Introduction

Wendy Wagner, J.D., and Rena Steinzor, J.D.

Scientists under Attack

To the casual observer, scientists might appear to be the most influential group in the United States with respect to public health and environmental policy. Exhortations that we must use "sound science" to make decisions about whether to prevent potential risks are ubiquitous. No less an authority than a Supreme Court justice, as well as a wide range of other decision makers in the legislative, regulatory, and judicial arenas, have urged that scientists be elevated to the pinnacle of power, entrusted by the rest of us with the authority to resolve our most important and complex problems.[1] Deference to scientists as the ultimate arbitrators of policy resonates every time Congress debates such controversies, suggesting that lawmakers and those who work to affect their decisions have nothing but respect for the sanctity and wisdom of the scientific process and its results, wherever they may lead us.

Why, then, do many scientists deployed at the front lines of the most heated disputes – over global warming, mercury in the human food chain, or the safety of antidepressants for adolescents – feel not like anointed and omniscient saviors, but instead like hunted prey? For all the lip service paid to the naïve but convenient notion that science has all the answers, the moment that researchers announce a discovery that has significant economic implications for industry or some other affected group, scientists in the spotlight quickly learn to run for cover.

[1] Stephen G. Breyer, *Breaking the Vicious Circle: Toward Effective Risk Regulation* (Cambridge, MA: Harvard University Press, 1993); Daniel R. Sarewitz, *Frontiers of Illusion: Science, Technology, and the Politics of Progress* (Philadelphia, PA: Temple University Press, 1996).

Beset by scientific misconduct allegations or threatened with breach-of-contract lawsuits if research is published over a private sponsor's objections, more and more scientists are finding themselves struggling to maintain their credibility in a climate designed to deconstruct the smallest details of their research. Studies are not criticized in an effort to advance research to the next stage of the search for truth, but rather are dissected in an effort to discredit both their results and their authors. Some experts are concerned that the severity of these problems could deter the best and the brightest young scientists from entering the very disciplines that have the greatest potential to inform public affairs.[2]

These events are disconcerting not just because they frustrate the goal of using reliable science to formulate policy, but because they could undermine scientific integrity, independence, and transparency to the point that we are deprived of the progress that objective science could offer on a wide range of pressing social problems. When scientists cannot control their own research agendas because they are preoccupied with responding to subpoenas and data requests, when private funding comes only with long strings attached, and when scientists are sanctioned for communicating results that do not serve the economic interests of their sponsors, the core values that define science are threatened.

An Overdue Debate

Rescuing Science collects perspectives from academics specializing in science, law, and philosophy on these worrisome developments. In their individual chapters, the authors describe important clashes between science and law with more precision and identify promising pathways toward reform. Since the focus of the book is on identifying problems and suggesting solutions, the authors consciously set out to find examples of how science has been distorted by special interests using legal tools. While subsequent researchers or commentators may ultimately debate the overall significance of these problems, the well-supported accounts provided in

[2] National Research Council, *Access to Research Data in the 21st Century: An Ongoing Dialogue among Interested Parties* (Washington, DC: National Academy Press, 2002), 14 (quoting Dr. Bruce Alberts' concern that "there is a danger that the [Data Access A]mendment could be used to harass scientists whose work is found objectionable by anyone, for any reason").

this book leave little doubt that the problems exist and that a variety of regulatory and legal pressures are causing unwarranted intrusions on science.

The book's collection of individual essays are organized around a set of neutral principles that were crafted in discussions with a wide range of experts on the use of science in policymaking. These principles should be non-controversial throughout the scientific and legal community. If the principles were followed, the threats to scientific integrity and objectivity posed by misuse of legal tools would diminish substantially.

This effort to document the adverse impacts of the law on science is long overdue. Others, including contributors to this book, have written eloquently and at length about mounting threats to scientific integrity in the area of food and drug safety and efficacy. But scholars have not yet focused on the broader problems that arise from the law's insensitivity to the basic principles of science, with particular attention to the protection of public health and natural resources. Nor has anyone endeavored to identify reforms that would forestall such interference. This book meets those challenges.

The Pressure on Science

Scientists unfamiliar with the legal system generally assume that the path of their research from the laboratory to policy makers is a straight and uncomplicated one. Research is published in a peer-reviewed journal so that it can be judged on the merits by knowledgeable colleagues. Well-designed studies with original discoveries can then play a significant role in formulating social policy, while studies with evidence of bias or unclear methodology are discounted. Scientists might also expect that when policy makers are confronted with important questions regarding scientific evidence, they will utilize a "weight of the evidence" approach, viewing available data as a composite and reaching conclusions only after considering the strengths and weaknesses of all of the individual pieces of research. After all, judicial, legislative, and regulatory institutions have the same objectives as scientific institutions: improving social welfare. Thus, scientists reason, rational use of research by policy makers is one of the most promising ways to make sure that this overriding objective is achieved.

