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# FOREWORD

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The contributors to this Symposium grapple with a persistent, multi-faceted topic: the role that science—specifically, information created by scientists—does and should play in decisions by federal regulatory agencies. My role as Special Editor of the issue is not to explain or critique the contributions of the individual authors; their works speak for themselves. However, I can help place their work in historical context and provide some biographical background that they are too modest to attempt to squeeze into the conventional author's footnote.

In various guises, the issues that our contributors address have generated debate and inspired proposals for reform since the 1970s, when Congress concluded a decade of feverish legislative activity now embodied in such laws as the National Traffic and Motor Vehicle Safety Act,[1] the Clean Air Act,[2] the Occupational Safety and Health Act,[3] the Clean Water Act,[4] amendments to the federal pesticide law,[5] the Toxic Substances Control Act,[6] the Safe Drinking Water Act,[7] and the Resource Conservation and Recovery Act,[8] to name just some of the health and safety landmarks of that era. The administrative actions these

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1. Pub. L. No. 89-563, 80 Stat. 718 (1966) (current version codified at 49 U.S.C. §§ 30,101-70 (2000)).
2. Pub. L. No. 88-206, 77 Stat. 392 (1963) (codified as amended at 42 U.S.C. §§ 7401-7671Q (2000)).
3. Pub. L. No. 91-596, 84 Stat. 1590 (1970) (codified as amended at 29 U.S.C. §§ 651-78 (2000)).
4. Pub. L. No. 92-500, 86 Stat. 816 (1972) (codified as amended at 33 U.S.C. §§ 1251-1387 (2000)).
5. Pub. L. No. 92-516, 86 Stat. 973 (1972) (codified as amended at 7 U.S.C. §§ 136-136y (2000)).
6. Pub. L. No. 94-469, 90 Stat. 2003 (1976) (codified as amended at 15 U.S.C. §§ 2601-92 (2000)).
7. Pub. L. No. 93-523, 88 Stat. 1661 (1974) (codified as amended at 42 U.S.C. §§ 300f to 300j-26 (2000)).
8. Pub. L. No. 94-580, 90 Stat. 2795 (1976) (codified as amended at 42 U.S.C. §§ 3301-20 (2000)).

laws authorized or, just as frequently, mandated, drew heavily upon still-emerging scientific disciplines—toxicology, epidemiology, environmental monitoring, and quantitative risk assessment, among others. This heavy reliance on scientific research and analysis generated new but still unresolved questions about the administrative process. Where should agencies turn for the evidence they need? How can they assure the relevance and integrity of the evidence they sought out or were proffered? How can interested parties and ordinary citizens be assured that officials will evaluate the evidence honestly and competently? What role should reviewing courts play in overseeing agencies' handling of scientific evidence? The list of unresolved questions goes on.

The issue of judicial responsibility first came to the surface in a series of decisions, perhaps more aptly described as debates, by the Court of Appeals for the D.C. Circuit in which Chief Judge David Bazelon and Judge Harold Leventhal ventured competing visions of the appropriate judicial role.[9] For Bazelon, the courts' responsibility began and ended with their insistence that agencies follow procedures that assured scientific issues were fully exposed to and ventilated with interested parties. Judge Leventhal, however, expected more from his colleagues. Judges, in his view, were obligated to learn enough about the underlying science to be able to assess whether the agency had analyzed it competently. Another colleague, Judge Carl McGowan, while not fully embracing either view, emphasized that the courts could not expect the usual level of empirical support for regulatory judgments "at the frontiers of science."[10] Although the courts of appeals, led by Judge Leventhal, came to espouse what came to be called "hard look" review of agency decisions, it is fair to say that agency decisions based on science generally received considerable judicial deference.

By the early 1980s, the focus of legal scholars and advocates of regulatory reform had shifted from the courts to the agencies themselves. The efforts of new agencies such as the Environmental Protection Agency ("EPA"), the Occupational Safety and Health Administration ("OSHA"), and the Consumer Product Safety Commission ("CPSC") to fulfill their responsibilities provoked a chorus of criticism, predominately from the industrial community. The critics leveled several charges at the bureaucrats, including that: (1) in their grasp of scientific information, the agencies were amateur, not expert; (2) the agencies failed to seek out or listen to experts outside government; and (3) the agencies were biased in their analyses of scientific evidence, which they misinterpreted or consciously distorted. This last criticism inspired a number of proposals to reorganize the administrative apparatus and to separate, in some fashion, science-based fact finding from regulatory policymaking.

