The Center for Global Energy, International Arbitration, and Environmental Law
The University of Texas-School of Law

Research Paper No. 11-10

Misunderstanding Models in Environmental and Public Health Regulation

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MISUNDERSTANDING MODELS IN ENVIRONMENTAL AND PUBLIC HEALTH REGULATION

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ABSTRACT

Computational models are fundamental to environmental regulation, yet their capabilities tend to be misunderstood by policymakers. Rather than rely on models to illuminate dynamic and uncertain relationships in natural settings, policymakers too often use models as "answer machines." This fundamental misperception that models can generate decisive facts leads to a perverse negative feedback loop that begins with policymaking itself and radiates into the science of modeling and into regulatory deliberations where participants can exploit the misunderstanding in strategic ways. This paper documents the pervasive misperception of models as truth machines in U.S. regulation and the multi-layered problems that result from this misunderstanding. The paper concludes with a series of proposals for making better use of models in environmental policy analysis.

INTRODUCTION

Computational models are largely invisible to most lawyers and policymakers, but they form the foundation for critical

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regulatory programs and exert a powerful, albeit unacknowledged impact on regulatory outcomes. The *Washington Post* and *The New Yorker* featured articles highlighting the critical role of models in addressing environmental problems such as water quality in the Chesapeake Bay[1] and global warming.[2] Recent books targeting a general readership document and ultimately criticize policymakers' over-reliance on environmental models to generate answers.[3] Outside the realm of environmental regulation, the ubiquity and shortcomings of computational models are also gaining notoriety: within a two-month time span, the *New York Times Magazine* and *Wired Magazine* devoted lengthy articles tracing the economic crisis of 2008 back to the deliberate misuse of arcane financial models.[4]

Computational models are tools that provide a simplified, quantitative view of a small slice of the world, but existing legal doctrine and regulatory programs are developed in ways that tend to conceive of these models as providing extravagant and largely accurate representations of reality.[5] Models—concocted by mathematicians and scientists—are expected to magically generate answers to urgent environmental questions, often with five significant digits and remarkable precision. Indeed, we learn of super computers that make modeling still more accurate and speedy, allowing mathematicians to turn out even more elaborate models, graphics, and three-dimensional projections for policymakers to use as the basis for regulation.

Yet, despite their extraordinary influence on environmental policy, models are often created, refined, and deployed in the backroom, behind the curtain, only to be hauled out for critical attention when things go very wrong. And in these moments when policy and legal analysts do encounter the basic realities of modeling, they find themselves in for a surprise. Much like the

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[1] Peter Whoriskey, *Bay Pollution Progress Overstated*, WASH. POST, July 18, 2004, at A1.

[2] Elizabeth Kolbert, *The Climate of Man–II*, NEW YORKER, May 2, 2005, at 64, 64.

[3] *See, e.g.*, ORRIN H. PILKEY & LINDA PILKEY-JARVIS, USELESS ARITHMETIC: WHY ENVIRONMENTAL SCIENTISTS CAN'T PREDICT THE FUTURE (2007).

[4] Felix Salmon, *Recipe for Disaster: The Formula that Killed Wall Street*, WIRED, Feb. 23, 2009, at 74, 74; Joe Nocera, *Risk Mismanagement*, N.Y. TIMES, Jan. 4, 2009, § 6 (Magazine), at 24.

[5] *See infra* Part II.A.

Wizard of Oz, when the actual mechanisms that make these models work are exposed, onlookers discover that, much like their human creators, computational models are fragile and contestable.[6] These inherent qualities may ultimately cause some decision-makers to reject models outright once it becomes clear that the models are not decisive. Of course, the fact that models are incomplete and uncertain does not mean that they lack value for policy analysis; indeed precisely the opposite. It simply means that models are not "truth machines"[7] but instead offer other assets to policymaking, such as providing a conceptual map of existing relationships, highlighting new interconnections, and elucidating important uncertainties, all of which significantly aid policy deliberation, but do not replace it.[8]

In most settings, however, policymakers are neither interested in nor able to peek behind the curtain, contenting themselves instead with the misperception of models as "answer machines." In environmental regulation, in fact, this wrong-headed conception of models appears not only to be pervasive, but deeply engrained in the regulatory programs themselves. As a result, confusion and even anxiety abounds within the regulatory sphere regarding the appropriate use and methods for assessing the reliability of models. When the U.S. Environmental Protection Agency (EPA) model for predicting health effects for families living near industrial or other major sources of toxic contamination was questioned as inadequately cautious, for example, the public uproar caused a loss of confidence in the agency and in existing regulatory protections.[9] Top journalists now dedicate book-length treatments to recording the travails and conflicts within both scientific and policymaking communities regarding the reliability of climate change models.[10]

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[6] *See infra* Part I.C.

[7] This term is borrowed from a similar reference to models as "answer machines" in John Leslie King & Kenneth L. Kraemer, *Models, Facts, and the Policy Process: The Political Ecology of Estimated Truth* 7 (Ctr. for Research on Info. Sys. & Org., Univ. of Cal., Irvine, Working Paper No. URB-006), *available at* http://www.crito.uci.edu/research-archives/pdf/urb-006.pdf.

[8] COMM. ON RISK CHARACTERIZATION, NAT'L RESEARCH COUNCIL, UNDERSTANDING RISK 100 (1996) (observing how "[m]odels provide a framework that defines the relationships that are valuable to study and specify how measured quantities are to be interpreted in relation to the real world").

[9] *See* Mark Obmascik, *EPA Home-Toxins Test 'Crude and Limited'; Widely Used Computer Model Often Wrong*, DENVER POST, Jan. 7, 2002, at A1.

[10] *See, e.g.*, CHRIS MOONEY, STORM WORLD: HURRICANES, POLITICS, AND THE BATTLE OVER GLOBAL WARMING (2007).

Even outside of the U.S., environmental models bump through the judicial and administrative system in zig-zag fashion. An agency's model may be vigorously challenged, only to be affirmed by a lower court and ultimately reversed by the highest court.[11]

This paper discusses this core misunderstanding of models within environmental policy and regulation and tallies some of the damage it is doing to the regulatory state. In the already fragile terrain of science and law, a strong and consistent misunderstanding of models creates significant chain reactions not only in policy circles, but rippling out to adversely affect the science of modeling and providing opportunities for new types of strategic regulatory games.

The argument that models are often misunderstood as "truth machines" in environmental policymaking is developed in three parts. The first part outlines the fundamental role that models play in most areas of environmental regulation and then examines the interior workings of models, including their basic assumptions and data sets. The second part identifies the ways that models are nevertheless viewed as truth machines within administrative and environmental law. After exploring the damage that this misunderstanding does to policymaking, the paper traces the ripple effects of the misunderstanding out to modeling science and to strategic games occurring in high stakes regulatory disputes. The final section explores ways that these interrelated problems might be addressed. Obviously the simplest solution is to correct the core misunderstanding that generates all the trouble. For well-established regulatory programs, however, this is not so easy. This final section grapples with practical realities and suggests a series of different adjustments that should lead to a more realistic appreciation of the value of models and increase their value to policymaking.

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[11] Consider, for example, the judicial flip-flop in the review of a risk assessment concerning the health effects of crop spraying in Britain. Downs v. Sec'y of State for Env't, Food & Rural Affairs [2008] EWHC (QB) 2666, *rev'd* [2009] EWCA (Civ) 664 (U.K.). A striking feature of these two decisions is that the judges took very different approaches, a fact suggesting that the judiciary has developed no clear approach for dealing with models. Another example of lower and upper courts taking very different approaches to reviewing a risk assessment model can be seen in the Australian case of Australian Pork Ltd. v. Director of Animal Plant Quarantine (2005) 216 A.L.R. 549, *rev'd* (2005) 146 F.C.R. 368.

I. THE TRUTH ABOUT MODELS

The aphorism that "all models are wrong, but some are useful" captures the central truth about models.[12] Models are needed to synthesize raw data, often from multiple sources, into computational forms that provide a more comprehensive picture about an ecosystem or environmental scenario under different conditions.[13] Without models, we have only data and theories that are largely disconnected from one another. Indeed, if we were to abandon the use of computational models in environmental policy, regulation would be set back to pre-1970 levels and most regulatory programs would come to a grinding halt. Yet at the same time, computational models are incomplete and provide only a partial, and often very imperfect representation of reality.

In this section, we take a tour inside computational models. This tour first highlights the basic characteristics of models (at least those under examination in this paper) and the rapidly growing use of models in environmental policy. The second subsection then peels back the sleek outputs of models to look at the interior data sets and algorithms. The third and fourth sections analyze the role that models play in environmental regulation. This discussion lays the foundation for the remainder of the article by establishing what models really are, before considering how they are misunderstood.

A. *Models in Environmental Regulation*

Scientists never have perfect data. Even if they did, models would still be vital tools to organize all of the data, make sense of it, and predict the future. Models help policymakers understand how the world works by taking information, assumptions, knowledge, and theories and translating them into a statement about critical interactions that in turn can be used to make decisions.[14] More specifically, models help structure how

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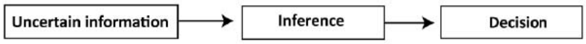
[12] GEORGE E. P. BOX & NORMAN R. DRAPER, EMPIRICAL MODEL-BUILDING AND RESPONSE SURFACES 424 (1987).

[13] *See, e.g.*, COMM. ON MODELS IN THE REGULATORY DECISION PROCESS, NAT'L RESEARCH COUNCIL, MODELS IN ENVIRONMENTAL REGULATORY DECISION MAKING 31 (2007) [hereinafter NRC] (defining a model as "a simplification of reality that is constructed to gain insights into select attributes of a particular physical, biological, economic, or social system. Models can be of many different forms.").

[14] *See, e.g.*, Naomi Oreskes, *Why Believe a Computer? Models, Measures,*

regulatory decision-makers can proceed from *uncertain information* to a *hypothetical view of the physical world* to a *rational, regulatory decision*.

Figure 1: A model's role in environmental policymaking



Environmental models are used to help structure uncertain scientific information into inferences that help justify regulatory decisions.

Although models are comprised of a wide array of synthesis tools, some of which are nonmathematical,[15] in this paper we focus only on models that provide mathematical representations of a system since it is these mathematical, esoteric qualities that create most of the problems for policy.[16] In these models, an analyst will select elements from a system and formalize relationships among these elements through mathematical equations that are codified within an algorithm, usually with the help of a computer program. For purposes of this paper, we use the term "model" to refer to a formal hypothesis about how the elements of a system are mathematically related, which will typically include multiple sources of data and algorithms.[17]

While they are central in economic policy, social policy, and a wide range of other areas of regulatory activity, models are perhaps of greatest importance to environmental and health regulation. In this setting, models are often used to provide the factual representation of the system at issue. In particular, they provide a characterization of issues of consequence in regulatory decision-making. Thus, models provide a means of assessing, measuring, and/or predicting exposure or harm. Model outputs

and Meaning in the Natural World, *in* THE EARTH AROUND US: MAINTAINING A LIVABLE PLANET 70, 70–82 (Jill S. Schneiderman ed., 2000) (discussing these attributes of models).

[15] *See, e.g.*, NRC, *supra* note 13, at 32 (describing nonmathematical models, like physical models).

[16] A *system*—whether it be the U.S. economy, the ecology of the Rhine River, or the European Commission's political system—is a set of phenomena that shares some common aspect(s) in which one is interested.

[17] *See* NRC, *supra* note 13, at 31–32 (describing computational models used for environmental regulation in similar terms).

can trigger heightened (or reduced) regulatory requirements under virtually all environmental regulatory programs.[18] Models also determine "how clean is clean" and establish remedial targets that can cost well into the billions of dollars.[19] Models inform how much manmade stress an ecosystem can endure without losing significant species diversity.[20] In short, models are not only "useful," but have become invaluable to virtually all facets of environmental decision-making.

This can be seen by analyzing the use of models by the EPA in its effort to satisfy its Clean Air Act (CAA) mandate to ensure that all areas of the United States do not exceed ambient standards for several major air pollutants.[21] Since the regulatory system demands that all areas in the United States fall below these pollutants levels in order to protect the public health with "an adequate margin of safety," models quickly became an integral part of the regulatory process.[22] EPA uses risk assessment models to determine the "safe" level of air pollution for sensitive subgroups in the population,[23] and it deploys models to predict how these pollutants disperse through the atmosphere after they have been emitted from various mobile and stationary sources.[24]

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[18] *See, e.g.*, Clean Air Act § 110, 42 U.S.C. § 7410 (2006) (requiring states to meet national ambient air quality standards); Clean Water Act § 303, 33 U.S.C. § 1313(c)(2)(A) (2006) (requiring states to meet water quality standards); *see also* NRC, *supra* note 13, at 47–48 (describing EPA modeling activities in greater detail).

[19] *See, e.g.*, Comprehensive Environmental Response, Cleanup, and Liability Act (CERCLA) § 121(b), 42 U.S.C. § 9621(b) (providing for cleanup of contaminated sites using risk assessment); *cf.* JAMES T. HAMILTON & W. KIP VISCUSI, CALCULATING RISKS? THE SPATIAL AND POLITICAL DIMENSIONS OF HAZARDOUS WASTE POLICY 212 (1999) (criticizing the Superfund program for dedicating excessive cleanup monies to minimal risks).

[20] *See generally* Robert L. Glicksman, *Bridging Data Gaps through Modeling and Evaluation of Surrogates: Use of the Best Available Science to Protect Biological Diversity Under the National Forest Management Ac*t, 83 IND. L.J. 465 (2008) (describing in detail the models used by the Forest Service for this purpose).

[21] *See* Clean Air Act §§ 109–110, 42 U.S.C. §§ 7409–7410 (2006).

[22] 42 U.S.C. § 7409(b)(1) (2006).

[23] *See, e.g.*, OFFICE OF AIR QUALITY PLANNING AND STANDARDS, EPA, REVIEW OF NATIONAL AMBIENT AIR QUALITY STANDARDS FOR OZONE: ASSESSMENT OF SCIENTIFIC AND TECHNICAL INFORMATION 73–103 (1996) (modeling the expected risk to children playing outdoors during heavy ozone concentrations in trying to determine risks to susceptible subgroups).

[24] James D. Fine & Dave Owen, *Technocracy and Democracy: Conflicts Between Models and Participation in Environmental Law and Planning*, 56

Since states generally implement CAA programs in their own jurisdictions under federal direction, states also have incentives to develop and run very precise models that will both predict and explain how the state will attain ambient standards presently and in the future.[25] States can lose valuable federal highway funds, for example, if they cannot establish—with models—that their air quality will meet the national standards by the requisite deadline.[26] Models—indeed, very elaborate models—have thus become a vital feature of this central Clean Air Act program.

Congress and federal agencies use computational models in a wide variety of other policy and regulatory settings as well.[27] See Table 1. For example, EPA and the states use models extensively in the Total Maximum Daily Load (TMDL) program of the Clean Water Act,[28] the CAA's residual risk program (for air toxics),[29] risk assessments for the cleanup of Superfund sites and defunct hazardous waste facilities,[30] and in setting drinking water standards under the Safe Drinking Water Act.[31] EPA uses quantitative risk assessment models to evaluate the safety of pesticides and toxic chemicals under its licensing programs.[32] Public land management

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HASTINGS L.J. 901, 912–16 (2005) (discussing this modeling effort).

[25] *See generally* North Carolina v. EPA, 531 F.3d 896 (D.C. Cir. 2008) (challenging EPA's Clean Air Interstate Rule because it will insufficiently protect downwind states from pollution from upwind states).

[26] *See, e.g.*, Abramowitz v. EPA, 832 F.2d 1071, 1079 (9th Cir. 1987) (holding that Southern California's failure to attain ambient air quality threshold must be redressed by EPA, even if changes were dramatic); JAMES E. MCCARTHY, CONG. RESEARCH SERV., HIGHWAY FUND SANCTIONS FOR CLEAN AIR ACT VIOLATIONS 2 (1997) ("[S]tates are free to choose their own approach, provided that their plan demonstrates sufficient reductions in emissions to demonstrate compliance, using approved EPA air quality models.").

[27] NRC, *supra* note 13, at 47–48.

[28] 33 U.S.C. § 1313(d) (2006); OLIVER A. HOUCK, THE CLEAN WATER ACT TMDL PROGRAM 58–59, 63 (2d ed. 2002).

[29] 42 U.S.C. § 7412 (2006).

[30] *See generally* National Oil and Hazardous Substances Pollution Contingency Plan, 40 C.F.R. pt. 300 (2009) (regulations governing cleanup at Superfund sites).

[31] *See, e.g.*, Safe Drinking Water Act, 42 U.S.C. § 300g-1(b)(4)(A) (2006) (maximum drinking water contaminants "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").

[32] Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), Registration of Pesticides, 7 U.S.C. § 136a (2006); Data Requirements for Pesticides, 40 C.F.R. § 158.34 (2009) (quantitative risk studies required for new pesticide registrations).

agencies also use models extensively:[33] "By one account, an inventory of simulation models available in 1993 for forest planning and ecosystem management identified 250 different software tools."[34] Models are even used by the EPA in the enforcement context to set penalties at levels that ensure adequate deterrence.[35] Finally, models are used outside of rulemakings in ways that nevertheless exert a significant impact on regulatory goals and requirements. Plaintiffs bringing toxic tort suits often rest their causation case in large part on computational models, for example.[36] Models are also used by agencies or Congress in assessing problems, setting priorities, or evaluating the efficiency of rules.[37]

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[33] *See, e.g.*, Glicksman, *supra* note 20, at 476–77 (discussing uses of models by land management agencies to predict impacts of oil and hazardous waste spills on natural lands and wildlife, to designate critical habitat, and to weigh risks of proposed land uses).

