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Edited by Wendy Wagner and Rena Steinzor

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## RESCUING SCIENCE FROM POLITICS

*Rescuing Science from Politics* debuts chapters by the nation's leading academics in law, science, and philosophy, who explore the ways that special interests can abuse the law to intrude on the way that scientists conduct research. The high stakes and adversarial features of regulation create the worst possible climate for the production and use of honest science, especially by those who will ultimately bear the cost of the resulting regulatory standards. Yet the academic or popular literature has paid scant attention to efforts by dominant interest groups to distort the available science in support of their positions. The book begins by establishing what should be noncontroversial principles of good scientific practice. These principles serve as the benchmark against which each chapter's author explains how science is misused in specific regulatory settings and isolates problems in the integration of science by the regulatory process.

Wendy Wagner is the Joe A. Worsham Centennial Professor at the University of Texas School of Law in Austin, Texas. She received a master's degree in environmental studies from the Yale School of Forestry and Environmental Studies and a law degree from Yale Law School. Wagner teaches courses in torts, environmental law, and regulation. Her research focuses on the law–science interface in environmental law, and her articles have appeared in numerous journals, including the law reviews of Columbia, Cornell, Duke, Illinois, Texas, Wisconsin, and Yale.

Rena Steinzor is the Jacob A. France Research Professor of Law at the University of Maryland School of Law and has a secondary appointment at the University of Maryland Medical School Department of Epidemiology and Preventive Medicine. She received her B.A. from the University of Wisconsin and her J.D. from Columbia Law School. Steinzor teaches environmental and administrative law, critical issues in law and science, and negotiation. She has written extensively on environmental federalism, alternative designs of regulatory systems, and law and science, publishing in the *Minnesota Law Review*, *Harvard Environmental Law Review*, *Duke Journal of Law and Policy*, *Yale Journal on Regulation*, *Environmental Forum*, and *Environmental Law Review*.

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# Rescuing Science from Politics

## **REGULATION AND THE DISTORTION OF SCIENTIFIC RESEARCH**

Edited by

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University of Texas School of Law

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Cambridge, New York, Melbourne, Madrid, Cape Town, Singapore, São Paulo

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32 Avenue of the Americas, New York, NY 10013-2473, USA

[www.cambridge.org](http://www.cambridge.org)

Information on this title: [www.cambridge.org/9780521855204](http://www.cambridge.org/9780521855204)

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First published 2006

Printed in the United States of America

*A catalog record for this publication is available from the British Library.*

*Library of Congress Cataloging in Publication Data*

ISBN-13 978-0-521-85520-4 hardback

ISBN-10 0-521-85520-9 hardback

ISBN-13 978-0-521-54009-4 paperback

ISBN-10 0-521-54009-7 paperback

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precautionary principle. He is a coauthor of a casebook, Applegate, Laitos, and Campbell-Mohn, *The Regulation of Toxic Substances and Hazardous Wastes* (Foundation Press 2000), and the editor of the two-volume collection of articles, *Environmental Risk* (Ashgate 2004). From 1993 to 1998, Applegate chaired the Fernald Citizens Advisory Board, which developed the blueprint for the environmental cleanup of the U.S. Department of Energy's nuclear weapons production facility at Fernald, Ohio. He has also been a member of the Department of Energy's National Environmental Management Advisory Board and has served as a member, presenter, or reviewer for National Research Council committees on radioactive waste management. Before entering teaching in 1987, Applegate practiced law with the Washington, D.C., law firm of Covington and Burling, and he clerked for the Honorable Edward S. Smith of the U.S. Court of Appeals for the Federal Circuit. He received his J.D. from Harvard Law School and his B.A. from Haverford College. Professor Applegate is a scholar with the Center for Progressive Reform.