These criticisms also precipitated a report by the National Research Council entitled *Risk Assessment in the Federal Government: Managing the Process*,

9. This dialogue is described and illustrated in JERRY L. MASHAW ET AL., ADMINISTRATIVE LAW: THE AMERICAN PUBLIC LAW PROCESS (5th ed. 2003).

10. Indus. Union Dep't v. Hodgson, 499 F.2d 467, 474 (D.C. Cir. 1974).

more commonly known as "the *Red Book*," one of the most influential analyses of environmental and health and safety regulation since the earlier flurry of legislative activity.[11] The *Red Book* rejected calls for institutional separation of risk assessment from risk management. At the same time, it emphasized the importance of keeping these functions analytically distinct. It endorsed greater agency use of and reliance on advisory committees composed of non-government experts and formulated what has become the common intellectual matrix for analyzing putative health and environmental hazards. Without question, however, the *Red Book*'s most important contribution was its recognition of the role that judgment, or "policy," if you will, must inevitably play in bridging the gaps in scientific understanding and experimental evidence.

In the years following publication of the *Red Book*, much of the literature dealing with environmental and safety regulation focused on the willingness of regulatory agencies to adopt and follow its recommendations. At the same time, more fundamental criticisms of agency handling of scientific evidence attracted attention. Several high-profile judicial decisions, commencing with the Supreme Court's famous *Benzene Case*,[12] set aside agency actions as lacking evidentiary or explanatory support. Skeptical scholars criticized what they saw as agency pretense—that controversial regulatory actions had to be, and could be, explained solely in scientific terms. And questions about agency competence in their treatment of scientific information again began to draw attention. Each of our authors has contributed to this ongoing discussion in prior works.

The debate over the role of science in regulation recently gained fresh intensity as a result of three developments that together form the focus of this collection of articles. First, the Supreme Court's decision in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*[13] triggered wide-ranging discussion about the legal system's acceptance and understanding of scientific evidence generally. Though the immediate context was civil litigation, it was predictable that some would advocate *Daubert*'s extension to the regulatory arena. More recently, and with little publicity, successive Congresses have enacted the so-called Shelby Amendment[14] and the Data Quality Act,[15] which in tandem expand public access to the raw data generated by research that takes on regulatory significance and potentially restrict agency release of research findings that could have significant societal impact.

The Shelby Amendment, the Data Quality Act, and the proposals to extend *Daubert* are recent developments that together provide the occasion or subtext for this Symposium. They represent the latest collective challenge to regulatory decisionmaking based on science and open a new era in our collective debate

11. NAT'L RESEARCH COUNCIL, RISK ASSESSMENT IN THE FEDERAL GOVERNMENT: MANAGING THE PROCESS (1983).

12. Indus. Union Dep't v. Am. Petroleum Inst., 448 U.S. 607 (1980).

13. 509 U.S. 579 (1993).

14. Pub. L. No. 105-277, 112 Stat. 2681 (1998).

15. Pub. L. No. 106-554, § 515, 114 Stat. 2763, 2763A-153-154 (2000).

over the role of science in the development of regulatory policy.

To address the merits and implications of these developments and explore the larger relationship between science and law, *Law and Contemporary Problems* has assembled an eminent group of contributors. We do not expect that casual readers will read all of the articles that comprise the issue, nor that conscientious readers will read the articles in the sequence they appear. Even so, it perhaps is useful to share the reasoning that led us to adopt the order you see.

Given the prominence that *Daubert* has acquired, and the implications its extension to the regulatory arena might have, it seemed logical to begin with Alan Raul and Julie Zampa Dwyer's defense of that extension. Mr. Raul has been the nation's most prominent advocate of this reform. Mr. Raul served as general counsel to the U.S. Department of Agriculture from 1989 to 1993 and as general counsel to the Office of Management and Budget from 1988 to 1989. Next, Donald Elliott, focusing specifically on EPA, dismisses the proposal of Mr. Raul and Ms. Dwyer, but not because he disagrees with their claim that science has for too long played too small a role in EPA's decisions. Rather, he believes that judicial review is too episodic and variable to provide sufficient incentives for enhancing the role of science at EPA. Instead, he advances three narrower proposals to elevate the role and voice of science within the agency. Mr. Elliott's essay is thus a logical companion to the Raul and Dwyer article. Mr. Elliott is uniquely qualified to address the role of science at EPA, having taught environmental and administrative law at Yale before serving as EPA's general counsel from 1989 to 1991.