[34] *Id.* at 490.

[35] *See, e.g.*, NRC, *supra* note 13, at 60–61 (discussing these models used to determine appropriate penalty amounts).

[36] *See, e.g.*, Matthew W. Swinehart, Note, *Remedying* Daubert*'s Inadequacy in Evaluating the Admissibility of Scientific Models Used in Environmental-Tort Litigation*, 86 TEX. L. REV. 1281, 1284–88 (2008) (providing an overview of the value of quantitative models in environmental litigation settings).

[37] *See* NRC, *supra* note 13, at 56–66 (describing various uses of models with examples of how Congress uses the environmental models).

Table 1: Some Uses of Computational Models in Environmental Regulation

1) CLEAN AIR ACT
   a. The most established use of models in environmental law occurs in EPA's effort to satisfy its Clean Air Act mandate to ensure that all areas of the United States do not exceed National Ambient Air Quality Standards (NAAQS) for several major air pollutants.
      i. EPA uses risk assessment models to determine the "safe" level of air pollution for sensitive subgroups in the population;
      ii. EPA also deploys sophisticated fate and transport models to predict levels of these pollutants after emissions reductions have been made from various mobile and stationary sources;
      iii. States also have incentives to develop and run very precise models that will both predict and explain how the state will attain ambient standards presently and the future.
   b. Although moving at a slow pace, the residual risk program of the Clean Air Act (for air toxics) involves the use of risk assessment models to help determine the safe level of air toxins in ambient air and fate and transport models to link sources to exceedances in local areas.
2) CLEAN WATER ACT: States and the EPA increasingly rely on models is to identify and regulate point and nonpoint contributors to degraded waters through the Total Maximum Daily Load (TMDL) program. Fate and transport models play a particularly important role since they help regulators trace the contributions of individual point and nonpoint dischargers into surface waters and help regulators predict how water quality would improve with reductions of pollutants from these individual sources.
3) HAZARDOUS WASTE CONTAMINATION: Risk assessments are often used to determine cleanup levels for hazardous waste sites and defunct hazardous waste facilities. Fate and transport models also help predict long-term maintenance needs for cleanup of these sites.
4) DRINKING WATER STANDARDS: Risk assessments are used to determine the goal for drinking water quality under the Safe Drinking Water Act (the Maximum Contaminant Level Goal (MCLG)).
5) LICENSING PESTICIDES AND CHEMICALS: EPA uses quantitative risk assessment models to evaluate the safety of pesticides and some toxic chemicals.
6) ENFORCEMENT: Models are used by the EPA in the enforcement context – for example, to determine penalty amounts.
7) COASTAL ZONE MANAGEMENT ACT: Models may be used to assess water quality in coastal zones and along the Great Lakes.
8) ENDANGERED SPECIES AND MARINE MAMMAL PROTECTION ACTS: These wildlife protection statutes rely on models to determine when species should be listed, and when their populations have recovered sufficiently to be removed, in identifying critical habitats, and allowing incidental takes.
9) LAND MANAGEMENT AGENCIES: Land management agencies, like the Forest Service, use models extensively to determine the best uses of public lands.
10) REGULATORY ANALYSIS: Cost-benefit models are used by EPA to assess the economic impact of those rules that impose significant costs on the economy. Agency compliance with the National Environmental Policy Act (NEPA) also leads EPA to rely on models to consider alternative scenarios to proposed agency actions with significant environmental impacts.
11) LESS FORMAL USE OF MODELS BY FEDERAL ACTORS: Models can also be used by agencies or Congress more informally in assessing problems, setting priorities, or evaluating the efficiency of rules. In these cases, the models do not create binding or direct obligations for members of the public or regulated parties, but instead provide information for "deliberating" about whether there is a problem in need of redress, like climate change and acid rain, or whether a proposed solution is the best among alternatives.
12) STATE MODELS: States can use and develop models for their own programs or to fulfill their responsibilities under federal statutes, particularly the Clean Air Act NAAQS and the Clean Water Act TMDL programs.

The use of climate change models by the federal government provides the most obvious contemporary example of the important role that models can play in developing policy.[38] For example, to regulate carbon dioxide (CO_2) as a greenhouse gas under the Clean Air Act, EPA must first issue a finding that CO_2 endangers public health and welfare.[39] EPA drew heavily from the Fourth

[38] For EPA's current activities with respect to climate change, many of which use or depend on models, see EPA's climate change home page, available at http://www.epa.gov/climatechange/index.html (last visited Mar. 10, 2010).

[39] Massachusetts v. EPA, 549 U.S. 497, 528–35 (2007); *see* Clean Air Act § 202, 42 U.S.C. § 7521(a)(1) (2006) (emission standards for new motor vehicles).

Assessment Report of the Intergovernmental Panel on Climate Change (IPCC) to reach the conclusion that most of the observed global warming in recent centuries can be attributed to the anthropogenic rise in greenhouse gases, including CO_2 and that as a result these gases endanger public health and welfare.[40] In turn, the IPCC report was based on evidence provided by multiple models describing the effect of greenhouse gases on atmospheric, oceanic, and land surface processes.[41] Entire chapters in the report were devoted to studies evaluating the models that served as the basis for the IPPC's conclusions.

The IPCC report highlights important themes that represent an extreme case of environmental models, but can nevertheless inform how other models should be treated.[42] First, the climate models simulate conditions that occur at spatial and temporal scales that do not lend themselves easily to observation. Second, these models simulate complex processes that are intricately interconnected. Although the model results must be treated with a cautious awareness of their limitations, the IPCC report also highlights the fact that formal evaluation techniques can be used to determine whether a model's ultimate conclusions are consistent with the evidence. For example, the results from climate models can be evaluated against historical and current climactic conditions. Additionally, the results of multiple climate models can be evaluated to determine consistencies in model results.

Even after issuing its finding on endangerment, EPA's task—and its continued reliance on models—is far from over. After reaching its decision regarding the environmental effects of CO_2 and climate change, a decision based largely on the results of *physical* models, EPA must now develop and evaluate *economic* models to value the net costs or benefits of these effects.[43]

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[40] Proposed Endangerment and Cause or Contribute Findings for Greenhouse Gases Under Section 202(a) of the Clean Air Act, 74 Fed. Reg. 18,886, 18,894–904 (Apr. 24, 2009).

[41] INTERGOVERNMENTAL PANEL ON CLIMATE CHANGE, CLIMATE CHANGE 2007: THE PHYSICAL SCIENCE BASIS 112–18 (2007).

[42] *Id.*

[43] *See generally* William Funk, *Political Checks on the Administrative Process*, *in* AM. BAR ASS'N, A GUIDE TO JUDICIAL AND POLITICAL REVIEW OF FEDERAL AGENCIES 211, 218–28 (John F. Duffy & Michael Herz eds., 2005) (summarizing the process of regulatory review by the Office of Management and Budget, which requires federal agencies to conduct cost-benefit analyses for major regulatory proposals).

Climate change models are only one example of the many types and uses of models for environmental regulation that indicate that the agencies' dependence on models over the last decade appears to be on a sharp incline. EPA has developed an office to provide oversight for models (the Council for Regulatory Environmental Modeling), added a models database to its website, and commissioned a National Research Council (NRC) report to help it assess models in the future.[44] Even some congressmen have become intimately involved in trying to understand the intricacies of models.[45]

To understand why models influence environmental policymaking and why their influence will likely increase in the future, one can look to the co-evolution of risk assessment and modeling. In 1983, an influential NRC report formalized the paradigm that has long guided the government's evaluation of chemical risks.[46] The report recognized that, faced with scientific complexity and uncertainty, regulatory agencies needed to make simplifying assumptions to fulfill their statutory mandates to protect human health, as reflected in the following words, taken from the report's working papers:

> Regulation—and the rule of law more generally—demands simplification . . . . The assessment of a public health risk is inherently complex, and ambiguities and probabilities abound . . . . Results that are conclusive enough to satisfy a scientist's professional standard of proof are rare. If public health risks are to be regulated at all, many assumptions—deliberate choices in the face of scientific uncertainty—must be made in order to satisfy a regulator's need for simplified answers . . . .[47]

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[44] *See* EPA Council for Regulatory Environmental Modeling (CREM), http://www.epa.gov/CREM (last visited Mar. 10, 2010); EPA CREM Models Knowledge Base, http://www.epa.gov/CREM/knowbase (last visited Mar. 10, 2010) (searchable database of computational models that are developed, used, or supported by EPA's offices); NRC, *supra* note 13, at 2.

[45] *See, e.g.*, THOMAS O. MCGARITY & WENDY E. WAGNER, BENDING SCIENCE: HOW SPECIAL INTERESTS CORRUPT PUBLIC HEALTH RESEARCH 275–78 (2008) (describing Congressman Joe Barton's communications with climate change modelers).

[46] COMM. ON THE INSTITUTIONAL MEANS FOR ASSESSMENT OF RISKS TO PUB. HEALTH, NAT'L RESEARCH COUNCIL, RISK ASSESSMENT IN THE FEDERAL GOVERNMENT (1983).

[47] Lawrence E. McCray, *An Anatomy of Scientific and Extra-Scientific Components in the Assessment of Scientific Data on Cancer Risks*, *in* COMM. ON THE INSTITUTIONAL MEANS FOR ASSESSMENT OF RISKS TO PUB. HEALTH, NAT'L

For example, the 1983 report acknowledged that human data were rarely available to evaluate a chemical's influence on cancer. Instead, agencies could rely on data from "a well conducted rat study"[48] and then use simplifying assumptions to extrapolate the rat dose-response model to potential effects on humans.

Today, laboratory techniques can now measure chemical concentrations and physiological responses at various scales of human biological organization—from genes to cells to tissues to organs to the entire body. At the same time, newer statistical techniques provide researchers with more systematic and holistic ways to analyze the data across these scales. As one might expect, the combination of more data and better analytical tools has led to demands for more sophisticated modeling. In 2007, a NRC report articulated a vision of toxicity testing that moved beyond animal testing to models that assimilated human data and that provided a more complete description of the mechanisms underlying the human response to toxic chemicals.[49] While the report recognized that scientific uncertainties continue to plague the risk assessment process, it also prescribed using more formal methods to quantitatively analyze a model's uncertainties. The call for better models, accompanied by better information about a model's limitations, was echoed in 2009 by yet another NRC report, which highlighted the need for formal analyses of model uncertainties.[50]

As an indication of a regulatory agency's inevitable use of models, the White House's Office of Management and Budget (OMB), which approves the cost-benefit analysis accompanying every major regulation, issued a circular requiring all executive agencies to conduct their analyses with more transparency by using formal model evaluation techniques.[51] By issuing the

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RESEARCH COUNCIL, RISK ASSESSMENT IN THE FEDERAL GOVERNMENT: WORKING PAPERS 83, 84 (1983).

[48] William M. Stigliani, *The Consumer Safety Commission's Risk Assessment for Formaldehyde*, *in* COMM. ON THE INSTITUTIONAL MEANS FOR ASSESSMENT OF RISKS TO PUB. HEALTH, NAT'L RESEARCH COUNCIL, RISK ASSESSMENT IN THE FEDERAL GOVERNMENT: WORKING PAPERS 4, 17 (1983).

[49] COMM. ON TOXICITY TESTING & ASSESSMENT OF ENVTL. AGENTS, NAT'L RESEARCH COUNCIL, TOXICITY TESTING IN THE 21ST CENTURY (2007).

[50] COMM. ON IMPROVING RISK ANALYSIS APPROACHES USED BY THE EPA, NAT'L RESEARCH COUNCIL, SCIENCE AND DECISIONS: ADVANCING RISK ASSESSMENT 93–126 (2009).

[51] OFFICE OF MGMT. & BUDGET, CIRCULAR A-4 ON REGULATORY ANALYSIS 2–3 (2003).

circular, OMB recognized that most regulations depend on models and wanted to encourage agencies to be more forthcoming about their models' assumptions and limitations.

B. *Categorizing Models*

Despite their prevalent use in regulation, policymakers' and lawyers' understanding and engagement with models are quite limited; as a result, models remain a mystery to those most involved in their application and use in policy. Much of this mystery derives from models' technical nature (which will be discussed in the next section), but also from the sheer variety of models. Models are not homogenous in nature: they vary in purpose, scale, size, and in technical content. Some are relatively simple, dealing with discrete issues;[52] others model complex ecosystems.[53] Models may be developed to be stand-alone[54] or to operate as part of a larger analytical process, such as a risk assessment.[55] Models may be supported by regulatory offices, or they may be the product of ongoing inter-institutional cooperation.[56] Models are developed by both the public and private sector, but in the field of environmental modeling the federal government has been the primary supporter of the development, utilization, and oversight of models used for regulation.

We offer several methods of categorizing models to further highlight variations in their intrinsic qualities. A first distinction between models lies in the difference between *mechanistic* and *statistical* models (although most models are usually a combination of the two). A mechanistic model attempts to simulate the mechanisms—the physical pathways—through which a natural system operates. For example, fairly sophisticated

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[52] *See, e.g.*, NRC, *supra* note 13, at 38 (describing simple, one-dimensional flow and transport equations used to model leaking underground storage tanks).

[53] *See, e.g.*, Guidelines for Ecological Risk Assessment, 63 Fed. Reg. 26845, 26864–91 (May 14, 1998).

[54] *See, e.g.*, EPA, Better Assessment Science Integrating Point and Non-point Sources (BASINS model), http://www.epa.gov/waterscience/BASINS (last visited Mar. 10, 2010) (geographic information system (GIS) watershed-based model and national dataset for analyzing water quality).

[55] *See, e.g.*, PHYSIOLOGICALLY BASED PHARMACOKINETIC MODELING 10–12 (Micaela B. Reddy et al. eds., 2005) (describing a type of biology-based modeling that typically fits within a larger risk assessment).

[56] *See* EPA Models Knowledge Base, *supra* note 44.

models will simulate the physical process through which particles of the metal chromium will leach through the soil and into the groundwater by taking into account physical and chemical attributes of each component in the system. A statistical model uses data to draw inferences about the natural system based on associations and correlations among the data. For example, a researcher might take measurements of chromium in the soil and in the groundwater and run a statistical analysis to develop a mathematical function relating the two. This distinction between *mechanistic* and *statistical* affects the inferences that can be drawn from the models. A mechanistic model based on physical constants that remain unchanged over time can, in theory, be used to make long-term predictions. On the other hand, statistical models assume related events conform to underlying probability relationships that may change over time. Therefore, long-term predictions based on these probability relationships should be made with this limitation in mind.

Second, with respect to their use, there are *physical* and *economic* models. The former type models the physical components of an environmental system; the latter type models how society values an environmental resource. For example, a physical model might describe how mercury disperses through the atmosphere and the ecosystem after being emitted from coal-burning electric utilities, while an economic model would predict the value that the nation places on avoiding the harmful effect of mercury on children's cognitive abilities. The distinction between *physical* and *economic* models influences the assumptions one can make during model development. For example, physical models typically assume that the underlying events of a physical system conform to probabilistic assumptions. However, the economic value that society attaches to environmental resources must often be estimated from human behavior and choices, which may not necessarily conform to probabilities that are stable over time.

Finally, one can sub-categorize physical models according to the stage of the life-cycle they seek to simulate. For example, *source* models might account for how many electric utilities across the U.S. burn coal and what the mercury content of their coal is in order to estimate how much mercury is emitted. An *exposure pathway* model might then simulate how mercury travels through the atmosphere; how much of the mercury ends up in surface waters; and how much of it is then converted to methylmercury, which makes the mercury available to organisms. A *receptor* model might then simulate how much of the methylmercury ends up in fish or in human beings. Finally, an *impact* model might then simulate how mercury might ultimately affect the cognitive abilities of a child whose mother has consumed fish contaminated by mercury.

Most of the models listed in Table 1—whether used to fulfill EPA's mandate to protect the nation's air or water quality or to regulate the flow of hazardous waste or toxic chemicals through commerce—are typically a combination of *economic* and *physical* models developed through a combination of *mechanistic* and *statistical* approaches. The physical models typically focus on a portion or on several portions of the process through which a pollutant proceeds from *source* to *receptor* and manifests itself in some adverse *impact* on the receptor.

C. *Examining the Interior Limits of Models*

Models play a central role in policymaking that is both irreplaceable and is growing more valuable over time. As we stated above, models assist regulatory decision-makers in making the most rational and reasonable decisions they can on the basis of uncertain information. Yet models also have limitations, and these limitations are substantial. In this section, we draw back the curtain to reveal some of the more significant limitations of models.

While the "troubled marriage between science and law" is now a familiar phenomenon,[57] models may best be thought of as the unhappy couple's inconsolable child. All of the challenges that afflict science used for policy also afflict models: significant uncertainties and subjective judgments loom in model design, in interpretation of the data, and in communicating that data to other scientists as well as lay persons.[58] Even more significant are the considerable judgments necessary to interpret and extrapolate a discrete research study to a larger policy problem (and the related

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[57] Oliver Houck, *Tales from a Troubled Marriage: Science and Law in Environmental Policy*, 302 SCI. 1926, 1926 (2003) (discussing areas of conflict and providing cautionary tales about introducing more "sound science" into environmental regulation).