Scientists who have been reluctantly drawn out of their laboratories into political or courtroom battles over the last few decades have learned that

legal processes are quite different from this idealized view. Rather than incorporating science into policy dispassionately and using research to further a quest for truth, the legal system makes most decisions through an adversarial process driven by affected parties who interpret and re-interpret the science to prove that they should "win." This method of making decisions is largely alien to scientific practice and counterproductive to the production of reliable research. Over the last three decades, as science has become increasingly influential in the regulation of industry, these adversarial processes have increased and now pose a substantial threat to scientists who work in controversial areas such as climate change, pesticide registration, toxic chemical risk assessments, and the protection of endangered species.[3]

Three concurrent developments, in particular, have placed science under intense pressure. The first is the dramatic expansion of the regulatory system, characterized by a growing body of statutory and administrative law, as well as multiple agencies that regulate products, manufacturing processes, and waste disposal activities through thousands of separate requirements. The multiplication of legal requirements reaches nearly every firm in the manufacturing sector, as well as large portions of the service sector. At the same time, regulators look to science for guidance when they make difficult decisions regarding the stringency of public health and environmental protection. The more emphasis that regulators place on science, the greater the affected parties' incentives to do what they can to control its content and production.

The second source of pressure is the expansion of liability for damages caused by defective products, including toxic chemicals. The American judiciary has led the world in developing liability principles for products and activities that cause unreasonable or significant harm to society, provoking great concern from the manufacturing sector. It is not uncommon for liability judgments to be in the millions of dollars for a single victim, and the science supporting plaintiffs' alleged injuries is critical in determining whether they win or lose.

The third development is the continuing failure of the U.S. government to provide meaningful financial support to public research on health and the environment. Rather than increasing funding as environmental and

[3] Feature Issue: Corporate Corruption of Science, *International Journal of Occupational and Environmental Health* 2, no. 4 (2005).

health sciences grow in importance, public investment in badly needed research has been relatively flat for the past several decades.[4] This dearth of research support may be based, at least in part, on the hope that private parties will pick up the slack.[5] Yet that expectation overlooks the intrinsic differences in incentives between companies that conduct research to develop new technologies and companies expected to conduct research on the adverse effects of their pollution and products. Pharmaceutical companies, for example, invest heavily in research in the hope of inventing a new miracle drug that will help humanity and earn large returns for investors, but research regarding the effects of industrial activities on public health and natural resources presents quite the opposite equation for most private companies. If the research suggests unexpected harms and other adverse effects, it leads directly to the expenditure – as opposed to the making – of money. In fact, manufacturers understand the significance of science to liability and regulation so well that they may actually resist conducting basic tests on their products or auditing the potential harms caused by their activities. As long as scientific information can be incriminating and lead to costly liability and regulatory requirements, ignorance is bliss.

While each of the three factors has a powerful effect on science, their synergism can be overwhelming. The Information Age intensifies these effects in ways not imaginable a decade ago. With the invention of the worldwide web, adverse information about a product circulating in commerce travels rapidly, prompting rapid fluctuations in markets and expanding liability for mistakes in amazingly short order.

Scientific discoveries were the foundation for crushing liability on industries engaged in the manufacture of asbestos, tobacco, beryllium, and a number of pharmaceuticals and medical devices.[6] The mere specter of liability leads virtually every industry to scrutinize research that suggests their

[4] National Research Council, *Trends in Federal Support of Research and Graduate Education* (Washington, DC: National Academy Press, 2001), 122–3.

[5] National Research Council, *Toxicity Testing: Strategies to Determine Needs and Priorities* (Washington, DC: National Academy Press, 1984), 48, 84–5.

[6] Paul Brodeur, *Outrageous Misconduct: The Asbestos Industry on Trial* (New York: Pantheon, 1985); Stanton A. Glantz et al., eds., *The Cigarette Papers* (Berkeley, CA: University of California Press, 1996); Gerald Markowitz and David Rosner, *Deceit and Denial: The Deadly Politics of Industrial Pollution* (Berkeley, CA: University of California Press, 2002); Morton Mintz, *At Any Cost: Corporate Greed, Women, and the Dalkon Shield* (New York: Pantheon, 1985); Christian Warren, *Brush with Death: A Social History of Lead Poisoning* (Baltimore, MD: Johns Hopkins University Press, 2000).

activities are more hazardous than generally supposed. Because scientific data appear to have gained the legal power of ending businesses and entire manufacturing sectors, isolated pieces of research can attract scrutiny more fierce than most researchers should be expected to withstand.