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*Physiology; Risk; Risk Analysis; Virginia Environmental Law Journal; and Yale Law Journal*. He has served on the State of California's Proposition 65 Science Advisory Panel (1989–92), a National Academy of Sciences Panel to Czechoslovakian Academy of Sciences (1990), several NSF peer review panels, and California's Science Advisory Panel on Electric and Magnetic Fields (1999–2002). In 1998 he was elected a Fellow of the American Association for the Advancement of Science and in 2003 he was elected a Fellow of the Collegium Ramazinni. Professor Cranor is a member scholar with the Center for Progressive Reform.

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Environmental Program. At North Carolina, he teaches environmental law, natural resources law, administrative law, and insurance law. He has won the law school's McCall Award for Teaching Excellence five times and, in 1999, he won the university-wide prize for Distinguished Teaching in Post-Baccalaureate Instruction. Among his many articles and publications, his article "Accounting for Science: The Independence of Public Research in the New Subterranean Administrative Law" was recently published in *Law and Contemporary Problems*. Professor Hornstein received his B.A. from UCLA and his J.D. from the University of Oregon School of Law, where he was editor-in-chief of the law review. After graduation, he clerked for Judge Abner Mikva of the United States Court of Appeals for the District of Columbia Circuit and worked as an honors attorney in the Environment and Natural Resources Division of the U.S. Department of Justice. He is a scholar with the Center for Progressive Reform.

**Donald Kennedy** is the Bing Professor of Environmental Science and President emeritus at Stanford University. He received A.B. and Ph.D. degrees in biology from Harvard. His research interests were originally in animal behavior and neurobiology – in particular, the mechanisms by which animals generate and control patterned motor output. In 1977, Dr. Kennedy took a two-and-a-half-year leave to serve as commissioner of the U.S. Food and Drug Administration (FDA). This followed an increasing academic interest in regulatory policy regarding health and the environment, which included the chairmanship of a National Academy of Sciences study on alternatives to pesticide use and membership on the committee to study world food and nutrition. Following his return to Stanford in 1979, Dr. Kennedy served for a year as provost and for twelve years as president, a time marked by renewed attention to undergraduate education and student commitment to public service, and successful completion of the largest capital campaign in the history of higher education. During that time, Kennedy continued to work on health and environmental policy issues, as a member of the Board of Directors of the Health Effects Institute (a non-profit organization devoted to mobile source emissions), Clean Sites, Inc. (a similar organization devoted to toxic waste cleanup), and the California Nature Conservancy. His present research program, conducted partially through the Institute for International Studies, consists of interdisciplinary studies on the development of policies regarding such transboundary

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environmental problems as: major land-use changes; economically driven alterations in agricultural practice; global climate change; and the development of regulatory policies. He codirects the Environmental Studies Program in the Institute for International Studies and oversaw the introduction of the environmental policy quarter at Stanford's center in Washington, D.C., in 1993. Dr. Kennedy is a member of the National Academy of Sciences, the American Academy of Arts and Sciences, and the American Philosophical Society. He holds honorary doctorates from several colleges and universities. He served on the National Commission for Public Service and the Carnegie Commission on Science, Technology and Government.

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and sharing knowledge and information, with the ultimate aim of preserving the fundamental value of the life and health of human beings and the natural environment.

**David Michaels** is Professor and Associate Chair of the Department of Occupational and Environmental Health at the George Washington University School of Public Health and Health Services. Trained as an epidemiologist, Dr. Michaels served as the U.S. Department of Energy (DOE) Assistant Secretary for Environment, Safety and Health from 1998 through January 2001. In that position, he had primary responsibility for protecting the health and safety of workers, the neighboring communities, and the environment surrounding the nation's nuclear weapons complex. He is the chief architect of the Energy Employees Occupational Illness Compensation Program, a historic initiative to compensate workers in the nuclear weapons complex who developed cancer or lung disease as a result of exposure to radiation, beryllium, and other hazards. He also oversaw promulgation of the DOE's Chronic Beryllium Disease Prevention rule. In the early 1990s, Dr. Michaels developed a widely cited mathematical model estimating the number of children and adolescents orphaned by the HIV/AIDS epidemic. He also was a Robert Wood Johnson Health Policy Fellow with the Committee on Education and Labor of the U.S. House of Representatives in 1993–4, the year Congress considered national health reform legislation.