[58] *See* MCGARITY & WAGNER, *supra* note 45, 64–76 (describing how research sponsors with a private interest in the outcome use these pressure points to "shape the science" to fit their needs).

temptation to misrepresent those judgments as primarily scientific). But models present even more complications for policymaking, in large part because they are so much more closely intertwined with policy-based assumptions than most of this applied and basic research.[59]

First and most important, models are developed in response to problems or questions; in most regulatory settings models do not exist without this prelude or invitation. Yet the question that frames the model limits its "domain" or applicability, in some cases dramatically.[60] This question—the purpose of the model—determines what type of data is relevant, establishes which assumptions are most important, and sets both the scope and the scale of the model in terms of how much detail is needed and even basic trade-offs between, for example, accuracy at a small scale and accuracy at a larger scale.[61] Indeed, the funding and marketability of commercial and academic models arises in large part because these models fill a niche in policy-relevant analysis. Thus, unlike models used in basic research, which push out from existing theory by testing it against new or unique questions, regulatory models tend to be developed with a policy need in mind. For example, a statutory requirement or a court-ordered deadline might compel EPA to assess the risks associated with potentially hazardous waste from coal combustion. To meet these directives, EPA may develop a risk assessment model based on available data, rather than embark on a new effort to collect more comprehensive and complete data. Or else EPA may focus only on the risk posed by a handful of highly toxic chemicals arising from coal combustion and limit its analysis accordingly. Either way, the documentation that accompanies a regulatory model should contain enough information about the underlying data, assumptions, and analytical approaches to allow an interested and objective stakeholder to assess the domain of the model.

Second, and also unlike a basic research study that collects

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[59] In general terms, *applied* science is research that promises direct impacts on the economy and jobs, and which is likely to enjoy more funding and political support than *basic* or *pure* science. Martin Carrier, *Knowledge and Control: On the Bearing of Epistemic Values in Applied Science, in* SCIENCE, VALUES, AND OBJECTIVITY 275, 275–76 (Peter Machamer & Gereon Wolters eds., 2004).

[60] *See* NRC, *supra* note 13, at 93–95 (describing the importance of specifying the model context, including identifying the domain).

[61] *Id.* at 89, 93–95.

data in order to test a hypothesis, a model seeks to answer a question using whatever data and theories are on hand.[62] As such, modeling is not an inflexible formula yielding strict results but something far more opportunistic. Modeling involves synthesizing disparate data, assumptions, uncertainties, and theories in the most robust way possible.[63] This, in turn, involves several different steps, each of which involves considerable judgment and thus introduces additional sources of uncertainty and variation between models.

The process of assembling a model is explained using Figure 2, which we have presented linearly for simplicity's sake.[64] As a first step, the modeler must decide the elements of a system on which to focus—this is sometimes determined quite clearly by the question put to the modeler. In most cases, even with a very specific question, there is still substantial room for judgment in determining what components should be left in a model and what should be left out. For example, to model a river's water quality, the modeler, as an initial matter, must decide which among many factors—oxygen concentration, river flow, and depth—actually drive the system. In the second step, the modeler collects data about the system, a process beset with uncertainties about whether she has chosen and properly applied the correct methods to gather representative data in characterizing the system. For example, in modeling the river, how should oxygen be measured, from which locations should measurements be taken, and how often? If the data that would ideally resolve the question are not available, then are the available data adequate or robust enough for use? Third, the modeler must then infer some mathematical description of the system from the data. For example, decreases in oxygen concentration might be observed to follow increases in nitrogenous run off, which may lead to fish kills. Because uncertainties permeate the modeler's understanding of the system, however, drawing these inferences is often extremely difficult.[65]

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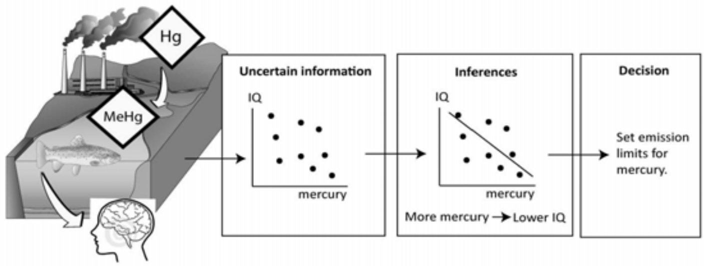
[62] *See, e.g.*, JO SMITH & PETE SMITH, INTRODUCTION TO ENVIRONMENTAL MODELING at ch. 2 (2007).

[63] *See* NRC, *supra* note 13, at 21, 25 (describing these advantages of models for decision-making).

[64] For a detailed description of factors relevant to design in the case of Clean Air Act models, see Fine & Owen, *supra* note 24, at 922–30.

[65] *See, e.g.*, Kenneth H. Reckhow & S. C. Chapra, *Modeling Excessive Nutrient Loading in the Environment*, 100 ENVTL. POLLUTION 197, 206 (1999) (discussing problems in water quality modeling, many of which stem from

Figure 2: Unpacking the Major Steps in Model Development



The procession from *uncertain information* to *inferences* to *decisions* is not as straightforward as Figure 1 seems to imply. For example, mercury is thought to adversely impact the cognitive abilities of children. Mercury (Hg) is emitted into the atmosphere when coal is burned in electric utilities. When mercury is deposited in aquatic areas, it is converted into methylmercury (MeHg), which is taken up by fish and passed on to humans who consume the fish. Uncertainty permeates any attempt to model this process. Uncertainty arises as soon as the modeler exercises some judgment to decide which major factors drive the system that is being modeled. This uncertainty is compounded by other uncertainties: (1) the modeler must decide how best to collect data about the system; (2) inferences about the data will vary depending on what assumptions about the data are justified and what analytical tools are used; and (3) because the system being modeled varies over time and space, a decision-maker must ascertain whether a model is sufficiently robust to be applied to prospective decisions.

The final source of uncertainty arises after a model has been created and involves its continual evaluation. Many models have no benchmark or yardstick against which they can be easily evaluated or compared. Oreskes et al., for example, take modelers to task when they represent that they are "verifying" or "validating" models instead of conceding that these determinist measures simply cannot be made for models.[66] Unlike basic

inadequate data, and concluding that "it should not be surprising that theoretically based improvements in a model often cannot be supported with the limited available observational data"). The biggest problem in this regard is drawing robust inferences from uncertain evidence. Natural systems are subject to random variability, and, as such, the modeler must somehow discern "signals" within the data—information about the general principles that define a system's essence—as distinguished from irrelevant, extraneous, or misleading "noise." To do so, the modeler must often view the world in probabilistic terms. For example, if nitrogen (and its consequences) did not affect fish mortality, then all things being equal, the modeler might assume that the pattern of fish kills over time might approximate a normal distribution or "bell curve," a pattern that indicates random variability and that is independent of nitrogen concentrations.

[66] *See* Naomi Oreskes et al., *Verification, Validation, and Confirmation of*

research, which can at least be replicated to ascertain whether the data is reliable and the interpretation of the data is sound, models consist of an amalgam of theories and datasets that can be compared to other model-amalgams without coherent criteria for making the comparison. It is thus difficult to compare the results of different models that purport to simulate the same environmental system. Regulatory decisions are intended to apply prospectively and the purpose of a regulatory model is to use information about the past to approximate a system so that predictions can be made about the system's future. Therefore, simply comparing model results to historical data is insufficient to evaluate the overall performance of a model.

Consider the system being modeled in Figure 2. Based on the data, the model being proposed is that the relationship between maternal exposure to mercury and the child's IQ is downwardly linear. But even given the same data and the same mathematical function (i.e., a straight line), two different models might still characterize this relationship very differently. To evaluate these two models, one would need to know more about the different assumptions and analytical techniques that underlie each.

To summarize, evaluating a model's soundness requires more than just comparing model outputs to other models or to historical data. It also requires information about the assumptions and analytical techniques through which a model was developed. When this information is not provided, then the model runs the risk of being too closely tethered to its creator and unavailable to public scrutiny. Having said that, the modeling community has yet to establish a coherent, universally-shared set of guiding principles through which regulators and interested stakeholders can evaluate whether one model (or set of models) can be said to be more appropriate for a given situation than another. Because these principles are often unavailable (*see infra* Part II.B.), judging the veracity of competing models can be quite difficult, even for the expert modeler. In the words of the statistician Richard Royall, evaluating scientific evidence is in a "theoretical and conceptual mess . . . . With no accepted principles to guide statistical reasoning, we can offer . . . nothing more than conflicting expert

Numerical Models in the Earth Sciences, 263 SCI. 641, 644 (2004) (arguing that "the burden is on the modeler to demonstrate the degree of correspondence between the model and the material world it seeks to represent and to delineate the limits of that correspondence").

judgments about what is sensible."[67]

D. *Contextualizing Models Used in Regulation*

As shown above, models are contingent on a number of judgments that are not just scientific. This final section takes an additional step back to view the broader role that legal and regulatory culture play in affecting how models are understood and integrated into policy. This broader perspective also highlights the uniquely technocratic features of U.S. regulation that may present a worst case scenario with regard to misunderstanding models. There are at least three features of regulatory culture that have some bearing on how models are developed and understood in policy circles.

First, since models are developed for regulation, the prevailing regulatory culture will intimately influence how they are designed and deployed. At a basic level, regulatory objectives will frame the purpose and role of a model. If a regulatory goal is "good ecological status," for example, then that is what a model will seek to measure. But that is not the end of the influence of the regulatory framework—regulatory culture will also have a role to play in how detailed a model has to be and how it provides its outputs. Models are thus not hermeneutically sealed off from the rest of regulatory practice, but closely related to it.

For example, in 2007 the Supreme Court ruled that the Clean Air Act authorized EPA to regulate carbon dioxide, and that EPA needed to issue a finding on whether the pollutant endangered human health and welfare.[68] Leading up to the ruling, much was made of the uncertainties in the climate change models, with trade associations[69] and university researchers[70] arguing opposite

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[67] Richard Royall, *The Likelihood Paradigm for Statistical Evidence*, *in* THE NATURE OF SCIENTIFIC EVIDENCE 119, 145–46 (Mark L. Taper & Subhash R. Lele eds., 2004).

[68] Massachusetts v. EPA, 549 U.S. 497, 528–35 (2007).

[69] *See, e.g.*, Brief For Respondents Alliance of Automobile Manufacturers et al. at 44–47, Massachusetts v. EPA, 549 U.S. 497 (2007) (No. 05-1120) (arguing that the Bush administration EPA correctly refused to regulate CO_2 in light of scientific uncertainty concerning the causal relationship between greenhouse gas emissions and climate change, citing the National Research Council's 2001 *Climate Change Science* report).

[70] *Compare* Brief for Climate Scientists David Batista et al. as Amici Curiae Supporting Petitioners at 9–10, Massachusetts v. EPA, 549 U.S. 497 (2007) (No. 05-1120) (arguing that the NRC *Climate Change Science* report "unambiguously

interpretations of the same National Research Council report on climate change.[71] Two years after the Supreme Court issued its ruling, EPA issued its proposed finding of endangerment, basing its finding on the scientific assessments and models documented by several science institutions: the International Panel on Climate Change, the U.S. Climate Change Science Program, and the National Research Council.[72] In the technical document accompanying its finding, EPA took pains to explain the scientific basis for its decision, detailing both the provenance of the scientific evidence (e.g., the peer review process, the underlying data and models used), as well as the dominant sources of uncertainties.[73] Regulatory demands, political conflicts, and modeling science were inextricably intertwined in influencing EPA's final modeling product.

Second, the overarching regulatory context lays out the blueprint for establishing which decisions will be recognized as authoritative. The role models will play within this blueprint is thus inextricably bound to this larger cultural understanding.[74] In some regulatory cultures, like the U.S., for example, there tends to be an overriding expectation that a decision-maker *should* follow a model if a model is deemed legitimate.[75] In this culture, regulators are expected to do more than simply consult models; they are ultimately expected to seek out or develop models to provide answers to regulatory problems.

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concluded that Earth's climate is changing" and "found strong evidence" for anthropogenic causation justifying EPA regulation of greenhouse gas emissions), *with* Brief for Climatologist Sallie Baliunas et al. as Amici Curiae Supporting Respondents at 5–8, Massachusetts v. EPA, 549 U.S. 497 (2007) (No. 05-1120) (arguing that the *Climate Change Science* report "unequivocally states our lack of comprehensive knowledge of the overall effects of human induced climate change").

[71] COMM. ON THE SCI. OF CLIMATE CHANGE, NAT'L RESEARCH COUNCIL, CLIMATE CHANGE SCIENCE: AN ANALYSIS OF SOME KEY QUESTIONS (2001).

[72] Proposed Endangerment Findings for Greenhouse Gases, *supra* note 40, at 18,894.

[73] CLIMATE CHANGE DIV., EPA, TECHNICAL SUPPORT DOCUMENT FOR ENDANGERMENT AND CAUSE OR CONTRIBUTE FINDINGS FOR GREENHOUSE GASES UNDER SECTION 202(A) OF THE CLEAN AIR ACT 3–7 (2009).

[74] On worthiness and legitimacy, see JÜRGEN HABERMAS, COMMUNICATION AND THE EVOLUTION OF SOCIETY 178–79 (Thomas McCarthy trans., Beacon Press 1979).

[75] *See* NRC, *supra* note 13, at 18 (explaining that EPA relies on model outputs to "inform and set priorities in environmental policy development and implementation").

The third aspect of regulatory context worthy of note affects whether and when a model is considered legitimate. Of course model legitimacy is not a neutral issue but instead is inherently normative and varies depending on the understanding of good public administration that operates in a regulatory culture at any one time. Thus, while models may be a constant feature of the regulatory landscape, what we understand their role and nature to be can vary dramatically, and lawyers and policymakers are constantly framing how models are understood, even if they do not do so consciously.

In the U.S., for example, the Supreme Court's decision in *Industrial Union Department, AFL-CIO v. American Petroleum Institute* (the "*Benzene*" case),[76] Judge Leventhal's interpretation of hard look review,[77] and the NRC's seminal 1983 study on risk assessment by federal agencies (known as the "Red Book")[78] all tended to equate model legitimacy with an ability of the model to provide regulators with an answer. The plurality in *Benzene* was concerned that the Occupational Safety and Health Act gave OSHA "unbridled discretion"[79] and the court thus introduced the requirement that OSHA first establish there was a "significant risk"—determined essentially with the help of a computational model—before regulating.[80] Likewise, in requiring that regulatory decision-makers establish the "reasonableness and reliability"[81] of their methodology, Judge Leventhal sought to ensure that agency technical decisions were made on prediction not prophecy:[82] The processes inherent in administrative decision-making and judicial review, such as cross-examination, should be "engines for truth."[83]

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[76] 448 U.S. 607 (1980) (holding that OSHA is not permitted to impose a "lowest technologically feasible" standard for exposure to a carcinogen absent proof of significant risk of harm to workers under the Occupational Safety and Health Act).

[77] Ethyl Corp. v. EPA, 541 F.2d 1, 68–69 (D.C. Cir. 1976) (Leventhal, J., concurring) (arguing for "hard look" review in which courts inquire into agency decisions whenever there is "some factual support" for a challenger's contention that the agency acted unreasonably).

[78] NRC, COMM'N ON THE INSTITUTIONAL MEANS FOR THE ASSESSMENT OF RISKS TO PUBLIC HEALTH, RISK ASSESSMENT IN THE FEDERAL GOVERNMENT: MANAGING THE PROCESS (1983).

[79] 448 U.S. at 614.

[80] *Id.* at 645.

[81] Int'l Harvester v. Ruckelhaus, 478 F.2d 615, 643 (D.C. Cir. 1973).

[82] *Id.* at 642.

[83] *Id.* at 631.

Each of these legal and policy developments advanced a particular vision of public administration that portrayed legitimate models in a technocratic light.

It is thus important to remember that model legitimacy and the larger role of models within regulation will vary significantly with differing understandings of good administration. In his dissent in *Benzene*, in fact, Justice Marshall exemplified a different, minority view in describing the plurality's decision as "extraordinarily unfair" because "its characterization of the Secretary's report bears practically no resemblance to what the Secretary actually did in this case."[84] Likewise Chief Judge Bazelon, in promoting a very different concept of hard look review than that promoted by Judge Leventhal, understood that while "scientists seek to conquer uncertainty, regulators needed to act in spite of it."[85] In so doing, regulators needed to be transparent, flexible, and deliberative, while acting on the basis of judgment calls.[86] In thinking about the role of models, then, one should not underestimate the power of the surrounding regulatory culture in how models are understood. Indeed and as discussed next, characterizations of models are often based less on what models *are* and more on assumptions about what an environmental regulator *expects them to be*.

II. MISUNDERSTANDING MODELS IN ENVIRONMENTAL REGULATION

Computational models are highly contingent mathematical approximations of what reality might be like, yet in policy and legal circles they are often viewed as tools that are capable of providing precise, definitive answers to pressing policy questions. This basic misunderstanding leads the legal analyst down one of two equally treacherous paths. In some and likely most cases the analyst will tend to place too much confidence in the model, viewing it as empirically determinative, and thus will fail to evaluate or qualify it in a rigorous way. In other cases, the policymaker will inquire further into the workings of the model

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[84] 448 U.S. at 695 (Marshall, J., dissenting).