Science has also distinguished itself as one of the main drivers of regulatory requirements. Learning of unexpected hazards or the possibility for adverse effects often leads to public demands for changes in regulations that will prevent or mitigate such threats. In the past three decades, certain pesticides, asbestos, polychlorinated biphenyls (PCBs), lead, and other common chemicals have been banned in whole or in part in the United States as a result of research that revealed the significant harm they could cause.

These trends and their complex interactions have multiplied the opportunities for destructive collisions between the worlds of law and science. Science is used and occasionally misused in making regulatory, legislative, and judicial decisions. Scientists, with little or no preparation and often without their consent, are drawn into combat between warring advocates within the legal system. Too often, these scientists become lightning rods in battles involving clashes between powerful institutions, both public and private.

Clashing Cultures

Underlying these conflicts between science and law are the two very different approaches that each discipline uses to assess the reliability of empirical evidence and establish the "facts." In contrast to the overriding principles of disinterestedness and collaboration that dominate scientific inquiry, the legal system is founded on the premise that the clash between equally represented disparate interests metes out justice. Lawyers who represent affected parties place a significantly lower value on objectivity than do scientists, and they are focused on winning immediate results rather than engaging in a lengthy quest to discover the true answer.

Science demands that, to the maximum extent possible, scientists have no stake in the outcome of the research. The law, by contrast, must solicit input from precisely the opposite types of participants – those who *are* sorely affected, aggrieved, and stand to lose or win from the outcome. Although documented facts and empirical knowledge are generally welcome, the law can proceed on negotiated truths and tentative assumptions as long as the affected parties are all participating vigorously in the process. The

primary criterion for evaluating the reliability of the science in court is whether the testimony of the expert survives challenge by the other interested parties in a highly stylized format (for example, cross-examination) before an audience comprised largely of lay people. In the legislative, regulatory, and judicial contexts, if the credibility of participating scientists is abused or impaired along the way, that injury is just another unavoidable byproduct of a vigorous adversarial system. Science is geared to a fundamentally different approach: maintaining colleagiality so that hypotheses can be vetted and new discoveries advanced.

While it is relatively easy for anyone familiar with both professional disciplines to see and accept these differences, problems arise when scientists are drawn into legal disputes in a way that invades their independence to conduct research. For example, affected parties in legislative, regulatory, and judicial disputes have on occasion commissioned research specifically to produce an outcome that will help them win their fight. Too often, researchers are asked, and even required, to sign contracts that compel them to suppress any findings contrary to the private sponsor's overall goals. Experts are also hired to engage in the "deconstruction" and "corpuscularization" of adverse research, casting doubt on every aspect of a study's methodology and findings. Such deconstruction is intended to discredit the research even though many of the methodological choices targeted by the attack may be perfectly acceptable to the broader scientific community.[7]

The tobacco industry is the most notorious intruder on the integrity of independent research, but it is by no means alone.[8] Virtually every category of stakeholder that participates in vigorous policy contests over public health and environmental protection has engaged in at least one of the underhanded assaults on science detailed in this book. Industry lawyers and trade associations, plaintiffs' attorneys, public interest groups, and grassroots citizen groups, as well as the scientists they hire to represent them, have distorted science, harassed researchers, or manufactured results.[9] Because public interest groups have fewer resources, however, the most accessible and well-documented cases tend to involve industry.

[7] Sheila Jasanoff, "Research Subpoenas and the Sociology of Knowledge," *Law and Contemporary Problems* 59, no. 3 (1996): 95, 98–100.
[8] Glantz et al., 171–200.
[9] Marcia Angell, *Science on Trial: The Clash of Medical Evidence and the Law in the Breast Implant Case* (New York: W.W. Norton, 1996).