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States (ACUS), and he has testified in Congress on regulatory policy and process issues. He recently published an article on the Office of Management and Budget's (OMB) peer-review proposal in the *Environmental Law Reporter*.

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## Acknowledgments

As the editors of a volume that was such a collaborative and interactive effort, it is difficult to acknowledge the many people, organizations, and institutions who contributed to it.

Nevertheless, it is fair to attribute the book's existence in large part to the active support of the Center for Progressive Reform (CPR), a virtual think tank comprised of forty-one colleagues, all of whom are working academics in the fields of law, economics, philosophy, and science. Eight of the authors contributing chapters to this book (Professors Adelman, Applegate, Cranor, Doremus, Hornstein, McGarity, Shapiro, and Squibb), as well as ourselves, are CPR member scholars.

We conceived of the principles that are at the heart of this book, and developed many of the ideas that are presented to explain them, at meetings organized and sponsored by CPR and the Project on Scientific Knowledge and Public Policy (SKAPP). We are especially grateful to CPR funders – the Beldon Fund and the Deer Creek Foundation – for providing the financial resources that made many of the key sessions possible. We also thank the University of Maryland and University of Texas Schools of Law for supporting our scholarship through summer grants and fall sabbaticals, and the Maryland Law School and the George Washington University Medical School for providing meeting facilities. A crucial session at the Maryland School of Law was supported by the Ward Kershaw Environmental Symposium Fund.

Professor Alyson Floumoy, a CPR board member and Director of the Environmental and Land Use Program at the University of Florida Levin College of Law, and Katherine Baer, a CPR senior policy analyst, provided invaluable insights and suggestions as peer reviewers of an early draft of



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## Acknowledgments

this book. Andrea Curatola provided superb research assistance, and Dottie Lee and Laura Mrozek provided excellent administrative support. We also thank Leslie Boden, Richard Clapp, Lynn Goldman, Linda Greer, Molly Jacobs, Celeste Monforton, Anita Nager, Erik Olson, and Jennifer Sass for their contributions to the conversations that helped shape the substance of the book. Joanna Goger and Polly Hoppin were particularly helpful in initiating the project and keeping the momentum going, and we are grateful for their energy and inspiration. Members of the SKAPP project, chaired by professors David Michaels and David Ozonoff, also provided much appreciated scientific insight. Dean Karen Rothenberg and Associate Dean Diane Hoffmann have been extremely generous in their efforts to assist the development of this dialogue regarding law and science, which has also enriched the University of Maryland Environmental Law and Science Program.

John Berger at Cambridge University Press was enthusiastic about this project from its inception, and Andy Saff provided a painstakingly careful edit of the book, front to back. We are most grateful to both of them for helping to make the book become a reality.

Last but not least, we thank our wonderful families for putting up with us as we saw this project through to conclusion: Mike, Will, Becky, Daniel, and Hannah – you are all the best!

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## Prologue

Donald Kennedy\*

These are difficult times for science in the zone where it converges with public policy. Of course it should not be expected that peer-reviewed science, even carefully done, will be a commanding presence in policy discussions, even where scientific issues are prominent. Other matters, like the relationship between costs and benefits of a project or distributive justice implications, may be more decisive, for perfectly good reasons. But science has been playing a critically important role in several areas that have become important exercises of government responsibility, including, but not limited to, environmental quality regulations, litigation over damages associated with the external costs of private activity (“toxic torts”), and the legal responsibility of manufacturers for product harms. What has happened, in this more political contemporary environment, to science and the people who practice it? That is the subject of this book. In this prologue, I hope to provide a quick overview of some features of the new terrain. In later chapters, others will deliver a much closer and more scholarly look at them.