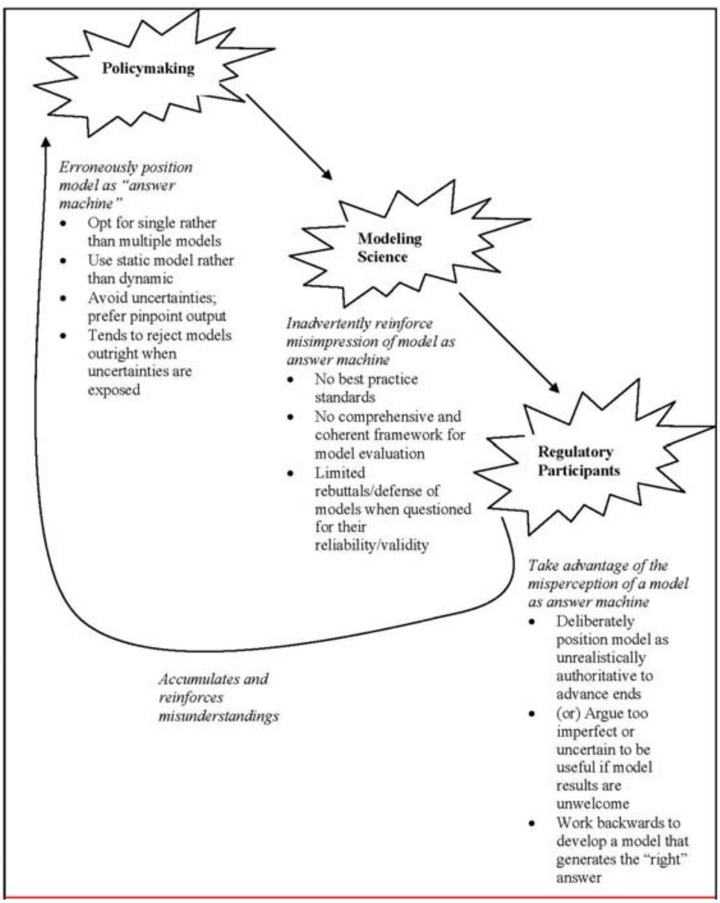
[85] David Bazelon, *Science and Uncertainty: A Jurist's View*, 5 HARV. ENVTL. L. REV. 209, 213 (1981).

[86] *See, e.g.*, *id.* at 212, 214; AFL-CIO v. Marshall, 617 F.2d 636, 651 (D.C. Cir. 1979); Natural Res. Defense Council v. Nuclear Regulatory Comm'n, 547 F.2d 633, 637–56 (D.C. Cir. 1976).

and become disillusioned with the uncertainties and multiple sources for judgment and reject it in total. In both cases, models are misused and their true contributions—about relationships, dynamic qualities, and even uncertainties in the system—are passed over.

This part traces the core misunderstanding of models as "truth machines" in U.S. regulation. The first section documents the prevalence of this misunderstanding throughout a great deal of environmental law and litigation, and identifies how the resultant misunderstanding causes significant harm to environmental policymaking. The second and third sections then trace out the chain reaction this misunderstanding creates in the science of modeling and in high stakes regulatory disputes. See Figure 3.

Figure 3: Models as Answer Machines: A Perverse Feedback Loop of Misunderstanding



A. *The Core Misunderstanding: Models as "Truth Machines"*

Models are embedded in and shaped by their institutional context, but from the perspective of the courts, many policymakers in Congress, and even the agencies, there is a widespread (though not uniform)[87] misconception that models provide deterministic answers.[88] Under this view, an environmental model is perceived as a value-neutral description of reality and any residual uncertainty is viewed as a defect, rather than an ineluctable attribute of the scientific endeavor. Specifically, models are used to *prove* that there is a relationship between source and effect, rather than *exploring* the nature and contours of this possible relationship, along with other variables, in dynamic ways.

1. *The Perception of Models as "Truth Machines" in U.S. Regulation*

An unrealistic expectation that models will provide "answers" for policy rather than more qualified and dynamic information pervades nearly all of the major environmental programs. The Clean Water Act expects modelers to isolate the precise point at which reductions in the pollutant load for a river will enable it to attain water quality standards.[89] Once the modeler provides this "answer," policymakers then return and determine how to allocate the appropriate shares of pollutant reduction.[90] The Clean Air Act

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[87] Decision-makers do not always err in their evaluation or use of models. There are circumstances where the agencies or the courts do an excellent job understanding the contributions and limitations of models. *See, e.g.*, NRC, *supra* note 13, at 176–77 (commending EPA's use of multiple models to assess uncertainties in estimating mercury bioaccumulation in fish). In this section we catalog the most common and most preventable errors.

[88] This argument is developed further in HOLLY DOREMUS & WENDY WAGNER, THE COURTS AND SCIENCE (forthcoming 2010); *see also* Daniel Sarewitz, *How Science Makes Environmental Controversies Worse*, 7 ENVTL. SCI. & POL'Y 385, 386 (2004) (observing the "pervasive and strongly held notion" in policy circles that science is "a source of verifiable facts and theories about reality"); Fine & Owen, *supra* note 24, at 909–10 (observing that "Congress assumed [in many environmental statutes] that science would drive decision-making and that agencies could interpret scientific information to set the right policies").

[89] *See* Houck, *supra* note 57, at 1928 (lamenting these fundamental problems in the design of the TMDL and Clean Air Act programs).

[90] Clean Water Act § 303, 33 U.S.C. § 1313(d)(1)(C) (2006) (requiring states to establish maximum daily effluent limitations necessary to meet waterway standards).

balances enormously expensive and protracted regulatory requirements on the outputs of air quality models and then uses those models to determine what steps must be taken—steps that can dramatically alter the region's economy—to meet that "output."[91] There is no middle ground in the model's use: it either generates this single answer or it does not. Additional variables, uncertainties, or other qualifiers highlighted by the model are considered an unwelcome distraction in these regulatory exercises.

In health risk assessments, the demand for a single number or output from a model is also quite common.[92] EPA has been berated repeatedly for its bad habit of using point estimates from risk assessments and otherwise representing model outputs as decisive, single numbers without error bars.[93] As the NRC warned in its condemnation of the practice, EPA's use of point estimates "suppresses information about sources of error that result from choices of model, data sets, and techniques for estimating values of parameters from data."[94]

Evidence of this "truth machine" conception of models in the U.S. regulatory system is perhaps easiest to trace through court opinions, where judges have the opportunity to look at models in specific contextual settings. Since courts appear to exert

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[91] *See supra* notes 21–26 and accompanying text.

[92] Although policymakers may deploy computer models to provide "answers" for policy, the responsibility for this misunderstanding in the capacity of models may rest with scientists as well. *See, e.g.*, Peter W. Preuss & Paul D. White, *The Changing Role of Risk Assessment in Federal Regulation*, *in* RISK QUANTITATION AND REGULATORY POLICY 331, 335 (David G. Hoel et al. eds., 1985) (noting that federal agencies have moved from simple, imprecise linear models of risk to "complicated model-fitting computer programs" and that "[t]he statistical techniques in these calculations are sophisticated and can be so involved that risk assessors themselves do not fully understand the details"); *see also infra* Part II.B.

[93] *See, e.g.*, NRC, *supra* note 13, at 7 ("Effective decision making will require providing policy makers with more than a single probability distribution for a model result . . . ."); RISK ASSESSMENT IN THE FEDERAL GOVERNMENT, *supra* note 46, at 7–8 (1983) (recommending that agencies prepare "written risk assessments that explicitly state the basis of choice among inference options").

[94] NRC, COMM. ON RISK ASSESSMENT OF HAZARDOUS AIR POLLUTANTS, SCIENCE AND JUDGMENT IN RISK ASSESSMENT 184 (1994). The NRC also suggests that instead EPA should "make uncertainties explicit and present them as accurately and fully as is feasible." *Id.* at 185. *But see* Preuss & White, *supra* note 92, at 340–42 (scientists expressing concern that point estimates mislead decision-makers, while EPA scientist, Dr. Roy Albert, argues that the scientist's job is to "take a position" regarding the risk and "if it isn't that position [i.e., point estimate], then it's got to be another one").

particularly strong influences on agency behavior, their opinions play an important role in the agency's use (or misuse) of models.[95] In resolving challenges to models, most courts perpetuate the pervasive misunderstanding and assume that since the model is mathematical, it is correct. As a result, they pass the model through the system without much, if any, scrutiny. The dominant trend in the courts follows this deferential, deterministic path, even in cases when there are reasons to suspect that the model may have significant problems.[96]

In analyzing the courts' review of the universe of EPA's models, for example, one of us found that by far the most common approach taken by the courts was nearly complete deference to models.[97] As one court noted:

> As long as an agency reveals the data and assumptions upon which a computer model is based, allows and considers public comment on the use or results of the model, and ensures that the ultimate decision rests with the agency, not the computer model, then the agency use of a computer model to assist in decision making is not arbitrary and capricious.[98]

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[95] The courts exert pressure on agencies when judges delve into the procedure and (less frequently) the substance of agency decision-making. They also indirectly become a tool of pressure insofar as litigation imposes substantial delays on agency action and drives up costs of proposed projects. *See* ROBERT A. KAGAN, ADVERSARIAL LEGALISM 224–25 (2001) (explaining that courts provide a "vehicle for substantial delay" by opponents who have only to file a lawsuit to set a burdensome process rolling); R. Shep Melnick, *Administrative Law and Bureaucratic Reality*, 44 ADMIN. L. REV. 245, 247–49 (1992) (observing that courts have imposed vague substantive standards, and that decisions often appear arbitrary, putting agencies on the defensive and changing their rulemaking strategies).

[96] *See* Jason J. Czarnezki, *An Empirical Investigation of Judicial Decisionmaking, Statutory Interpretation, and the* Chevron *Doctrine in Environmental Law*, 79 U. COLO. L. REV. 767, 817–19 (2008) (concluding based on sample that courts "are well aware of their limitations in addressing issues of scientific expertise" and that the Circuits "have built upon the Supreme Court's statements in both *Chevron* and *Baltimore Gas* [*& Electric Co. v. NRDC*] to create strong principles of deference when environmental science is involved").

[97] Thomas O. McGarity & Wendy E. Wagner, *Legal Aspects of the Regulatory Use of Environmental Modeling*, 10 ENVTL. L. REP. 10,751, 10,757 (2003) (observing the considerable deference that courts generally afford EPA models, despite extensive nitpicking by stakeholders).

[98] Sierra Club v. U.S. Forest Serv., 878 F. Supp. 1295, 1310 (D.S.D. 1993), *aff'd* 46 F.3d 835 (8th Cir. 1995); *see also* Nat'l Oilseed Processors Ass'n v. Browner, 924 F. Supp. 1193, 1217 (D.D.C. 1996) (after noting the extensive effort EPA dedicated to identifying appropriate candidates for listing on the national Toxic Release Inventory list, the district court concluded that, although

Some courts, particularly in the earlier years of regulation, do not even insist on a full explanation of the assumptions or basis for the model itself.[99] Instead these courts conclude that "it is not for the judicial branch to undertake comparative evaluations of conflicting scientific evidence."[100]

In his analysis of judicial review of forest planning models, Professor Glicksman similarly found that the "courts were . . . very deferential to the manner in which the Forest Service used the FORPLAN model."[101] Glicksman was able to locate only one reported case where a Forest Service model was struck down, despite a number of credible attacks in other cases that on their face warranted closer examination.[102] For example, in rejecting an attack on a travel zone model that the Forest Service used to project travel patterns in a wilderness area, the court deferred to the Forest Service's model because (in the court's words) the model "was developed over nearly two decades and includes extensive studies based on travel diaries, as well as expert opinion and a computer model. . . . The law is clear that a court may not second-guess methodological choices made by an agency in its area of expertise."[103]

In far fewer opinions, which nevertheless produce a formidable body of precedent, some courts take the opposite tack to approaching models as answer machines and reject a model when there is evidence of unresolved issues or uncertain calculations. The judiciary's rejection of models because the models are unable to produce definitive answers is evidenced in

EPA's explanations were not always as complete as the court wished, "the principles of administrative law do not demand perfection in the administrative process . . . . EPA went to great lengths to separately evaluate each and every chemical on the basis of the relevant data, and to make scientific and technical judgments which are clearly outside the expertise of a reviewing court."), *aff'd in part, rev'd in part on other grounds sub nom.* Troy v. Browner, 120 F.3d 277 (D.C. Cir. 1997).

99 The Supreme Court encouraged this super-deference in *Baltimore Gas & Electric Co. v. Natural Resources Defense Council*, 462 U.S. 87, 103 (1993) ("When examining this kind of scientific determination [i.e., one at the "frontiers of science"], as opposed to simple findings of fact, a reviewing court must generally be at its most deferential.").

100 *Nat'l Oilseed Processors*, 924 F. Supp. at 1209 (internal quotations omitted).

101 Glicksman, *supra* note 20, at 492.

102 *Id.* at 484–86, 492.

103 *Id.* at 493, quoting Inland Empire Pub. Lands Council v. Schultz, 992 F.2d 977, 981 (9th Cir. 1993).

several high profile cases that may have played an equal or even more important role in influencing agency behavior.[104] A particularly good example of this premature rejection of a robust computational model is *Gulf South Insulation v. Consumer Product Safety Commission*, in which the court overturned the Consumer Product Safety Commission's (CPSC) ban on the use of urea-formaldehyde insulation (UFFI) in residences and schools.[105] Much of this invalidation of CPSC's rule was based on the court's underlying rejection of the agency's use of a "Global 79" risk assessment model used to predict the increased risk of cancer to a person living in a UFFI home. The court found CPSC's policy-based assumption in that model, which extrapolated human effects from one large rat study, to be arbitrary.[106] "To make precise estimates," the court reasoned, "precise data are required."[107] The court's opinion flew in the face of many cases upholding the ability of agencies to extrapolate laboratory animal data to humans when human evidence is scarce,[108] and the court seemed to reject

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[104] *See* Daniel A. Farber, *Modeling Climate Change and its Impacts: Law, Policy, and Science*, 86 TEX. L. REV. 1655, 1675–77 (2008) (discussing *Daubert v. Merrell Dow* standard for admissibility of expert evidence and the effect of this ruling on courts' acceptance of models).

[105] 701 F.2d 1137, 1143–47 (5th Cir. 1983).

[106] *Id.* at 1146.

[107] *Id.* Legal scholars and scientists have been very critical of the *Gulf South* opinion, accusing the court of overreaching in an area that was beyond judicial competence. *See* Howard Latin, *Good Science, Bad Regulation, and Toxic Risk Assessment*, 5 YALE J. ON REG. 89, 130–31 (1988) ("The court's opinion reflects . . . a fundamental misunderstanding of the limited evidence on which most risk assessments of carcinogens are based."); Richard A. Merrill, *The Legal System's Response to Scientific Uncertainty: The Role of Judicial Review*, 4 FUNDAMENTAL & APPLIED TOXICOLOGY 418, 424–25 (1984) ("The opinion's close scrutiny of an exercise that is fraught with uncertainty, but yet promises improvement in regulation of health hazards, is disconcerting."); Nicholas A. Ashford et al., *A Hard Look at Federal Regulation of Formaldehyde: A Departure from Reasoned Decisionmaking*, 7 HARV. ENVTL. L. REV. 297, 363–68 (1983) ("[W]e find the Fifth Circuit's analysis to be unpersuasive in its evaluation of CPSC's cancer risk assessment for formaldehyde."). *But see* Cass R. Sunstein, *In Defense of the Hard Look: Judicial Activism and Administrative Law*, 7 HARV. J.L. & PUB. POL'Y 51, 53 (1984) (praising the Fifth Circuit for relying on the hard look doctrine to "ensure that regulatory controls are well-founded" and to promote "private ordering").

[108] *See, e.g.*, Environmental Defense Fund, Inc. [EDF] v. EPA, 598 F.2d 62, 86–89 (D.C. Cir. 1978) (upholding EPA rule on PCB discharges based in part on animal cancer studies); Hercules, Inc. v. EPA, 598 F.2d 91, 110 (D.C. Cir. 1978) (finding EPA's "concern" about carcinogenicity of pesticide in context of setting an "ample margin of safety" was adequately supported by animal study); EDF v.

the model because it disappointed the judiciary's unrealistic demand for empirical decisiveness.

In *Leather Industries of America, Inc. v. EPA*, the D.C. Circuit invalidated EPA's model in part because it was dissatisfied with an assumption built into the model regarding the phytotoxicity of selenium.[109] Even though EPA relied upon some preliminary research and other logical assumptions to justify the level it selected for selenium in the model, the court held that more data-backed justification was required. "While the EPA may err on the side of overprotection, it may not engage in sheer guesswork."[110] The court did not suggest, however, that the agency had ignored relevant information, nor did it explain how the EPA would go about gathering additional information.

In *Ohio v. EPA* (*Ohio I*), the Sixth Circuit rejected an EPA air model because EPA had failed to benchmark its computerized atmospheric model, CRSTER, against real data collected from the particular locale.[111] On petition for rehearing, the court upheld its earlier ruling that EPA had not adequately demonstrated that the CRSTER model took into account the "specific meteorological and geographic problems" of the emissions of sulfur dioxide from the smokestacks of two power plants.[112] As a result, EPA's model allowed for too much sulfur dioxide in an area that was already designated nonattainment for that particular pollutant. The court held this type of ground-testing of a model to essentially be required before EPA could legally employ the model to determine emissions limits, and it was arbitrary for EPA to allow a 400 percent increase in emissions without validation or empirical testing of the model at the site.[113] While the court seemed to base its holding in part on EPA's failure to comply with an earlier

Costle, 578 F.2d 337, 345 (D.C. Cir. 1978) (citing evidence of carcinogenicity of water pollutants based on animal studies); EDF v. EPA, 548 F.2d 998, 1005–08 (D.C. Cir. 1976) (allowing EPA to extrapolate from mice and rat studies of carcinogenicity of pesticides).

[109] 40 F.3d 392, 403 (D.C. Cir. 1994).

