) Although this science charade appears to pervade virtually every toxics rule promulgated since the late 1970s, [\[FN60\]](#) 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. [\[FN61\]](#) A ***1632** statutory mandate that appears to require protective standards to be based at least in part on science, [\[FN62\]](#) coupled with a deficient understanding of the science-policy nature of risk assessment, [\[FN63\]](#) 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. [\[FN64\]](#)

Once given responsibility for setting a single, quantitative standard, agency scientists generally take one of two approaches: [\[FN65\]](#) 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. [\[FN66\]](#) In either case, the results are disturbing.

***1633** 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. [\[FN67\]](#) In so doing, however, the scientist nevertheless continues the charade by embarking on an endless search for nonexistent scientific answers, [\[FN68\]](#) thereby halting many standards in the research phase and leaving significant gaps in the regulation of toxics. [\[FN69\]](#) The small number of toxic risk standards promulgated under science-based mandates, coupled with ***1634** 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. [\[FN70\]](#)

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. [\[FN71\]](#) 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. [FN72] In other cases a scientist may enjoy being *1635 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. [FN73] 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. [FN74] . . .

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. [FN79] The National Research Council (NRC) has repeatedly *1638 criticized EPA's affinity for "a single point estimate" [FN80] 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. [FN81] 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. [FN82] 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. [FN83] In their study of the 1979 Interagency*1639 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." [FN84]

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. [FN85] 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. [FN86] 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. [FN87] These inconsistencies can even include the decision about *1640 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. [FN88] 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. [FN89]

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 [\[FN90\]](#) can be seen when one compares EPA's actual decisionmaking process for revising the *1641 ozone standard under the Clean Air Act [\[FN91\]](#) with the agency's public account of that decision published in the Federal Register. [\[FN92\]](#) 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, [\[FN93\]](#) leaving scientifically justified possibilities ranging from 0.25 parts per million (ppm) to 0.08 ppm. [\[FN94\]](#) In selecting a final standard, the EPA Administrator essentially struck a compromise between White House concerns for the economy on the one hand [\[FN95\]](#) and public health concerns on the other. [\[FN96\]](#) 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 . . . [I]t was a value judgment.” [\[FN97\]](#)

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. [\[FN98\]](#) *1642 EPA concluded its fifteen page presentation of mind-numbing scientific justification in the final rulemaking [\[FN99\]](#) 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.” [\[FN100\]](#) The economic impact of the selected standard or alternate standards, which *1643 were clearly considered by the Administrator, [\[FN101\]](#) were publicly disregarded by EPA as statutorily irrelevant [\[FN102\]](#) and summarized in four sentences near the end of the lengthy preamble. [\[FN103\]](#) In reviewing a challenge*1644 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.” [\[FN104\]](#)

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. [\[FN105\]](#) Rushefsky concludes that “[g]uidelines issued during the entire period under discussion (1976 1984) were permeated with values, even if they were not explicit.” [\[FN106\]](#)

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 *1645 in order to scientifically justify the predetermined standard. [FN107] 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. [FN108] During that period *1646 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. [FN109] 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) [FN110] because of the lack of conclusive data on the risk formaldehyde presented to human health. [FN111] EPA presented its decision as based almost exclusively on science [FN112] and insisted that risk assessment was a “ ‘scientific and *1647 not a legal matter.’ ” [FN113] EPA's supporting scientific explanations, however, deviated significantly from both the prevailing scientific evidence regarding health effects of formaldehyde [FN114] and accepted EPA risk assessment assumptions [FN115] -- deviations which EPA uniformly failed to identify *1648 or explain. [FN116] 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. [FN117] 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. [FN118] Not surprisingly, after a series of congressional hearings and considerable controversy within the scientific community, [FN119] EPA rescinded its decision [FN120] and determined in 1984 that formaldehyde did present a major health risk and should be regulated, a decision that *1649 was based on the same scientific information available in 1982. [FN121] 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. [FN122]

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. [FN123] Although Congress did not ultimately charge EPA with the deliberate manipulation of science, [FN124] 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.” [\[FN125\]](#) 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 *1650 with policies of national importance.” [\[FN126\]](#) 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.” [\[FN127\]](#) . . .

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[\[FN15\]](#). Toxic Substances Control Act s 6(a), [15 U.S.C. s 2605\(a\)](#) (1994); see also Federal Insecticide, Fungicide, and Rodenticide Act s 3(c)(5)(D), [7 U.S.C. s 136a\(c\)\(5\)\(D\)](#) (1994) (prohibiting pesticides that “cause unreasonable adverse effects on the environment.”); Clean Water Act s 303(c)(2)(A)-(B), [33 U.S.C. s 1313\(c\)\(2\)\(A\)-\(B\)](#) (1988) (states' water quality standards must ensure that states' designated use of waters will be protected); Clean Water Act s 307(a)(1), [33 U.S.C. s 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 s 1412(b)(4), [42 U.S.C. s 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 s 109(b)(1), [42 U.S.C. s 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 s 112(a)(1), [42 U.S.C. s 7412\(a\)\(1\)](#) (1988) (amended 1990) (standards for toxic air pollutants should be set at levels lower than “may reasonably be 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 s 121(b)(1), [42 U.S.C. s 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 s 6(b)(5), [29 U.S.C. s 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 s 3004(m), [42 U.S.C. s 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.

[FN16]. 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).

[FN17]. 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.

[FN18]. 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’ ”).

[FN19]. 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).