Restoring Scientific Integrity

The increased number of attacks on science and the influence of private sponsorship on research have generated alarm within the scientific community. In their struggle to fend off such intrusions, a number of scientific organizations have developed positions and tools to preserve the independence of science. Biomedical journal editors, for example, now require the disclosure of possible conflicts of interest before allowing scientists to publish scientific findings or serve as peer reviewers in order to ensure that colleagues are alerted to their potential financial biases.[10] The Union of Concerned Scientists collected signatures from hundreds of scientists, including dozens of Nobel Prize winners, in protest of the politicized use of science by the Executive Branch.[11] Even large, apolitical societies such as the American Association for the Advancement of Science have passed resolutions and filed comments on the increasing problems of biased research and literature reviews that damage scientific credibility.[12]

This book reinforces these efforts. As mentioned earlier, we have organized the twelve chapters, this introduction, and the conclusion around a set of fundamental principles of scientific practice. These principles are grounded in the values long assumed to be the bedrock of scientific independence, disinterestedness, and transparency. They help to identify how far the legal system has strayed in its use of science, threatening scientific integrity at its core. We begin and end with these fundamental principles in order to propose a more productive and honest process for incorporating science into policies that protect public health and the environment:

- *Independence:* Scientists must be able to conduct research without unjustified restrictions, including undue influence by research sponsors.
- *Transparency*: The data and results of research must be communicated honestly and expeditiously to the research community and broader

[10] International Committee of Medical Journal Editors, "Uniform Requirements for Manuscripts Submitted to Biomedical Journals" (Oct. 2004) (available at http://www.icmje.org/index.html).
[11] Union of Concerned Scientists, "Restoring Scientific Integrity in Policymaking" (Feb. 18, 2004) (available at http://www.ucsusa.org/global_environment/rsi/page.cfm?pageID=1320).
[12] Peg Brickley, "Attack on Panel Politics," *Scientist* (March 12, 2003) (available at http://www.biomedcentral.com/news/20030312/01/).

public. Researchers and those using their research must be careful to represent the findings accurately, including the limitations of that research.

- *A Public Infrastructure for Science*: Government support of independent research is essential to produce discoveries that benefit the public good. In appropriate circumstances, peer review may serve an important role in assisting the government's decision making regarding the use and funding of science, but peer review must never be used to censor research.

These principles, which are specified in more detail in the "Principles of Good Regulatory Science" beginning on the following page, were drafted after extensive discussions among a community of scientists, lawyers, and philosophers, many of whom are authors of the chapters in this book. Yet the general consensus supporting these principles is evident throughout the scientific literature. As we discuss in more detail, sociologists of science and reports produced by scientific communities, especially the National Academy of Sciences and the American Association for the Advancement of Science, confirm that these principles of objectivity, independence, and transparency are cornerstones of high-quality science. Scientists appear committed to these principles not only in their own research, but also in their review of others' research. They value and nurture honest and open communication about the limitations of research and the underlying data. And they acknowledge the need for public support of important areas of research.

Independence and Freedom

The first principle underscores the widespread view that objectivity and independence are central to the development of high-quality science. The central value of disinterested inquiry runs through all phases of science, from initial funding to final publication decisions.[13] Indeed, the very productivity of the scientific enterprise depends, in large part, on the commitment of each researcher to perform studies in a disinterested way. While studies must be replicable, and typically are, precious research resources

[13] Robert K. Merton, "The Normative Structure of Science," in *Sociology of Science*, ed. Jerry Gaston (San Francisco: Jossey-Bass, 1973), 267, 275.

Principles for Good Regulatory Science

Scientists must be able to conduct research without unjustified restrictions, including undue influence by research sponsors.

- Sponsors must never place restrictions or otherwise influence the design or conduct of a study in an attempt to obtain results favorable to their interests.
- Research must never be suppressed because it produces results that are adverse to a sponsor or other interested party.
- No publication or summary of research should be influenced – in tone or content – by the sponsoring entity. Scientists must be able to conduct research without unjustified restrictions.
- If vested interests use the legal system to harass scientists whose research or expert testimony calls into question the safety of their practices or products, the harassers must be held accountable with sanctions and must compensate injured scientists for the resulting interference with their research and damage to their reputations.

Researchers and those using their research must be careful to represent their findings accurately, including the limitations of that research. The data and methods of research that inform regulatory decisions must be communicated honestly and expeditiously to the research community and broader public.

- Researchers and those using their data must be honest about the limits of the research and remaining uncertainties. If others misrepresent research to suggest an outcome not supported by the study, researchers must correct these misstatements as soon they become aware of them.
- Research must never be dismissed or excluded because it does not provide a complete answer to a larger policy or science question. Research, by its nature, is incomplete, and to dismiss research because it does not provide a definitive answer could result in the exclusion of valuable science from regulatory decision making.
- The data underlying a published study, as well as a comprehensive description of the methods, must be available to other scientists and the public at large upon publication of the study or submission of the results to a federal agency, in compliance with prevailing rules for preserving the privacy of human research subjects. Regulatory agencies should rigorously review and challenge exaggerated claims, however, that underlying data must be kept confidential for business and other reasons.