[110] *Id.* at 408 (internal quotations omitted).

[111] 784 F.2d 224, 228–31 (6th Cir. 1986).

[112] Ohio v. EPA (*Ohio II*), 798 F.2d 880, 882 (6th Cir. 1986).

[113] *Ohio I*, 784 F.2d at 231; *Ohio II*, 798 F.2d at 882. For a sharp critique of the approach taken by the court in *Ohio v. EPA*, see Michael S. McMahon and Steven D. Hinkle, State of Ohio v. EPA*: Does the Sixth Circuit Have a New Standard for Its Review of the EPA's Use of Air Quality Modeling?*, 18 U. TOL. L. REV. 569, 582–85 (1987).

remand requiring the agency to collect ambient data on sulfur dioxide concentrations in the area, the panel went further to state an overarching expectation that an agency must "back up its regulations [and models] with checks against real world data" generated for the particular site where the model is applied.[114] The possibilities that this data might be quite expensive to collect, might be quite limited in terms of its locale-specific value, and might take more than a year to gather were effectively dismissed as illegitimate reasons to depart from this rigorous validation requirement.[115] Indeed, the fact that the model had already been validated in other locales only strengthened the case, in the court's view, for requiring similar types of locale-specific tests in the application of the model to these two power plants.[116] The decision effectively hamstrung the ability of agencies to rely on models when data is too time-consuming or expensive to collect by demanding location-specific data to ground test the model.

A similar misunderstanding of models as truth machines can be seen in an analysis of scientific admissibility rulings in private tort litigation, many of which involve environmental disputes. There are significant conflicts between the Supreme Court's deterministic test for admissibility of expert testimony (embodied in part in *Daubert v. Merrell Dow Pharmaceuticals*)[117] and the true nature of models.[118] Perhaps most problematic was the Court's standard that a model be falsifiable and testable. As Swinehart observes:

> Instead of considering the viability of the model as a whole, a falsifiability examination invariably focuses on finding fault with the constituent parts of a model—its assumptions, algorithms, and data set—robbing a valid model of its

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[114] *Ohio I*, 784 F.2d at 230.

[115] *Id.* at 229.

[116] *Id.* at 229–231.

[117] 509 U.S. 579, 592–595 (1993). The court interpreted Rule 702 of the Federal Rules of Evidence to ask of a scientific "theory or technique" (1) whether it is capable of "testing" to see if it can be "falsified"; (2) whether it has been subjected to peer review and publication; (3) what is its "known or potential error rate"; (4) what are the "standards controlling the technique's operation"; and finally (5) whether it is "generally accepted" within the scientific community. The inquiry is "flexible" and the factors should not be considered determinative or exhaustive. *Id.*

[118] Swinehart, *supra* note 36, at 1301–11 (reviewing each of the *Daubert* factors and describing problems with applying the standards to determine the reliability of models).

coherency, while possibly upholding an ultimately flawed model that is composed of "good" parts.[119]

In his extensive analysis of toxic tort litigation Carl Cranor observes a somewhat similar phenomenon: Some courts exclude expert testimony based on animal models and related research "simply because it does not represent a complete or definitive answer to a larger policy or science question."[120] These courts find that these "weight of the evidence" models are insufficiently rigorous or probative and insist instead that plaintiffs support their causation claims with epidemiological research, despite the fact that this evidence is often unavailable or inconclusive.[121]

2. *Implications for Policy Analysis*

The dominant view of models as 'fact-generators' is not only wrong—or at least at odds with what we know models to be—but it also leads to a series of problems that get in the way of the high quality use of models for policy analysis. A variety of misconceptions radiate from this central misunderstanding. See Table 2. We discuss a few of the most important ramifications of these misunderstandings here.

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[119] *Id.* at 1305.

[120] *See* Carl F. Cranor, *The Dual Legacy of* Daubert v. Merrell-Dow Pharmaceutical*: Trading Junk Science for Insidious Science*, *in* RESCUING SCIENCE FROM POLITICS: REGULATION AND THE DISTORTION OF SCIENTIFIC RESEARCH 120, 121, 126 (Wendy Wagner & Rena Steinzor eds. 2006).

[121] *Id.*

Table 2. The Proper Way to Understand Models vs. Models Misunderstood as "Answer Machines"

	Models properly understood	**Models misunderstood as "Answer Machines"**
Purpose of Model	To assist in problem solving; to spark deliberation	To prove that a regulation is supported by "sound science"
Basis of Model	Analysis; judgment based on experience; assumptions	Scientific analysis, without any policy or related judgments
Scientific uncertainty	Inherent feature that needs to be explained	Undesirable feature that needs to be reduced: uncertainty can undercut the perceived reliability of a model
Model output	Dynamic, iterative process	Static, one-time answer
Primary Administrative Purpose	To aid in the process of establishing reasons for regulating	Accurately proving a relationship between source and effect
Relationship to Public Participation	Facilitate deliberation among disparate parties	No relationship: public participation is inappropriate for this "scientific" exercise
Approaches to Public Administration[122]	Deliberative-Constitutive	Rational-Instrumental
Accountability	Through showing that there has been an effective problem-solving process	Through showing accuracy and adherence to the legislative mandate
Means of Assessing the Quality of the Model	Through assessing how it has contributed to problem-solving	Through assessing the model's accuracy

First, the view of models as "truth generators" is likely to give policymakers the unrealistic expectation that a single "perfect" model will produce the truth. Modelers, by contrast, generally take the view that multiple models are essential to good modeling and that reliance on a single model is likely to lead to serious blind spots and make poor use of models.[123] In keeping with their misunderstanding, however, policymakers may dismiss efforts by

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[122] ELIZABETH FISHER, RISK REGULATION AND ADMINISTRATIVE CONSTITUTIONALISM 26–35 (2007). "The *rational-instrumental* theory of administrative constitutionalism construes public administration to be an 'instrument' of the legislature—a 'robot' or 'transmission belt' whose task is strictly to obey the pre-ordained democratic will as it is expressed in legislation." *Id.* at 28. In contrast, the *deliberative-constitutive* paradigm "promotes a model of public administration that is designed to address the factual and normative complexities of technological risk evaluation by granting to public administration substantial and ongoing problem-solving discretion in relation to particular issues." *Id.* at 30.

[123] *See, e.g.*, Farber, *supra* note 104, at 1666–67 (discussing the importance of using multiple models in the climate change modeling context).

scientists to model scenarios using alternative assumptions or to employ different models in order to reach a better understanding of a system.[124] The policymakers' understanding that good modeling culminates in a single, perfect model thus diverges significantly from what modelers view as appropriate and correct.

Second, a fact-generator view of models causes policymakers and judges to be caught in a paradox. On the one hand, they view themselves as the non-participating recipient of a model product, and as such under no obligation to acknowledge the values and policy inputs that are needed to frame the proper development of the model.[125] Indeed, such acknowledgement runs counter to an understanding of models as "truth machines."

On the other hand, the values and policy inputs become blatantly obvious in any dispute over the model. Thus, for example, in a recent English legal challenge to a risk assessment concerning the health risks from crop spraying the judge noted, "[W]e are here at the very fringe of what should properly be the subject of judicial review," while at the same time finding himself drawn into arguments about the veracity and quality of the model.[126] In that case, a risk assessment model for bystander pesticide exposure was developed by the UK Department of Environment, Food, and Rural Affairs (DEFRA) to fulfill its obligations under EU law. The model, however, was heavily criticized by another independent government body, the Royal Commission on Environmental Pollution, which argued that it should be "replaced by a computational model which is probabilistic, looks at a wider range of possible exposure routes and more robustly reflects worst case outcomes."[127] In particular, the risk model did not consider either cumulative risks (that often occur over years or even a lifetime) or risks to particularly susceptible groups, such as children.

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[124] The value of multiple models and multiple scenarios in using models for policy is well-established in the modeling literature. *See, e.g.*, Robert Evans, *Economic Models and Economic Policy: What Economic Forecasters Can Do for Government*, *in* EMPIRICAL MODELS AND POLICY-MAKING 206, 222–24 (Frank A.G. den Butter & Mary S. Morgan eds., 2000).

[125] *See* NRC, *supra* note 13, at 92–93 (describing the central importance of delimiting the purpose of the models).

[126] Downs v. Sec'y of State for Env't, Food & Rural Affairs, [2008] EWHC (QB) 2666, [38].

[127] Sec'y of State for Env't, Food & Rural Affairs v. Downs, [2009] EWCA (Civ) 664, [4]–[8] (U.K.) (appeal taken from Q.B.).

Thus while the judge made clear that "the alleged inadequacies of the model and the approach to authorization and conditions of use have been scientifically justified,"[128] he found himself reviewing the decision closely and ultimately striking it down. Moreover, this decision was appealed and the Court of Appeal also found itself drawn into the arguments concerning the assumptions on which DEFRA's models were based.[129] It also came to a different conclusion. Likewise, the use of models in the evaluation of medicinal drugs by the English National Health Service has raised a number of legal challenges concerning the procedural rights in relation to access to models.[130] Models may be highly technical but they raise fundamental legal questions about basic issues such as what is procedurally fair.

Models are thus not separate from regulatory and legal decision-making. They are deeply intertwined, and as a result a more effective use of models for regulation requires continuous interactions between policymakers and modelers in developing models that answer the right questions and use the appropriate assumptions.[131] If policymakers instead view themselves as wholly detached from the modeling exercise and only as consumers of model products (at least until the model comes under challenge), they miss the opportunity to engage in these critical decisions that may be made without them. Moreover, they remain largely oblivious to the fundamental questions that models raise, but are unable to answer.

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[128] Downs v. Sec'y of State for Env't, Food & Rural Affairs, [2008] EWHC (QB) 2666, [39].

[129] Sec'y of State for Env't, Food & Rural Affairs v. Downs, [2009] EWCA (Civ) 664, [4]–[8] (U.K.) (appeal taken from Q.B.).

[130] Eisai Ltd, R (on the application of) v. National Institute for Health and Clinical Excellence (NICE) [2008] EWCA (Civ) 438 (01 May 2008); Servier Laboratories Ltd, R (on the application of) v. National Institute for Health & Clinical Excellence & Ors [2009] EWHC (Admin) 281 (19 February 2009); Bristol-Myers Squibb Pharmaceuticals Ltd, R (on the application of) v. National Institute for Health and Clinical Excellence [2009] EWHC (Admin) 2722 (06 November 2009).

[131] Hali J. Edison & Jaime Marquez, *U.S. Monetary Policy and Econometric Modeling: Tales from the FOMC Transcripts 1984–91*, *in* EMPIRICAL MODELS AND POLICY-MAKING, *supra* note 124, at 187, 203 (concluding that "far from being mechanistic providers of policy constraints, models shape and are shaped by the judgment of policy makers"); *see also* Frank A.G. den Butter & Mary S. Morgan, *Preface*, *in* EMPIRICAL MODELS AND POLICY-MAKING, *supra* note 124, at xiv, xiv (noting that the interaction between modelers and policy-makers is important but under-researched).

Third, policymakers who view models as truth machines believe they are receiving answers from models that resolve a problem once and for all. They will tend to be content with very limited or nonexistent expressions of the uncertainty and assumptions within a model, and they will be inclined to codify the models into policy, without providing any means of updating or revising the models in adaptive fashion. Under existing administrative law this inclination for static, precise model outputs follows the path of least resistance. An outdated but "final" model supporting a rule is generally immune from challenge; but as soon as the agency revises the model supporting that rule, multiple layers of regulatory oversight begin anew.[132] For example, when minor errors are discovered in a model or slight adjustments are needed to an algorithm, the agency risks being challenged if it does not engage in full notice and comment on the model changes since the challenger can argue that the adjustments were material changes that required public participation.[133] Again, this wrong-headed approach to models as static "answer machines" causes policymakers to lose much of what the model has to offer in terms of highlighting the dynamic nature of the system.

Finally, a "fact generator" view of models could lead to adverse reactions in other arenas.[134] An unrealistic expectation

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[132] Lynn E. Blais & Wendy E. Wagner, *Emerging Science, Adaptive Regulation, and the Problem of Rulemaking Ruts*, 86 TEX. L. REV. 1701, 1712–15 (2008) (describing the problem of rulemaking ruts that impede the revision of standards and models used to set those standards); NRC, *supra* note 13, at 166–67 ("In such an adversarial environment, [the agency] might perceive that a rigorous life-cycle model evaluation is ill-advised . . . . [R]eview may expose the model to a greater risk of challenges . . . because the agency is documenting features of its models that need to be improved.").

[133] Jack M. Beermann & Gary Lawson, *Reprocessing* Vermont Yankee, 75 GEO. WASH. L. REV. 856, 893–900 (2007) (criticizing courts for expansive interpretation of the "meagre" statutory requirements of the Administrative Procedure Act to mandate that agencies go through a follow-up notice and comment process whenever a final rule is not the "logical outgrowth" of the proposed rule, and discussing how this impedes agency adaptability to new information during the notice and comment period).

[134] This same phenomenon was noticed in some policymakers' use of economic models, which seem more susceptible to common-sense limitations in their accuracy. *See, e.g.*, John Bradley, *Policy Design and Evaluation: EU Structural Funds and Cohesion in the European Periphery*, *in* EMPIRICAL MODELS AND POLICY-MAKING, *supra* note 124, at 129, 143 (observing from case study that "the policy makers were posing empirical questions to the modelers that were almost impossible to answer adequately with the present state of knowledge").

that models will resolve policy problems can lead to unnecessary expense and delay in reaching solutions to pressing policy problems when a model disappoints these expectations.[135] As we suggest in the next two sections, this misunderstanding also provides fodder for strategic manipulation and model misrepresentation. For example, it puts a strain on modelers who find themselves in the difficult position of either disappointing policymakers, with the attendant adverse consequences for possible future funding, or providing unreliable answers for policymakers who might not fully appreciate the limitations in the model output.

The view of models as truth machines, then, is not innocuous. Instead it leads to policymaking approaches that miss the true value of models and distort their outputs in damaging ways. Even more concerning is the possibility that this "answer machine" view is particularly engrained in the U.S. administrative system of regulatory decision-making as compared with other countries. Fisher documents how debates over public administration in environmental and public health regulation have swung between two different extremes that vary, in large part, in their attitude towards technical tools like models.[136] One approach—generally not followed in the U.S.—views administrative policymaking as a substantial and ongoing problem-solving exercise between experts and affected parties in a cooperative, non-adversarial setting (the *Deliberative-Constitutive* paradigm).[137] In this type of decision-making environment, models are viewed more realistically as highly contingent and uncertain, but still quite useful for the light they shed on a problem. Fisher isolates certain policymaking events in Australia and Great Britain that represent this type of deliberative approach where regulatory outcomes are based on a

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[135] *See, e.g.*, DANIEL SAREWITZ, FRONTIERS OF ILLUSION: SCIENCE, TECHNOLOGY, AND THE POLITICS OF PROGRESS 86 (1996) ("[P]oliticians [will not] find that an improved understanding of the intricacies of atmospheric process can much help them to evaluate policy options for responding to global change."); Leslie Roberts, *Learning from an Acid Rain Program,* 251 SCI. 1302, 1304–05 (1991) (describing a five-year gap between the time Congress stopped asking about the scientific basis of acid rain and moved on to political questions of who would pay, and the release of the authoritative scientific report on acid rain. The time-consuming scientific effort produced "an extraordinary model, capable of dazzling resolution," but too late for Congress and at the expense of "simpler models that would have been more useful for policy analysis.").

[136] FISHER, *supra* note 122, at 26–35.

[137] *See id.* at 30–33.

range of factors, of which multiple models would be part.[138]

Since at least 1980, U.S. courts have largely rejected this more flexible and cooperative approach to decision-making, instead favoring a technocratic approach to policy development that relies on "answers" generated from technical and empirical analysis (the *Rational-Instrumental* paradigm).[139] This Rational-Instrumental paradigm is reinforced by strategic calls for "sound science" as the prerequisite for regulation, which in turn leads to the mistaken view that science provides a neutral and complete answer that can be neatly fitted into a policy need or question.[140] According to this paradigm, public administration is an "instrument" of the legislature—a "transmission belt"—whose task is strictly to obey the pre-ordained democratic will as it is expressed in legislation.[141] In so doing, an agency acts simply by identifying, assessing, and applying the relevant facts and value preferences to the issue at hand.[142] This perspective fortifies the view of models as "truth generators." The malleability and uncertain nature of models is simply irreconcilable with a vision of decision-making that proceeds with technocratic answers and processes. While the administrative law process alone does not lead inevitably to this technocratic perspective of models, over the years it has become the dominant view that tends to crowd out a more scientifically realistic and conditional view of models.

3. *Summary*

The misunderstanding of models as truth generators is reflected in the basic constitution of contemporary U.S.

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[138] *Id.* at 48–88, 125–161.

[139] *See id.* at ch. 3. Elements of this approach can be seen in the following sources: THOMAS O. MCGARITY, REINVENTING RATIONALITY: THE ROLE OF REGULATORY ANALYSIS IN THE FEDERAL BUREAUCRACY 10–16 (1991) (comprehensive analytical rationality); MARTIN SHAPIRO, THE SUPREME COURT AND ADMINISTRATIVE AGENCIES 67–91 (1968) (synoptic model); CASS SUNSTEIN, THE COST BENEFIT STATE 19–29 (2002) (cost-benefit analysis); MAX WEBER, FROM MAX WEBER: ESSAYS IN SOCIOLOGY 196–244 (H.H. Gerth & C. Wright Mills eds. & trans., Oxford Univ. Press 1946) (theory of bureaucracy); Richard B. Stewart, *The Reformation of American Administrative Law*, 88 HARV. L. REV. 1667 (1975) (interest representation model).