[FN20]. 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.*

[FN21]. 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 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.

[FN22]. 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.

[FN23]. 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).

[FN24]. 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.

[FN25]. 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.

[FN26]. 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, 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 abstrac-

tions 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.”).

[FN27]. 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.”).

[FN28]. 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.

[FN29]. 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).

[FN30]. See Ashford et al., *supra* note 26, at 310 11; McGarity, *supra* note 14, at 732 49, 750.

[FN31]. 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 resolving science-policy issues that cannot be determined solely by technical considerations).

[FN32]. 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”).

[FN33]. 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.*

[FN34]. 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; (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”).

[FN35]. 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).

[FN36]. 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.

[FN37]. 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”).

[\[FN38\]](#). 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.

[\[FN39\]](#). 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.”).

[\[FN40\]](#). See *supra* note 33.

[\[FN41\]](#). 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).

[\[FN42\]](#). See Graham et al., *supra* note 12, at 151.

[\[FN43\]](#). 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 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”).

[\[FN44\]](#). 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.

[\[FN45\]](#). 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”).

[\[FN46\]](#). 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.

[\[FN47\]](#). 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.”).

[\[FN48\]](#). See *supra* notes 31, 36 43 and accompanying text.

[\[FN49\]](#). See supra notes 32 34 and accompanying text.

[\[FN50\]](#). See infra Part III.C.1.

[\[FN51\]](#). 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”).

[\[FN52\]](#). Gieryn, supra note 22, at 793.

[\[FN53\]](#). 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”).

[\[FN54\]](#). 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.”).

[\[FN55\]](#). 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 multi-stage 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”).

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).

[\[FN56\]](#). 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).

[FN57]. 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).

[FN58]. 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 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.

[FN59]. 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).

[FN60]. 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").

[FN61]. 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 uncertainties] ... in the carcinogen guidelines represents an instance of scientific tunnel vision or a deliberate attempt to impede effective regulation”).

[FN62]. See *supra* note 15 and *infra* Part III.B.4.

[FN63]. See *supra* Part I.B.

[FN64]. 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).

[FN65]. 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.*

[FN66]. 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., *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.*

[FN67]. 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 regulators should not be.”).

[FN68]. 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).

[FN69]. 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).

[FN70]. 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).

[FN71]. 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.

[FN72]. 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’”).

[FN73]. 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”).

[FN74]. 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.*

[FN75]. Greenwood, supra note 14, at 175. Dr. Greenwood went on to conclude that assigning 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 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).

[FN76]. 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).

[FN77]. National Primary and Secondary Ambient Air Quality Standards for Lead, 43 Fed. Reg. 46,246, 46,253 (1978).

[FN78]. 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.*

[FN79]. One computer model may contain dozens of hidden policy assumptions, which exert a profound effect on the resulting numerical standard. See Graham 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 Assessment in Federal Regulation, in Risk Quantitation and Regulatory Policy, *supra* note 76, at 331, 335.

[FN80]. Point estimates are single quantitative figures that are not accompanied by error bars, standard deviations, or other indications of the range of experimental error.

[FN81]. 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 assess-

ments 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”).

[FN82]. 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).

[FN83]. 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”).

[FN84]. 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).

[FN85]. 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 Ac-

counting 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.”).

[FN86]. 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”).

[FN87]. See Rushefsky, *supra* note 14, at 45.

[FN88]. 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).

[FN89]. 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)).

[FN90]. 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 accounts of the intentional science charade are

missing only because of the limited number of in-depth case studies of agency standard-setting.

[FN91]. [42 U.S.C. s 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.

[FN92]. 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].

[FN93]. See Melnick, *supra* note 17, at 284, 288 89.

[FN94]. See *id.* at 287 88 tbl. 8-2.

[FN95]. 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.

[FN96]. 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.

[FN97]. 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.

[FN98]. 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 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.

[\[FN99\]](#). 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.

[\[FN100\]](#). *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.*

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. s 7409 \(1988\)](#). See *infra* notes 102 and 201 and accompanying text.

[\[FN101\]](#). 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 in-

volvement 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).

[FN102]. 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).

[FN103]. 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 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.

[FN104]. [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](#).

[FN105]. 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 un rebutted 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 publicly 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").

[FN106]. Rushefsky, *supra* note 14, at 175.

[FN107]. 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 non-threshold pollutants, for example, EPA recognized the essential nonscientific nature of the problem, but "chose 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.

[FN108]. 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 guidelines); 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 [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.

[FN109]. 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.").

[FN110]. [15 U.S.C. s 2603\(f\)](#) (1994).

[FN111]. 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)).

[FN112]. John Todhunter's primary justification for recommending against regulation in his memo was his "scientific" conclusion that although formaldehyde is a " 'potential 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 significant risk among the U.S. population. Ashford et al., *supra* note 26, at 327 28 (excerpting John Todhunter Memorandum (Feb. 10, 1982)).

[FN113]. 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).

[FN114]. 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-significance 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).

[FN115]. 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).

[FN116]. 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”).

[FN117]. 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 designed 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)).

[FN118]. 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).

[FN119]. 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).

[FN120]. See [48 Fed. Reg. 52,507, 52,507 \(1983\)](#).

[FN121]. 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.”)

[FN122]. 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.

[FN123]. 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.

[FN124]. 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).

[FN125]. *CHESS Investigative Report*, *supra* note 123, at 12.

[FN126]. *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).

[FN127]. Rushefsky, *supra* note 14, at 95 96.

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