In the mid-1970s – a few years after the first volley of laws protecting environmental quality – there was little public skepticism about, and only limited political pressure against, the role of science in regulation under these statutes, or its influence in legal proceedings about product harms. When I became commissioner of the Food and Drug Administration early in 1977, the Medical Devices Amendments were only a year old, and we were just trying to figure out how to implement them. Our only model was the approval process for new drugs – a much older part of the law, and

\* Editor-in-chief, *Science*

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one about which there were chronic complaints from both left and right. Was it too fast, exposing Americans to unsuspected hazards, or too slow, robbing them of potentially useful therapies? That debate is alive and well and scheduled for a long run. After all, there is no normative standard by which we may judge whether the cost of foregone innovation is perfectly balanced against the cost of iatrogenic illness. Points of optimum social utility are notoriously hard to identify. But the science used by the agency, and the role of science in the other contexts I have mentioned, generally enjoyed respect in those years.

My impression is that things are quite different now, and the difficulties analyzed in the succeeding chapters afford a rich sketch of the current environment. I suggest that the change is the result of a major policy shift – one that began before the Bush Administration took office but was extended and made more forceful by policies advocated during both of the last two presidential election campaigns and made explicit by legislative and administrative actions since. The overarching theme has been that government is too large and complex and that the effect of its combination of size and regulatory mission unnecessarily disrupts the efficient operation of a market economy. President George W. Bush in his election campaigns repeatedly called attention to the size of the federal bureaucracy. He has not set specific goals for its reduction in force, and indeed has achieved none. But the call is still heard from more colorful Republican Party conservatives such as Grover Norquist, who says that he hopes for a government that he can “take into his bathroom and drown in the tub.”

Thus, to the extent that science still plays an important role in most regulatory decisions, its role has become more suspect by those who find regulations burdensome or of questionable legitimacy. The challenges to science do not all come from the right; members of consumer organizations and others have often charged science establishments with paying too little attention to legitimate representatives of the public – “stakeholders” in the current patois. But the strongest current challenge comes from a quite different quarter. It probably evolved from the Republican congressional sweep in 1994, when Representative Newt Gingrich and his newly elected allies promised a radical deconstruction of environmental regulation. They discovered that the American public actually liked the environmental rules, and that campaign largely failed. But it left behind a Republican majority and antiregulatory embers that could be fanned into flames by the interest of

Cambridge University Press

0521540097 - Rescuing Science from Politics: Regulation and the Distortion of Scientific Research

Edited by Wendy Wagner and Rena Steinzor

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President Bush and his cabinet in redistributing power in the agencies and in the courts. A particular objective was the challenge to scientific findings as dispositive, or even influential, in determinations about regulation or product harm.

One early theme fits under the heading of “tort reform.” Administration spokespersons regularly point to the health care costs associated with medical malpractice litigation, taking advantage of public skepticism about lawyers. They have also emphasized the charge that plaintiffs’ attorneys regularly introduce “junk science” in support of malpractice or product liability claims. Of course, there is some truth here: Some expert witnesses have offered questionable scientific conclusions in support of plaintiffs, and that has led to the series of three Supreme Court decisions regarding the admissibility of expert testimony in jury trials. The so-called “*Daubert* trilogy” (*Daubert*, *Kumho Tire*, and *Joiner*, all discussed in much greater detail in Chapters 1 and 6) has had a lingering effect on product liability litigation. In the view of most observers, the “*Daubert* criteria” for permitting expert testimony have made it more difficult for scientists to present evidence, adding up to some degree of bias in favor of defendants.

The *Daubert* principle, however, has invaded other provinces of the law only to a very limited extent. In criminal courts, it has almost never been applied to challenge the “expert” testimony of police or other government experts (medical examiners, fingerprint experts, and the like) despite a general sense among scientists that forensic data are very open to question. Nor have *Daubert* challenges been characteristic of administrative law procedures in the regulatory arena. But this is not a time for confidence that the latter, in particular, may be just over the horizon.