[140] *See, e.g.*, Chris Mooney, Op-Ed., *Beware Sound Science: It's Doublespeak for Trouble*, WASH. POST, Feb. 29, 2004, at B2.

[141] Stewart, *supra* note 139, at 1675.

[142] *See* FISHER, *supra* note 122, at 28–29.

administrative law and expressed through a number of regulatory programs. Yet this misunderstanding is decidedly problematic if the goal is to encourage the smart use of models for environmental policy. Models are not just products of theory and data but also are shaped by the priorities of the decision-makers who are deploying them.[143] If the policymakers are unaware of their own critical role in model development, and also have little clue about how to use model outputs in an accurate or useful way, then much of what models have to offer policy will be lost. Models do not generate final answers, but they do generate useful insights that aid both deliberation and analysis. Without an appreciation for the difference, the agency runs the risk of accepting badly incomplete answers and missing the true value of models.

B. *Weaknesses in Modeling Science that Do Not Dispel, and May Even Reinforce, the Misunderstanding of Models as "Truth Machines"*

The fact generator view of models would ideally be shattered by scientists who provide extensive discussions of uncertainties, assumptions, and related contingencies of models. But this is not occurring, or at least not occurring in a regularized, consistent way.[144] This section explores why scientists have not managed to overthrow policymakers' misconception of models as truth machines, and how their inactivity may be partly to blame for exacerbating existing misunderstandings between science and

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[143] In this regard it can be thought of as a subset of "regulatory science." *See* SHEILA JASANOFF, THE FIFTH BRANCH: SCIENCE ADVISERS AS POLICYMAKERS 80 (1990) (comparing *regulatory science*, practiced by government agencies and regulatory stakeholders in pursuit of "policy truths" and subject to political pressure for timely and definitive answers, with university-based *research science*, an open-ended search for "truths of originality and significance").

[144] One computer model may contain dozens of hidden policy assumptions, which exert a profound effect on the resulting numerical standard. *See, e.g.*, JOHN D. GRAHAM ET AL., IN SEARCH OF SAFETY: CHEMICALS AND CANCER RISK 158–159 (1988) (comparing widely-varying formaldehyde risk estimates for rats based on alternative mathematical models, and noting that agencies, when choosing between models, adopt methods and "intentionally aim high" from a fear of underestimating cancer risks). The choice of a model, however, is rarely, if ever, presented in its full mixed science-policy light. 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.").

policy.

Much of the modelers' silence about, or even complicity in, the misunderstanding of policymakers may be due to the fact that computational modeling is a relatively new field. As such, modelers may simply not be sufficiently organized to provide a coherent corrective to this pervasive misunderstanding.[145] Indeed, perhaps because computational modeling is struggling for acceptance and authority, modelers might find that policymakers' misunderstandings cut in their favor.

The absence of a set of accepted best practice principles to guide high-quality computational modeling may be the most significant void in modeling science. This missing ingredient may be a consequence of the fledgling state of the science, but the absence of accepted best practices could also be attributed to the fact that models are often developed by scientists from a wide variety of disciplinary areas like meteorology, hydrology, risk assessment, and economic analysis. These disciplines have few opportunities to communicate with one another, which impedes their collective ability to develop generally accepted principles for modeling. The varying uses of models in regulation—ranging from primitive research tools to finely-tuned instruments for predicting change—further complicate the ability to create a "one size fits all" set of best practices for the use of models in policy.[146]

Without a coherent set of best practice guidelines, however, it is difficult for modelers to provide a counterweight to policymakers' expectations of models as fact generators. Instead, the flexible, even permissive space within which modeling occurs allows for models to be portrayed as fact generators without consequence.[147] Because policymakers want "outputs" and

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[145] *See* NRC, *supra* note 13, at 20–21 (discussing the rapid growth in modeling over the past twenty-five years and the gradual shift in understanding about models).

[146] *See id.* at 56–62 (describing the varied uses of models by the EPA to determine when to regulate, how much to regulate, for determining compliance, to set penalties, and to assess the success of regulatory efforts). Nevertheless, as discussed in Part III *infra*, it may still be possible to develop best practices to foster regulatory models that are transparent and conform to the scientific evidence. For example, modelers should disclose the role of sponsors in model development when those models are used for regulation; should account for the assumptions underlying their inferences (e.g., does a model assume that the data conform to a normal distribution?); and should constantly re-evaluate their models in light of changing theories or new data.

[147] Efforts by climate change modelers to develop rigorous, consensus-based

assume them to be correct, diverse and even sloppy practices can occur with some frequency.

A second challenge faced by modelers is how to appropriately characterize uncertainty. As discussed in Part I.C., multiple sources of uncertainty are embedded in the basic steps of model development. The diversity of models and of disciplines using models make the communication of these fundamental uncertainties challenging because of the lack of a generally accepted approach to characterizing uncertainty. Expectations that the model will provide a decisive answer compound these challenges substantially since the audience is not even receptive to such a discussion.

Again, by acceding to or failing to correct policymakers' unrealistic demands for answers there is a danger that some modelers will inadvertently reinforce core misunderstandings. Indeed, some modelers may conscientiously comply when asked by policymakers for a single answer or even a point estimate. These modelers may present their models as "answer machines" and model outputs as point estimate "truths" without violating scientific codes or any unwritten mutual understandings of good modeling science. As a result, policymakers may assume from these decisive-looking outputs that their understanding of models as answer-machines is correct while at the same time rewarding modelers who help satisfy their unrealistic expectations. Through this vicious cycle, the model misunderstandings can grow more and more entrenched.

Finally, with some exceptions modelers have not yet agreed on general principles for comparing models or separating out the good from the bad, again creating room for poor modeling practices. Some models will do better than others in representing the empirical world, but modelers lack a coherent framework for distinguishing between models with regard to the appropriateness of the analytical methods and assumptions in a given setting.[148]

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models have led to much more comprehensive forms of scientific oversight in areas of physical climate change modeling. Farber, *supra* note 104, at 1658 (describing how "[c]limate scientists have created a unique institutional system for assessing and improving models, going well beyond the usual system of peer review"). Vetting efforts involve standardized experiments carried out internationally by different modeling groups, model intercomparison projects, and an archive of models and outputs available for study by the working groups and independent researchers. *Id.* at 1677–78.

[148] *See* Swinehart, *supra* note 36, at 1290–91 (discussing how difficult it is for

For example, many models rely on the basic assumption that the relationships among the components of a model can be estimated using a latent structure of probabilities. It is extremely difficult to ascertain whether this assumption conforms to physical reality, however. As Box and Draper remind us: "[A]ll models are wrong; the practical question is how wrong do they have to be to not be useful."[149] Modelers do not yet have clear standards to explore and answer that question.

An industry challenge to EPA's regulations and a report from the National Research Council highlight why this current gap in modeling science is so important. When assessing the risk from chemical pollutants, EPA typically relies on so-called *default options* to facilitate inferences in the face of scientific uncertainty. For example, absent evidence to establish the biological mode of action for a tumor site, the relationship between the chemical dose and a carcinogenic response is assumed, by default, to be linear.[150] A linear model can be used to argue that there is a cancer risk associated with a chemical for any dose above zero. In 1998 EPA used such a linear model to promulgate a rule setting the standard for chloroform in drinking water at zero parts per million. The rule was overturned when the Chlorine Chemistry Council argued successfully that EPA disregarded evidence that chloroform is a threshold carcinogen requiring an alternative, non-linear model.[151] In a recent report, an NRC panel recommended that EPA replace a default assumption when the underlying evidence is "clearly superior" to that for the default.[152]

The panel equated the "clearly superior" evidential standard to a "beyond a reasonable doubt" legal standard and advised against interpreting this term quantitatively.[153] But because the rules used to evaluate model performance are incoherent, it is difficult to state why the "clearly superior" evidence embodied in a proposed model should trump the use of defaults. The need to

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the modeler "to determine which modeling methodology will most accurately portray the chosen modeling parameters in light of the collected empirical data").

[149] BOX & DRAPER, *supra* note 12, at 74.

[150] RISK ASSESSMENT FORUM, EPA, GUIDELINES FOR CARCINOGEN RISK ASSESSMENT § 1.3.2 (2005).

[151] Chlorine Chemistry Council v. EPA, 206 F.3d 1286, 1290–91 (D.C. Cir. 2000).

[152] NRC, SCIENCE AND DECISIONS, *supra* note 50, at 201.

[153] *Id.* at n.7.

develop coherent rules for evaluating evidence embodied in a model was in fact highlighted by a panel member, who observed that replacing default assumptions has less to do with actually gathering new data about risk, but instead about developing competing inferences from alternative models based on existing data.[154] The panel even hinted at the existence of some formal rules for model evaluation, pointing to the statistical P value as an analogy for how one might determine that evidence is "clearly superior."[155] Beyond this, however, the panel offered little guidance on how to determine how this "clearly superior" evidentiary standard might be met.[156] Instead, it turned to EPA to resolve this question. The question still remains unresolved: on what basis can it be said that one model provides stronger evidence of an environmental event, rather than another?

While general principles for model comparison cannot be hard and fast rules, the absence of guidelines makes for a soft scientific base in model evaluations and comparisons.

C. *Models and Strategic Game-Playing*

Fueled by gaps in modeling science, the ripple effects from a core misunderstanding of models by policymakers radiate out to an even more undesirable set of adverse consequences occurring within the regulatory state itself. Many rulemakings have significant economic implications for one or more affected industries, and strategic actors face incentives to exploit the misunderstanding of models as "answer machines" to advance their own narrow ends.

There are three intimately related but distinguishable strategies that a devious regulatory participant can deploy to reap

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[154] *Id.* at 190–91, 191 n.2.

[155] NRC, SCIENCE AND DECISIONS, *supra* note 50, at 201. The committee explained that "clearly superior" should be taken to mean that the "plausibility [of an alternative assumption] clearly exceeds the plausibility of the default," and equated "clearly superior" to a "beyond a reasonable doubt" legal standard. *Id.* at n.7.

[156] The NRC report addressed this issue and, in an interesting foot-noted discussion, one of the panel members observed that the choice to forgo a default model in favor of an ad hoc examination of the data and possible alternatives often has less to do with having access to better data, but rather with choosing "*among* models (inferences, assumptions), which are not themselves 'data' but which are ways of making sense of data." NRC, SCIENCE AND DECISIONS, *supra* note 50, at 190–91, 191 n.2 (2009) (emphasis in the original).

benefits from the prevailing misunderstanding of models. The first exploits the false expectation that models are fact generators. From the agency's perspective, portraying models as answer machines allows the agency to sidestep at least some unpleasant accountability and controversy by shrugging off criticism with the response that the "model made me do it." Agencies may thus choose to do this, even when they know better, because it protects them from scrutiny by institutional authorities like Congress and the courts.[157] Examples abound of agencies perpetuating the misunderstanding of models as answer machines, while at the same time secretly cramming contested, value-laden assumptions into their highly technical models behind the scenes. In the areas of risk assessment, public land management, and even economic modeling, the propensity of agencies to use models as facades for underlying value choices is well established.[158] As Glicksman

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[157] Wendy E. Wagner, *The Science Charade in Toxic Risk Regulation*, 95 COLUM. L. REV. 1613, 1654–69 (1995) (discussing incentives for agencies to exaggerate the scientific basis for regulation).

[158] *See* TED GREENWOOD, KNOWLEDGE AND DISCRETION IN GOVERNMENT REGULATION 18–19 (1984) (distinguishing *knowledge* (i.e., scientific expertise) from *discretion*, and warning that, although most regulatory decisions require agencies to exercise both, "advocates—both inside and outside agencies—can . . . readily disguise advocacy and discretion as knowledge"); *see also, e.g.*, Holly Doremus, *Using Science in a Political World: The Importance of Transparency in Natural Resource Regulation*, *in* RESCUING SCIENCE FROM POLITICS: REGULATION AND THE DISTORTION OF SCIENTIFIC RESEARCH 143, 147–59 (Wendy Wagner & Rena Steinzor eds., 2006) (describing how stakeholders in endangered species management prefer "couching their claims as scientific ones to openly arguing for their values," even though regulatory decisions "inevitably" require policy judgments); Winston Harrington et al., *What We Learned*, *in* RES. FOR THE FUTURE, REFORMING REGULATORY IMPACT ANALYSIS 215, 224 (Winston Harrington et al. eds., 2009) (discussing the false appearance of precision in complex and lengthy regulatory impact analyses); MARC K. LANDY ET AL., THE ENVIRONMENTAL PROTECTION AGENCY: ASKING THE WRONG QUESTIONS 279 (1990) (describing how EPA misled the public on issues of safety and regulatory costs through the use of scientific explanations that obscure underlying policy judgments and distort the relative significance of the problems); MARK E. RUSHEFSKY, MAKING CANCER POLICY 6, 13–17 (1986) (criticizing EPA's public distinction between risk assessment (supposedly objective, scientific) and risk management (subjective, value-laden, political) for carcinogens as unrealistic and misleading, and therefore subject to political abuse); Cary Coglianese & Gary E. Marchant, *Shifting Sands: The Limits of Science in Setting Risk Standards*, 152 U. PA. L. REV. 1255, 1290–91 (2004) (describing EPA's attempt to "cloak [its] policy decisions in science" as a "charade" to justify ambient air standards for ozone and fine particulate matter); Howard Latin, *Good Science, Bad Regulation, and Toxic Risk Assessment*, 5 YALE J. ON REG. 89, 93–95 (1988) (discussing how model-based risk assessment

notes, "[T]he use of modeling by [public land agencies] is susceptible to the criticism that the agencies, intentionally or not, have masked their value judgments in the language of technical determinations."[159]

In a related vein, the rational agency may not only find itself tacitly rewarded for misrepresenting its model as an "answer machine" but, quite independent from that, will find it beneficial to be opaque about assumptions and uncertainties incorporated into the model, even if it ultimately concedes the tentative nature of the modeling exercise. This opacity helps insulate the agency's many assumptions and modeling decisions from critical review, particularly by adversarial stakeholders. As Glicksman observed in this context, agencies "can isolate themselves [in part] by making their decisions in secret, without soliciting the views of knowledgeable experts and lay persons."[160] This type of strategic opacity helps conceal from participants "the subjective decisions and policy choices made by planners and modelers during the modeling process."[161]

As a result, the prospect of an open season on agency models by aggressive stakeholders, coupled with the threat of a lawsuit over technical disagreements, create incentives for rational agencies to make their models relatively indecipherable with regard to the underlying assumptions and uncertainties. Once a stakeholder engages with the agency's model and begins asking fundamental questions about the framing and assumptions, it is less clear that an agency is wise to stonewall. But, at least at the outset, developing an opaque model is a useful strategy to insulate the model and attendant policy decisions from critical review. In their examination of the use of air models to determine the reductions needed to meet the national ambient ozone standard in

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has become the primary justification for standards-setting policy judgments for toxic hazards); Oreskes et al., *supra* note 66, at 642–43 (observing that modelers too quickly capitulate by presenting their model as producing a positive result, and quoting scientists as misrepresenting their models on those terms).

[159] Glicksman, *supra* note 20, at 481–82; *see also* Holly Doremus, *Listing Decisions under the Endangered Species Act: Why Better Science Isn't Always Better Policy*, 75 WASH. U. L.Q. 1029, 1035 (1997) (criticizing the Endangered Species Act, which requires "science-only" listing decisions, for "forc[ing] listing agencies into a 'science charade,' in which they must pretend to make non-scientific decisions entirely on the basis of science").

[160] Glicksman, *supra* note 20, at 520.

[161] Fine & Owen, *supra* note 24, at 932.

the San Joaquin Valley, Fine and Owen identify this pattern of agency behavior:

> [The agency's] uncertainty discussions were far from comprehensive. The [air quality] plan includes some blanket generalizations about the pervasiveness of uncertainty in modeling, but its discussion of particular sources of uncertainty was too general to allow a reader to discern how those uncertainties were managed or what economic and public health risks they might pose.[162]

Indeed, opacity may be a safer legal strategy than conceding the stark limitations in models that undergird a regulatory decision.[163] "Highlighting uncertainties associated with the technical basis for decisions can make the job of defending decisions more difficult, and decision-makers—and the attorneys who will ultimately represent them—may be reluctant to hear information that might undermine the certainty of their decisions."[164] Even more perversely, this opacity in models may be accepted as appropriate by policymakers and courts in light of their misunderstanding of models and the modelers' own silence or failure to correct these misimpressions.[165]

A different strategy that exploits this same erroneous portrayal of models as decisive demands an unobtainable level of empirical certainty,[166] a demand that may succeed not only in blocking the use of the model, but in blocking the policy as well.[167] Given that uncertainty permeates the entire modeling process,[168] a

[162] *Id.* at 960; *see also id.* at 960–62 (describing the lack of discussion in detail).

[163] *See supra* Part II.A.1.

[164] Fine & Owen, *supra* note 24, at 929.

[165] *See supra* Part II.B.

[166] *See* Mooney, *supra* note 140 (arguing that political rallying cries for "sound science" and "peer review" are often used "to put a pro-science veneer" on "industry-friendly" policies that, in effect, would require "such exhaustive analysis that federal agencies could have a hard time taking prompt action to protect public health and the environment").