Professor Wendy Wagner, author of the third article in our Symposium, challenges both the premises and the recommendation of Mr. Raul and Ms. Dwyer, and then extends her attack to encompass both the Shelby Amendment and the Data Quality Act. While Professor Wagner does not directly address Mr. Elliott's proposals, it will be obvious from her broader critique that she would find them unconvincing on their own terms and, in any case, unresponsive to what she takes to be the real source of frustration for critics of public safety and environmental regulation. Professor Wagner's contribution to this Symposium is a logical sequel to her widely admired, indelibly titled article, *The Science Charade in Toxic Risk Regulation*.[16]

Professor Jerry Mashaw's article at once broadens the discussion—beyond the distinctive area of toxics regulation, where toxicology, epidemiology, and cancer risk assessment are the driving disciplines—and deepens the analysis. Professor Mashaw's examination of the influence of another professional discipline—engineering—in the Department of Transportation's vehicle safety program represents a return to yet another subject on which he is the nation's leading expert.[17] The article also permits him to explore, on a broader stage, the

16. 95 COLUM. L. REV. 1613 (1995).

17. *See*, *e.g.*, JERRY L. MASHAW & DAVID L. HARFST, THE STRUGGLE FOR AUTO SAFETY (1990); Jerry L. Mashaw & David L. Harfst, *Regulation and Legal Culture: The Case of Motor Vehicle Safety*, 4 YALE J. ON REG. 257 (1987).

institutional and cultural impediments to integrating technical knowledge with regulatory-policy formation. His thoughtful analysis at least invites one to question the utility of legal moves of the sort urged by Mr. Raul, Ms. Dwyer, and Mr. Elliott.

Any one of several of Professor Thomas McGarity's many published articles would have fit naturally in this Symposium. He has long been a trenchant analyst of science-based regulation.[18] Happily, however, the editors found him willing to rejoin the discussion. Professor McGarity confronts Mr. Raul and Ms. Dwyer's proposal to "Daubertize" administrative law in the context of agency risk assessments. Using the case study of the debate over the health risks of environmental tobacco smoke, he concludes that such a development, while unlikely to improve the quality of agency science, would almost certainly lead to fewer and less stringent regulations—an end he suspects to be the true impetus for the "regulatory *Daubert*" proposals.

Professor Donald Hornstein returns us to the Shelby Amendment and the Data Quality Act. Like Professor Wagner, Professor Hornstein seeks to probe behind these ostensibly "procedural" reforms to grasp the programmatic objectives of their proponents and predict their practical effects. EPA's programs again provide the institutional context and the vehicle for Professor Hornstein's speculations about the reforms' practical effects. A prominent scholar of environmental law (and, like Professor McGarity, a former EPA attorney), Professor Hornstein brings impressive credentials to the task.

Our final article, by Dean Bernard Goldstein and Professor Russellyn Carruth, introduces a scholarly perspective that views scientific evidence through the eyes of a scientist. In his government career, Dr. Goldstein was responsible not only for helping policymakers understand technical evidence, but also for planning and executing new research to broaden and deepen the informational base for decisionmaking. The goal of Dr. Goldstein and Professor Carruth, however, is not to defend how EPA uses science, but rather to dramatize Professor Wagner's hypothesis that it is the law's assignment of the burden of proof that ultimately matters. They make the case, in the face of European claims to the contrary, that regulation in the United States in fact exhibits a "precautionary" mindset. Whether one accepts their characterization, by the end of the Symposium it is hard to escape the conclusion that the debate about "science quality"—about *Daubert*'s relevance in regulation—is, in major part, a debate about probative force, or, to put it somewhat differently, about how policymakers should account for ignorance and uncertainty.

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18. *See, e.g.*, THOMAS O. MCGARITY & SIDNEY A. SHAPIRO, WORKERS AT RISK: THE FAILED PROMISE OF THE OCCUPATIONAL SAFETY & HEALTH ADMINISTRATION (1993); Sidney A. Shapiro & Thomas O. McGarity, *Reorienting OSHA: Regulatory Alternatives and Legislative Reform*, 6 YALE J. ON REG. 1 (1989).