Developments in the legislative arena have also broadened the zone for attacks on science. In fulfilling its responsibility under the Clean Air Act to use scientific data in establishing National Ambient Air Quality Standards, the Environmental Protection Agency cited a study done by researchers at the Harvard School of Public Health on the effect of small (PM<sub>2.5</sub>) particles in the air-sheds of several cities. It was cited in the proposed regulation, but a late-night Senate amendment opened the primary data in the study to examination by other interested parties. The “Shelby Amendment,” more formally called the Data Access Act, made federally supported research project data eligible for public access through the Freedom of Information Act. In issuing governing regulations under the statute as required, the

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Office of Management and Budget limited the scope to scientific findings used in regulatory actions that had significant policy or economic impacts.

But the amendment widened a zone that industry had already opened through discovery proceedings in litigation. For example, well before the Shelby Amendment, Professor Herbert Needleman's studies on the effect of lead toxicity on intellectual development in children had been made the subject of a lawsuit by the lead industry. In the course of discovery, "expert witnesses" for the industry had obtained Needleman's research records. They developed a basis for a charge of research misconduct, which went to the Office of Research Integrity at the National Institutes of Health (NIH), the funder of Needleman's work. Needleman's campus at the time was the University of Pittsburgh, perhaps not an ideal venue for someone contesting with the heavy metals industry. When the university was asked to investigate, the process was prolonged until a faculty body arranged for a session in which Needleman and his attorneys were able to confront the claimants and cross-examine them. The charge was found baseless, but the matter died, leaving some damaged confidence behind it.

That incident and others have made many scientists worry that more recent actions will open their work to reinterpretation and to whatever revision critics want to make in the findings. The worry has been exacerbated by recent regulatory developments, as well as by new events in an area where the science has become especially political. The Shelby Amendment was followed by another statutory initiative, the Data Quality Act – sometimes referred to as "son of Shelby." Regulations under this statute permit petitioners to challenge the quality of science proffered by the government to educate consumers or to support other actions. This new zone of challenge has produced challenges to agencies and to the science on which they have based advice to the public – for example, on salt consumption. But there have also been challenges to the scientists themselves, including demands for underlying data.

Perhaps the most recent and most alarming development has come from congressional friends of those with particular economic and political interests. A well-organized opposition to the scientific consensus on global climate change has produced little original science of its own, but it has campaigned successfully to obtain primary data from scientists whose findings have supported global warming. As a journal editor, I sometimes get reasonable requests from a scientist-reader for reagents, materials, or data

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in a paper we have published. That's a strong scientific tradition, and it is our policy to support it. Recently, however, the requests for data from climate scientists have taken on a pattern that borders on harassment. Worse still, Representative Joe Barton (R-TX), chair of the House Committee on Energy and Commerce, sent a series of demand letters to prominent climate scientists, asking for detailed accounts of methodology and data analysis. These inquiries came only to scientists whose work supported the involvement of greenhouse gas emissions in recent global warming. The chair of the House Science Committee, Representative Sherwood Boehlert (R-NY), objected to this harassment on jurisdictional grounds, but Barton has not given it up.

How does all this add up? You will have to draw your own conclusions after exploring what follows. But I know what many of my fellow scientists are saying to one another, because *Science* has a news page that receives a lot of submissions from researchers, and my colleagues and I talk to them often. Many are wary of work that may find use in some regulatory proceeding. They wonder whether the data underlying their findings may be subject to examination and reinterpretation, perhaps with some "spin" supplied by the revisionists. They know that charges of research misconduct could arise from hostile access to their scientific work. They know they are vulnerable to personal attack from those whose interests may be adversely affected by the product of their research.

In some ways, there has never been a better time for science. It is exciting, and the fact that it is subject to political attention means that it matters – more than ever. But though it is a good time for science, it is a perilous time for scientists.