[167] *See, e.g.*, Ellen Paul, *Science: The Newest Political Football in the Endangered Species Game*, 52 BIOSCIENCE 792 (2002) (describing how property rights advocates and land developers have vigorously argued that the incomplete status of the scientific research on the severity of most species' decline were intended to deprive the Fish and Wildlife Service of authority to regulate private property under Endangered Species Act's Habitat Preservation Program); Sasha Gennet, *New ESA Amendments: Sound Science or Political Shell Game?*, 54 BIOSCIENCE 1070 (2004) (same).

[168] *See supra* Part I.C.

resourceful stakeholder can demand perfection while running the agency's preferred model so full of holes that it sets the regulatory effort adrift with scientific demands that can never be satisfied.[169] As Professor Farber observes, "[w]ords like uncertainty, systematic biases, and important deficiencies [used by modelers in describing their climate change models] are music to the ears of cross-examiners."[170]

These attacks on models, usually accompanied by clarion calls for "sound science," occur even when Congress has demanded that an agency err on the side of protecting public health. Under the George W. Bush administration, for example, despite being confronted with evidence from the Intergovernmental Panel on Climate Change (IPCC) and from EPA's own independent science panel regarding health and environmental threats from both CO_2 and from particulate matter at levels lower than existing standards, EPA Administrator Steve Johnson declared that uncertainty precluded regulatory action on either front.[171] (Ironically, it appears that robust characterizations of uncertainty were in part the basis for this rejection of the models.) After judicial review, EPA's decisions not to regulate in both cases were eventually overturned, in part because they lacked a rational basis in light of the available scientific evidence.[172]

Interested parties have also pointed to specifically contestable coefficients in a model as failing to meet the demand for "sound science," a deficiency that they argue necessitates the wholesale rejection of the model.[173] Their objective is to destroy the

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[169] *See generally* MCGARITY & WAGNER, *supra* note 45, 128–56 (describing tactics used to discredit research and researchers).

[170] Farber, *supra* note 104, at 1675.

[171] Massachusetts v. EPA, 549 U.S. 497, 513 (2007) (describing EPA uncertainties about the connection between greenhouse gas emissions and global temperatures); Janet Wilson, *New EPA Rules on Soot and Dust Set*, L.A. TIMES, Sept. 22, 2006, at B1 (EPA Administrator attributing his rejection of recommended annual limits on coarse particulate pollution on scientific uncertainty).

[172] *See* Massachusetts v. EPA, 549 U.S. at 532–35 ("Nor can EPA avoid its statutory obligation by noting the uncertainty surrounding various features of climate change . . . . That EPA would prefer not to regulate greenhouse gases because of some residual uncertainty . . . is irrelevant. The statutory question is whether sufficient information exists to make an endangerment finding."); Am. Farm Bureau Fed'n v. EPA, 559 F.3d 512, 523–24 (D.C. Cir. 2009) (striking down parts of EPA's particulate regulations as insufficiently supported).

[173] *See, e.g.*, David Michaels & Celeste Monforton, *Manufacturing*

credibility of "good" or "plausible" models by criticizing the model on every picky and generally insignificant detail.[174] This was in fact an explicit strategy of the tobacco industry.[175] Climate change models also appear to have been subject to this type of ends-oriented type of attack. In a challenge mounted against several federal agencies under the Data Quality Act,[176] for example, the petitioner, the Competitive Enterprise Institute (CEI) (an organization funded in part by industries adversely affected by carbon reduction policies) argued that the National Assessment on Climate Change (NACC) models should be stricken from public databases because the models could not be "verified by observed data" and were therefore "junk science."[177] Specifically, CEI argued that:

Uncertainty: Contested Science and the Protection of the Public's Health and Environment, 95 AM. J. OF PUB. HEALTH (SUPPLEMENT ISSUE) S39, S41 (2005) (relating how the lead, asbestos, chemical, and tobacco industries have exploited scientific uncertainty to delay adoption of new regulations, and to challenge evidence of causation in toxic tort cases).

[174] Thomas O. McGarity, *Defending Clean Science from Dirty Attacks by Special Interests*, *in* RESCUING SCIENCE FROM POLITICS: REGULATION AND THE DISTORTION OF SCIENTIFIC RESEARCH 24 (Wendy Wagner & Rena Steinzor eds., 2006) (describing the "attack science" strategy of risk-producing industries bent on discrediting studies documenting the hazards of their trade and the scientists who engage in this research); *see, e.g.*, Michaels & Monforton, *supra* note 173 (reviewing several such "attack science" campaigns).

[175] MCGARITY & WAGNER, *supra* note 45, at 138–139 (documenting Philip Morris' public relations campaign to "discredit EPA's report on ETS"); Michaels & Monforton, *supra* note 173, at S40, S43.

[176] The Data Quality Act originated as a two-paragraph rider in a 2001 appropriations bill. Treasury and General Government Appropriations Act for Fiscal Year 2001, Pub. L. No. 106–554, § 515, 114 Stat. 2763, 2763A-153 to -154. It directs the Office of Management and Budget (OMB) to issue government-wide guidelines to "ensure and maximize data quality," and to establish procedures allowing formal challenges to information disseminated by federal agencies. Michaels & Monforton, *supra* note 173, at S44. OMB's guidelines allow parties to seek correction or retraction of data that doesn't meet its standards. Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies, 67 Fed. Reg. 8452, 8459 (Feb. 22, 2002) ("[A]gencies shall establish administrative mechanisms allowing affected persons to seek and obtain . . . timely correction of information maintained and disseminated by the agency that does not comply with OMB or agency guidelines.").

[177] Letter from Christopher C. Horner, Senior Fellow, Competitive Enterprise Institute, to Director, Office of Science and Technology Policy, Executive Office of the President (Feb. 20, 2003), *available at* http://cei.org/pdf/3360.pdf (petition to cease dissemination of the National Assessment on Climate Change pursuant to the Data Quality Act).

> [T]he climate models upon which NACC relies struck out. Strike one: they can't simulate the current climate. Strike two: they falsely predict greater and more rapid warming in the atmosphere than at the surface—the opposite is happening. Strike three: they predict amplified warming at the poles, which are cooling instead.[178]

Even the columnist George Will has demonstrated this type of "sound science" attack, whether consciously or not, by arguing that any contestable assumptions in models make the models useless for policy. In one column Will noted how models developed by some scientists in the 1970s predicted a "major cooling of the planet" and implied that if these models were wrong in the past, current models predicting global warming must also be wrong today.[179] Will also suggested that if models *cannot* provide definitive, fool-proof answers, they should not be used to help formulate policy.[180]

In sum, discrediting a model by picking at every instance of error or uncertainty offers critics of regulation the easiest path to attack policies based on model results when models are misunderstood as answer machines.[181] It puts upon proponents of regulatory intervention the entire burden of persuasion, the entire burden of accumulating the available evidence, and the burden of drawing credible, defensible inferences from the evidence. It simultaneously relieves critics of the burden to develop alternative explanations of environmental risk.

Strategic game playing can also involve technical trickery: working backwards from a desired regulatory result, a stakeholder can tweak model assumptions and even data sets until they develop a favorable model to support their position.[182] Stakeholders can also cherry-pick models (and modelers) based on the results of the model rather than on its reliability for the use in question.[183] Using rigged models to support value-based positions lends the patina of

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[178] *Id.* (internal citations omitted).

[179] George Will, Op-Ed., *Dark Green Doomsayers*, WASH. POST, Feb. 15, 2009, at B7.

[180] *See id.*

[181] *See supra* notes 173–180 and accompanying text.

[182] MCGARITY & WAGNER, *supra* note 45, 60–96 (describing technique in broader context of scientific information used for regulation).

[183] *See, e.g.*, Swinehart, *supra* note 36, at 1297–98 (describing this phenomenon in litigation).

scientific credibility to a legal or political argument.[184] Moreover, when policymakers and legal analysts view models in a deterministic way, they are unlikely to be aware of the extent to which models can be misused in this way and generally would not have the capability to look inside a model to better understand the assumptions and related choices that have been made in an effort to sort the honest from the dishonest models.

Another related strategy attempts to influence the development of basic modeling practices themselves. For example, challenges have been waged against government risk assessments that rely primarily on mechanistic animal studies to classify substances as known carcinogens. Challengers insist that in these cases epidemiological evidence is essential.[185] Such positions obviously ignore the statistical challenges of isolating effects in human populations and the fact that for many chemicals, there are few or no human studies available.[186]

In an ideal world, strategic efforts by stakeholders to hijack models to suit their interests would be fended off by stakeholders of the opposing stripe. Through adversarial contests at least some of the intentional misuse of models by interest groups would cancel each other out. In fact, one study of models suggests that this type of balanced participation is actually a prerequisite to the effective use of models in policymaking spheres.[187]

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[184] Robert Evans argues that "economic theory and models function as legitimizations (and quantifications) of particular political and moral theories about the world which can be selectively invoked by policy makers and this flexibility, as much as their econometric properties, accounts for the appeal of economic models." Evans, *supra* note 124, at 223; *see* Swinehart, *supra* note 36, at 1298 (observing that "litigation creates incentives for parties to present their model as the definitive answer").

[185] *See, e.g.*, Tozzi v. Dep't of Health and Human Services, 271 F.3d 301, 311–12 (D.C. Cir. 2001) (arguing that HHS's risk assessments should be based primarily on epidemiological studies); *see also* Siharath v. Sandoz Pharm. Corp., 131 F. Supp. 2d 1347, 1370 (N.D. Ga. 2001), *aff'd sub nom.* Rider v. Sandoz Pharm. Corp., 295 F.3d 1194 (11th Cir. 2002) (holding that to prevail after *Daubert*, plaintiff must provide "at least some support for the causal hypothesis in . . . epidemiological literature, a predictable chemical mechanism, general acceptance in learned treatises . . . a plausible animal model, and dozens of well-documented case reports"); *see also* Cranor, *supra* note 120, at 137–38 (discussing similar case law).

[186] *See* NRC, RISK ASSESSMENT IN THE FEDERAL GOVERNMENT, *supra* note 46, at 11 ("Because our [scientific] knowledge is limited, conclusive direct evidence of a threat to human health is rare.").

[187] *See generally* King & Kraemer, *supra* note 7 (describing how models are used extensively "as weapons in political and policy warfare," in which role they

Unfortunately, the real world also departs from the idealized realm of balanced and diverse participation and is often afflicted with very lopsided participation by only one set of interested parties.[188] Imbalance in participation is one of the primary problems the authors identified in the San Joaquin Valley air model for example: the authors hypothesize that a more robust and expert group of diverse stakeholders would have caught errors in the models and held the agency accountable.[189] To the extent that only one party or stakeholder is on hand, then, the model faces a higher likelihood of being hijacked or at least biased heavily towards one set of interests.

In sum, because they are contingent and technically complex, and yet at the same time enter a policymaking world that is not well prepared to use them wisely, models are fodder for abuse and manipulation. Agencies themselves may misrepresent the certainty of a model or obscure controversial assumptions in order to ensure that the model survives hostile review from sister branches of government or stakeholders. However, the worst abuses in modeling likely arise from private interests that have developed sophisticated strategies for undermining the credibility of good models and encouraging policymaker reliance on models that may be quite biased.[190] As long as the policymakers' misunderstanding remains and the modelers fail to correct it,

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can play a more constructive part than as neutral "arbiters of truth").

[188] *See, e.g.*, Jason Webb Yackee & Susan Webb Yackee, *A Bias Towards Business? Assessing Interest Group Influence on the U.S. Bureaucracy*, 68 J. POL. 128, 133–38 (2006) (finding that businesses are the principal non-agency participants in notice and comment rulemaking, and that agencies alter their final rules to suit the expressed desires of businesses, but not for those of other kinds of interests); Wendy E. Wagner, *Administrative Law, Filter Failure, and Information Capture*, 59 DUKE L.J. (forthcoming 2010) (describing how private interests benefit by undermining agency accountability and raising participation costs for the public when they flood the decision making process with complex information). Moreover, in many environmental and public health settings, there are different endowments in expertise and information relevant to participation. So, for example, in models of the effects of a substance on health, often the manufacturer has far more information than other stakeholders and even the agency itself. In some cases, stakeholders not only benefit in an adversarial way from these information advantages, but even conceal the information so that others are operating with less complete information. Asymmetries in the relevant information only serve to further tilt the playing field towards some participants and away from others. *Id.*

[189] *See, e.g.*, Fine & Owen, *supra* note 24, at 967–69.

[190] *See* MCGARITY & WAGNER, *supra* note 45, 128–56 (describing tactics used to attack research results and discredit and intimidate researchers).

models are quite vulnerable to these forms of manipulation.

III. WHAT TO DO?

There is an inescapable irony in the state of affairs described above: the image of models as "fact generators" has been driven by a desire to ensure accountable and rigorous administrative governance, yet in the end, the process produces exactly the opposite effect. In this final section we offer suggestions for correcting the core misunderstanding as well as redressing the subsequent ripple effects that lead to adverse consequences in modeling science and regulatory deliberations.

A. *Highlighting the Importance of Models in Environmental Regulation*

Before turning to ways that the core misunderstanding and resulting adverse consequences might be corrected or at least minimized, it is useful to reconsider the benefits of models lest some readers be tempted to throw the baby out with the bathwater. "If models create this much confusion for policy," some might reason, "perhaps we are better off without them."

Models provide several irreplaceable contributions to policy that must be retained and reintroduced into environmental regulation. First, models provide a much more rigorous and explicit conceptual map about the real world than intuition and hunches, which are the next best alternative. Anchoring the dialog in explicit assumptions and model algorithms or other types of consistent measurements introduces analytical rigor to decision-making deliberations that otherwise would be too unwieldy to think through, much less debate.[191] Models thus play a vital role as "a clarifier of issues in debate. . . . The critics can then question why certain variables are included vs. excluded, or why this variable is treated exogenously vs. endogenously, or why variables are weighted as they are."[192] Models also help track in a rigorous way how various policy alternatives might play out in the natural

[191] *See* Frank A.G. den Butter & Mary S. Morgan, *What Makes the Models-Policy Interaction Successful?*, *in* EMPIRICAL MODELS AND POLICY-MAKING, *supra* note 124, at 279, 295 ("Without the model there is . . . no way that the large amount of information on economic developments could be generated, and updated, and put together rapidly enough to be used in policy-making.").

[192] King & Kraemer, *supra* note 7, at 7.

world.[193]

Environmental models can also be integrated across disciplines in ways that capitalize on their separate strengths. By synthesizing a wide array of information into a single analytical tool, models also limit the opportunities for miscommunication between specializations.[194] In this way, models enforce "a discipline of analysis and discourse"[195] and of "shared understandings" among a wide range of actors.[196]

Finally, models help decision-makers evaluate sources of uncertainties in the modeling process; sort out the more significant causes, contributions, or reforms from the less significant;[197] and determine the degree to which model results conform to empirical data. They provide a useful and effective (but not fool-proof) antidote to the dangers of over-determinism and empirical relativism. With regard to the former danger, model evaluation reminds a policymaker: "No model is completely right." And regarding the latter, it assures the policymaker, when faced with having to choose among (or to synthesize results from) multiple models: "Some models are completely wrong."

All of these virtues highlight the need to clearly explain the limits of models when employing them in policymaking. Without robust descriptions of key assumptions, uncertainties, and even the framing of a model, policymakers will not be able to rise above the core misunderstandings and make the best use of these important regulatory tools.

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[193] *Cf.* Bradley, *supra* note 134, at 143 (noticing similar benefits of models used in economics).

[194] *See* Bryan G. Norton, *Building Demand Models to Improve Environmental Policy Process*, *in* MODEL-BASED REASONING 198, 198 (Lorenzo Magnani & Nancy J. Neressian eds., 2002) (describing how creating a shared model to answer a social problem or issue can clarify differences among competing interests and improve communication and cooperation).

[195] King & Kraemer, *supra* note 7, at 8.

[196] Evans, *supra* note 124, at 223; *see also* den Butter & Morgan, *supra* note 191, at 307 (noting the "specific kind of interaction" enabled by quantitative models "which involves making explicit and integrating the tacit knowledge of both groups of participants: modellers and policy makers").

[197] *See* Oreskes et al., *supra* note 66, at 644 (explaining that models are helpful as heuristic tools, representations "useful for guiding further study but not susceptible to proof"); Edison & Marquez, *supra* note 131, at 203 (reporting this same virtue in some economic models).

B. *Correcting the Core Misunderstanding*

Much of the U.S. approach to administrative governance appears to rest on the tenuous assumption that rational, technocratic analysis, including the false precision in models, can guide policy.[198] A number of institutional mechanisms, including rules for judicial review, have sprouted around this central misperception. Yet to the extent that an "answer machine" perspective does capture the prevailing view of policymakers and analysts, it is not an easy one to redress.

Indeed, it seems unlikely that at least in the short-term the U.S. will abandon its technocratic approach to rulemaking in favor of a more deliberative, flexible decision-making approach. Solutions, then, may need to be introduced piecemeal in the hope of leveraging them to gradually effectuate a larger shift the overarching understanding of models. For example, if the courts alter their rules for judicial review to provide better oversight of models, while at the same time appreciating that models cannot provide definitive answers, then this can change the agency's incentives as well as the broader legislative and public understanding of models. In addition, it needs to be remembered that the relationship between models and policy is not a one-way street. Changes to how modelers explain what they do *can* result in changes in what policy-makers and lawyers expect of models. In this section, we propose a series of smaller changes to current administrative processes that should correct some of the worst problems while also gradually shifting the larger, meta-characterization of models towards a more realistic and accurate understanding of models.

The first and most important recommendation is to alter judicial review rules to reflect a more realistic approach to the courts' oversight of models. Rather than providing courts with judicial discretion to micro-manage agency technical decisions, the approach to judicial review we advocate retains the courts as enforcers of good modeling *processes* rather than policing model

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[198] *See*, FISHER, *supra* note 122, at 28–30; *see also, e.g.*, STEPHEN BREYER, BREAKING THE VICIOUS CIRCLE: TOWARD EFFECTIVE RISK REGULATION 59–68 (1993) (recommending that an elite group of "super regulators" make regulatory decisions rather than basing regulations on public preferences, as is currently the case); Cass R. Sunstein, *Cognition and Cost-Benefit Analysis*, 29 J. LEGAL STUD. 1059 (2000) (recommending the use of cost-benefit analysis to correct for numerous cognitive deficits in public assessment of risk).

outputs. Under our recommended approach, the courts' primary job is to ensure that the models used by regulators comply with guidelines for ensuring transparency of the methods and assumptions and follow best practices with regard to employing multiple models and multiple scenarios. The courts should also oversee the success of the agencies in inviting diverse oversight by regulatory participants of the model's creation and use.[199] While some of these issues will be technical and contestable, courts in general will be resolving disputes about whether a model complied with guidelines, rather than deciding whether a model is "good science" or "arbitrary" compared to an alternate model propounded by a litigant.[200]

Our proposed approach resonates with judicial review under the National Environmental Policy Act (NEPA), but it is considerably stronger in large part because the court under our proposal must ensure that the model meets relatively specific, rigorous requirements identified by modeling scientists.[201] Rather than a checklist of general features that must be contained in a prolix report (as under NEPA), the principles for modeling that we envision would include requirements that the model be subjected to diverse and rigorous peer review and oversight, evaluation mechanisms, explication of uncertainties and policy-relevant

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[199] *See infra* Part III.D.

[200] For example, Professor Glicksman suggests that courts could play a more useful function in judicial review by, for example, insisting that agency's modeling exercises "abide by whatever procedural devices Congress has chosen to impose upon them to facilitate transparent decision making," and that agencies:

> reveal the assumptions upon which their models proceeded, as well as descriptions of the remaining scientific uncertainties and how they affected the agency's choices. Finally, the courts should vacate or remand agency decisions in which the agency's explanation fails to demonstrate either that the model used is an appropriate one for dealing with the particular data gaps the agency is trying to fill, or that a relevant model has been misapplied.

Glicksman, *supra* note 20, at 526.

[201] Almost forty years of experience with NEPA reveals that, although its analytical requirements may help eliminate some of the very worst projects, much of NEPA's promise of probing policy analysis and agency transparency has given way to agencies that now "act as if the detailed statement called for in the statute is an end in itself, rather than a tool to enhance and improve decision-making," and turn the environmental impact statement into a "litigation-proof" document that does not adequately raise or consider alternatives. COUNCIL ON ENVTL. QUALITY, THE NATIONAL ENVIRONMENTAL POLICY ACT: A STUDY OF ITS EFFECTIVENESS AFTER TWENTY-FIVE YEARS at iii (1997).

assumptions, and a discussion about how the model was extrapolated from its setting to address a larger issue or question. This type of specificity is more difficult to establish for the extraordinarily diverse range of projects and actions covered under NEPA. Moreover, the added disclosures and assurances of diverse oversight of regulatory models will serve to increase the opportunity for interested parties to review and challenge the model, thus mitigating the need for a high level of judicial scrutiny when the model principles are satisfied. Conversely, when the guidelines have not been followed (i.e., a diverse group has not been engaged in reviewing the model), then the courts' role becomes more focused.

Shifting the courts' focus to best practice guidelines and away from the substance of models reflects the suggestions other authors have made in the context of the judicial review of models.[202] The judge would view models with an eye to ensuring that the best analytic-deliberative modeling practices have been followed. If one or more best practices have been ignored, the judge would expect a reasonable explanation from the agency for the divergence.[203]

Second, agencies need to develop the capacity to revise and evaluate models in a continuous process, rather than incorporating models into their decision-making processes in a way that is static and cannot be changed.[204] This is a more difficult problem to fix in administrative law since the current rewards to reviving decided policies are low, particularly when regulated parties (typically the most powerful stakeholders) will be economically disadvantaged by the changes.[205] Under the conventional approach to rule promulgation, any change in the model—even minor adjustments—legally requires the agency to revise the rule, to re-open notice-and-comment, and ultimately to endure the risk of being sued. The Administrative Procedure Act (APA) thus

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[202] *See, e.g.*, Fine & Owen, *supra* note 24, at 977–79 (citing *Sierra Club v. Costle*, 657 F.2d 298 (D.C. Cir. 1981) for the proposition that courts consider public disclosure of assumptions and data in the model; agency acceptance and consideration of public comments; and admission of model uncertainties); Glicksman, *supra* note 20, at 526.

[203] *See* Doremus & Wagner, *supra* note 88 (developing this reformed approach to judicial review in greater detail).

[204] NRC, *supra* note 13, at 161–62.

[205] Blais & Wagner, *supra* note 132, at 1712–15 (discussing this problem and calling it a "regulatory rut").

discourages model revisions and leads to a very static approach to regulatory models.[206]

There are several ways that the rulemaking process could accommodate the need for model revisions. The first, suggested by the National Research Council, is to build room into the final rule promulgation—for example, through a programmatic rule allowing for model revisions—so as to leave flexibility for later model adjustments, provided they are not significant changes, and provided that interested parties have an opportunity to comment on them.[207] For more significant model adjustments, the agency could be statutorily required to review its model periodically (much like the Clean Air Act's National Ambient Air Quality Standards) to incorporate changes in information and modeling methods.[208] Since this approach is both costly and time-consuming, it would be reserved for only the most significant regulatory models. Alternatively, a petition process could be added by Congress that allows stakeholders to petition the agency to revise its model when significant developments have occurred that lead to material differences in how the model works.[209] In the end, the best approach will likely depend on what model revisions are expected in the foreseeable future. Inevitably, too, there are other ways to adjust current, inflexible rulemaking processes to accommodate revisions to models as knowledge develops.

Third, we recommend that agencies and legislatures, where possible, be part of the modeling process, and that they ensure that the modelers understand the vital interaction required between

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[206] *Id.* at 1705–06.

[207] NRC, *supra* note 13, at 167–68.

[208] *See* Clean Air Act § 109, 42 U.S.C. § 7409(d)(2)(A)–(C) (2006) (creating an independent scientific review committee, the Clean Air Scientific Advisory Committee, charged with reviewing EPA's ambient air quality standards at five-year intervals). A similar form of scientific review is required for EPA's registration of pesticides. Federal Insecticide, Fungicide, and Rodenticide Act § 25, 7 U.S.C. § 136w(d)–(e) (2006) (creating the Scientific Advisory Panel to review the scientific basis for major regulatory proposals concerning pesticides, and to adopt peer-review procedures for scientific studies carried out pursuant to the Act).

[209] *See* Thomas O. McGarity, *Some Thoughts on "Deossifying" the Rulemaking Process*, 41 DUKE L.J. 1385, 1454–55 (1992) (proposing an amendment to the APA that would "lower the threshold for initiating rulemaking [by the public] and . . . signal [Congress's] intent that judicial review of agency refusals to initiate or to complete existing rulemakings be more stringent in some or all circumstances").

science and policy.[210] A continuous two-way dialog helps ensure that information and assumptions are shared between the two groups. Not only will the policymakers' intelligent use of models improve through this discursive interaction, but there is reason to expect that the modelers also will become more attentive to the role that values and policy play in their models. For example, in a book examining the use of empirical models for economic forecasting and related policies, the editors note that:

> [I]t also seems to be the case that modelers take policy problems and questions more seriously when they themselves form part of the policy-analysis process and may even have some responsibility for explaining policy . . . rather than being kept in the back-room, at arm's length from policy makers and those affected by the policy.[211]

Maintaining this type of dialogue is perhaps one of our most challenging proposals. As a practical matter, legislatures and regulators tend to position themselves as recipients of "facts" rather than as co-creators of technical knowledge. Consequently, fact-finding processes may need to be completely revamped to create room for two-way discussion between scientists and policymakers. Moreover (and perhaps partly explaining the current arrangement), there are risks that too much policymaking intervention could lead—either intentionally or unintentionally—to the manipulation of models to produce desired outcomes.[212] Because of this risk, it is also essential that the next two sets of reforms be in place at the same time lest modeling be held captive to the whims of government itself.

C. *Reforms in the Science of Modeling*

The scientific community must ultimately achieve some level of consensus around a coherent approach to how models should be used to draw inferences from uncertain evidence. Such principles

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[210] *See* den Butter & Morgan, *supra* note 191, at 307 (emphasizing the extremely important nature of this two-way interaction to the intelligent use of models for policy).

[211] *Id.* at 304–05.

[212] *Cf.* Edison & Marquez, *supra* note 131, at 190–91 (describing three ways in which policy makers influence model development through requests for model respecification: (1) *direct requests* for the model to incorporate a certain feature; (2) *persuasive requests*, as when their concerns involve modifying the model; and (3) *idiosyncratic requests*, which are best answered with tailor-made models).

need to be grounded in an understanding of modeling as an analytic-deliberative process, rather than as a predetermined "truth machine." Specifically, a coherent treatment of evidence in models would: (1) describe the assumptions underlying an inference, (2) justify why the assumptions apply to the circumstances on hand, and (3) explain how the inferences derive from the interplay between the assumptions and the evidence.[213]

By this definition of coherence, models and their results are not innately objective scientific constructs that yield a single, verifiable depiction of reality. Rather, even when developed according to the best principles of science, models may yield multiple versions of reality, each of which may be coherent within its own framework of assumptions and each of which may result in an alternative set of legal responsibilities. Moreover, each may lay claim to advocates who use administrative and legal procedures to contest or support competing viewpoints.

In light of this, modeling principles should provide, at the very least, guidelines on how to expose value-laden choices in model framing, in assumptions, and in choices made necessary by data uncertainties.[214] Additionally, and particularly for assumptions and related choices falling in the "values" portion of the range, models should be created with a variety of assumptions and scenarios that illustrate the differences these assumptions and choices make for policymakers.[215] The alternate scenarios also help educate policymakers to features of the model that prove most significant in affecting final outcomes. In most situations, the deployment of multiple models will also help modelers identify biases within models and distinguish important areas of convergence between different models.[216] Simply putting error bars around the final result is inadequate in capturing the full uncertainties and complexities of models.

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[213] To point to one common example of incoherence, it is *not* coherent when assumptions for controlled experiments are used to draw inferences about non-experimental data drawn from uncontrolled natural phenomena.

[214] *See, e.g.,* Fine & Owen, *supra* note 24, at 971–74 (discussing the importance of robust "sources of error" discussions in model development documentation as a means of holding modelers accountable).

[215] *See generally* ROGER A. PIELKE, JR., THE HONEST BROKER: MAKING SENSE OF SCIENCE IN POLICY AND POLITICS (2007) (advocating throughout the use of scenarios to educate policymakers about scientific insights).

[216] Farber, *supra* note 96, at 1691–92 (describing how this technique has been deployed to control for uncertainty among climate change models).

Ideally, a comprehensive explication of uncertainties, assumptions, and model framing would be based on best model practices that apply across scientific fields. Since this seems unlikely to occur spontaneously, however, we recommend that EPA continue to take the laboring oar—working with scientists—to develop principles for qualifying and explaining the assumptions in models; for exposing alternate scenarios and model approaches; and for clarifying whether the inferences made were consistent with the assumptions. Disclosing the provenance of a model would also be central to ensuring transparency: if the modeler has a conflict of interest, such as creating the model for an interested party under contract, then this feature should be disclosed along with basic features of the model.[217] These best practice guidelines need not be "mandates" or requirements for models used for policy, but instead best practice codes against which modeling exercises are to be evaluated. EPA has already taken a step in the right direction by providing a general set of practices for modeling.[218] This work should be expanded to provide even more detailed guidance.

When models are developed or used for binding regulation, it might be appropriate to go even further than voluntary guidelines and actually require accessible descriptions of all significant assumptions, sources of uncertainty, and basic model framing. An agency's failure to provide this type of explication would be considered arbitrary and subject the accompanying rule to judicial reversal. Other authors also recommend legal reversal when an agency fails to explain the basic uncertainties inherent in a model.[219]

A number of commentators have suggested that simpler models are more amenable to policy-making because they are easier to explain. A presumption might also run in favor of simple over complex models for regulation, where possible.[220] The NRC

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[217] David Michaels & Wendy Wagner, *Disclosure in Regulatory Science*, 302 SCI. 2073, 2073 (2003).

[218] COUNCIL FOR REGULATORY ENVTL. MODELING, EPA, GUIDANCE ON THE DEVELOPMENT, EVALUATION, AND APPLICATION OF ENVIRONMENTAL MODELS (2009).

[219] Fine & Owen, *supra* note 24, at 972; Glicksman, *supra* note 20, at 526.

[220] *See* den Butter & Morgan, *supra* note 191, at 294 (noting that if models are to play a coordinating and communicative role between different parties, they cannot be so complex as to create difficulty in explaining and sharing information).

report on regulatory models touts the use of simple models for this same reason.[221]

D. *Balanced Participation to Provide a Check on Strategic Game Playing*

A final set of challenges arising from the fact-generator vision of models occurs when regulatory participants exploit this misunderstanding to advance their own ends. Our main focus here is on finding ways to infuse more balance in stakeholder participation and engagement with agency models, thus precluding some of the worst types of one-sided games. Without diverse stakeholder oversight, the potential for agencies to be hijacked by a dominant party or political insider is high.

If the other reforms are implemented, the opportunities for this strategic exploitation should begin to subside, perhaps significantly. For example, greater scientific forthrightness about the contingencies of models should make it easier for a broad range of stakeholders to participate in overseeing models used for policy. This scientific forthrightness will also enable stakeholders to more readily judge whether they have a stake in the issue (for example, critical assumptions run against their core value choices or, conversely, critical assumptions are all congenial to their interests and thus enhance their support for the model). Accessible and transparent explications of uncertainties, inferences, and assumptions help lower at least some costs of public participation and engagement which, in turn, enables a greater number of those interested and attentive to a model and its attendant policy to engage in the regulatory process.

Still, greater forthrightness about model qualities is unlikely to be sufficient, and in some settings could even backfire to the extent these qualifications add to the complexity of the models. To better balance the groups overseeing models, there are several preliminary steps that could be taken. First, and perhaps particularly when stakeholder participation is noticeably skewed, agencies should be encouraged or even required to use science advisory groups to scrutinize their models.[222] These science

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[221] NRC, *supra* note 13, at 10–11 (recommending parsimony in model selection, development, and use).

[222] *See* Glicksman, *supra* note 20, at 522–23 (arguing that, because solicitation of input from all interested members of the public "is essential to the

advisory groups would not only assess the agency's use of models and alternate scenarios, including the analytical frameworks for the models as well as the assumptions, but would also consider how well the agency used a model for a particular application.[223] We hasten to add that the use of advisory groups is much more helpful than simply ensuring that a model has been "peer reviewed" or published in the peer reviewed literature. As Swinehart notes, simpler forms of peer review are likely to miss most of the important facets and contributions that models make (or don't make, as the case may be) to policymaking.[224]

Second, unrepresented sets of stakeholders might be subsidized to better enable them to participate in the oversight of regulatory models. This could be accomplished in part by ensuring that the agency's discussions of model assumptions and uncertainties are readily accessible to less expert participants.[225] For instance, the software package Analytica provides an effective way to represent nearly all facets of a complex model, starting with the framing of the problem.[226] One adjustment, then, would be to add to the best practices devised by scientists or EPA supplemental best practices that make model choices accessible to stakeholders with limited technical knowledge.

Finally, agencies could be encouraged to ensure this balanced participation indirectly through revised judicial review rules. For example, courts could provide "super" deference when the record reveals a diverse group of vigorous stakeholders engaged in oversight of a model used to support a rule.[227] Conversely, if only

making of informed judgments on . . . extra-scientific questions," agencies must explain its use of models in terms accessible to non-experts).

[223] Swinehart also suggests this type of focus for evaluating models, although his recommendation is targeted to the courts' oversight of models in judging the reliability of scientific testimony in private tort litigation. Swinehart, *supra* note 36, at 1319 (arguing that judges should always consider whether "the model [was] applied correctly within its practical boundaries and theoretical limits").

[224] *Id.* at 1306–07 (describing at least three ways peer review can be a misleading criterion for determining model reliability in policy settings).

[225] Fine & Owen, *supra* note 24, at 975–76.

[226] Analytica is a software package for creating, analyzing, and communicating decision models designed around user-friendly interfaces and marketed to consumers with a range of computer proficiencies. What is Analytica?, http://www.lumina.com/ana/whatisanalytica.htm (last visited Mar. 10, 2010).

[227] *See generally* Wagner, *supra* note 188 (describing this proposal in greater detail).

one set of stakeholders is present through much of the rulemaking and the agency makes no effort to ensure balanced participation from a mix of stakeholders in its modeling effort, the agency's rule would receive a hard look if challenged by an underrepresented party.[228] Although there are some reasons why this might not work as planned, such a review standard might help create a responsibility by the agency to ensure their models are vetted by the full range of interested parties.

CONCLUSION

By isolating the core misunderstanding of models used for policy and tracing the ripples out from this misunderstanding in the development and use of models for regulation, we have isolated some regulatory problems that deserve attention. Because models provide rich sources of valuable information, it is in policymakers' interest to take a leadership role to correct their common misunderstanding. We hope that very soon agencies, policymakers, and legal analysts will take the lead and use models more productively in the future.

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[228] *Id.*