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

by Wendy Wagner and Rena Steinzor

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This Center for Progressive Reform white paper is a brief summary of the policy recommendations put forward in the new book, Rescuing Science from Politics: Regulation and the Distortion of Scientific Research, edited by CPR member scholars Wendy Wagner and Rena Steinzor. The book is available for purchase at <u>www.amazon.com</u> and from Cambridge University Press.

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. 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.

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.

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.

The Pressure on Science

S cientists unfamiliar with the legal system generally assume that the path of their research from the

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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.

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 greater the 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 health sciences grow in importance, public investment in badly needed research has been relatively flat for the past several decades. This dearth of research support may be based, at least in part, on the hope that private parties will pick up the slack. 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.

Attacks on Science

hese trends and their complex interactions have multiplied the opportunities for destructive collisions between the worlds of law and science. Science is withheld, compromised, and distorted in the legislative, judicial, and regulatory arenas in multiple ways, with affected parties working overtime to ensure that contradictory data do not defeat their causes. Not only do these activities impose artificial limits on the supply of reliable research, they prevent science from informing policies designed to protect public health and natural resources. Four types of attacks on science are especially prominent and worrisome.

The first is legally backed efforts by special interests to silence scientists and discredit their work. A number of scientists who embark on research that suggests that industrial activities or products are more harmful than originally supposed have been the victims of unfair attacks on the validity of their research and their professional integrity. Not only do these assaults fly in the face of an essential characteristic of scientific inquiry – honest, disinterested debate over methods and data – they cannot help but deter the best and the brightest from entering the disciplines where they are needed the most. Second, shortfalls in public funding of research and the absence of standardized testing requirements combine to place the private sector at the helm of crucial research. When the stakes are high enough, private interests can commission research to suit their needs, inappropriately influencing study design and the publication of results. Legal instruments, such as nondisclosure clauses in contracts, make these arrangements enforceable. Despite widely publicized lamentation about the "kept university," academic administrators and lawyers too often are illprepared to defend scientists enmeshed in such disputes.

Third, government officials and stakeholders sometimes manipulate scientific information to make it look like the decisive basis for the policies they support, when in truth the decisions necessarily hinge on obscured value choices. The resulting lack of accountability and transparency alienates the public from the policy making process by making such debates so complex and technical that the average lay person cannot hope to keep up. This alienation is destructive when policies informed by science ultimately

depend on public support and participation for their implementation.

The fourth and arguably most pernicious category includes the related approaches of scientific deconstruction and "corpuscularization," the term coined by Professor Thomas McGarity. Deconstruction means taking apart a piece of research by questioning choices made about research methodologies, even though these choices are accepted by the vast majority of scientists as suitable resolutions of nonessential research questions. For example, deconstructionists might challenge the choice to keep six amphibians under study in a ten-gallon tank, asking why neither the number four nor eight was chosen, or why a 15-gallon tank would not be more appropriate. These admittedly arbitrary judgments most often have nothing to do with the merits of the research, but succeed nevertheless in creating an aura of suspicion about it.

Science is particularly susceptible to deconstruction because scientists themselves believe in subjecting research to vigorous scrutiny. But scientists undertake such scrutiny with system's adversarial approach to decision making invites attacks on all aspects of a study, including generally accepted features of research methodology, for the sole purpose of undercutting the support of an opponent's arguments. These attacks continue regardless of whether they are scientifically legitimate or productive.

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"corpuscularization," legal adversaries work to undermine entire bodies of evidence by disassembling them into individual studies and critiquing each one in such tedious detail that its credibility is undermined. Opponents then demand that each discredited study be excluded from consideration because it is flawed, even if the study includes otherwise useful information. Successful corpuscularization reduces the body of evidence to the point of creating important data gaps. It also prevents the use of important data in the traditional "weight of the evidence" approach that scientists

themselves utilize. Under this alternative, weight of the evidence framework, scientists take all of the available and relevant research as they find it, recognizing the inevitable weaknesses in individual studies, but not accepting aspects of the research that offer some insight into their larger inquiry. Corpuscularization produces a decision making process that is mired in significantly greater scientific uncertainty than would exist under a weight of the evidence analysis. Legal tools such as the Daubert rule, which requires judges to screen "junk" science before it reaches a jury, and regulatory challenges under the Data Quality Act (also known as the Information Quality Act), have made this technique not just available, but inviting to adversaries throughout the legal system.

Scientists Respond

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.

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. Even large, apolitical societies such as the American Association of the Advancement of Science have passed resolutions and filed comments on the increasing problems of biased research and literature reviews that damage scientific credibility. Universities and other scientific organizations have convened conferences to explore and educate scientists about the harassment that has occurred when special interests are adversely affected by the results of their research.

To reinforce these efforts, the scientific community and policymakers who deal with science need to reaffirm a set of fundamental principles of scientific practice. These principles must be grounded in the values long assumed to be the bedrock of scientific independence, disinterestedness, and transparency. They should help to identify how far the legal system has strayed in its use of science, threatening scientific integrity at its core.

Fundamental Principles

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 potential 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 as 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 and biomaterials 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 that underlying data must be kept confidential for business reasons.

overnment support of independent research is essential to produce discoveries that benefit the public good. In appropriate circumstances, peer review may play 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.

• Legitimate scientific peer review does not encompass processes that enable outside stakeholders to pressure scientists to change their views in light of an anticipated policy outcome.

• Peer review should be done by a balanced group of peer reviewers who have no present or past conflicts of interest likely to affect their review and who specialize in the area. Peer reviewers should disclose the limits of their expertise in assessing the research. • Entities that select peer reviewers should disclose any financial conflicts of interest and affiliations or perspectives that may influence their choice of reviewers. The selection of reviewers must never be politicized.

• Much research that benefits the public good does not generate private compensation for its production. Generous public funding of research is essential for advancements in scientific knowledge, especially in areas where there are no private benefits to be gained from the discoveries.

• All research produced or used by the government should be subject to basic quality-assurance/quality-control checks, especially if that research is not published or disseminated widely within the scientific community.

• Public research monies should be allocated in ways that are disinterested and do not have a stake in the outcome of the research.

The general consensus supporting these principles is evident throughout the scientific literature. 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.

Launching the Rescue

I f the past decade is any indication of the future, efforts to undermine valuable research and discredit researchers will continue to increase in number, vigor, and creativity. To halt or at least slow these incursions, the legislative, regulatory, and judicial systems must be reformed with the goal of protecting scientists' ability to undertake research without outside interference. Each of the three principles points the way toward several concrete changes that will assist in rescuing science from politics.

Protecting the Fundamental Role of Scientists

Over the past five years, scientific institutions have become more involved in challenging legal intrusions on science. Expanding and intensifying these efforts are the quid pro quo for real reform. Collective efforts by scientists to stave off unwarranted intrusions to science are an important first step, but these efforts must be supplemented with more proactive roles for scientists in informing public policy. Rather than positioning the scientific community as just another interest group forced to lobby for changes in regulatory proposals, policy makers must give scientists a more formal role in reviewing and revising legal rules that directly or indirectly utilize or affect scientific research.

In the future, laws and rules that would directly affect scientific freedom, quality, or transparency should be vetted through a panel of highly respected scientists before they are proposed. While the panel of scientists would not have "veto" power, their review of legal innovations at the front end of their development would identify potential problems and allow the establishment of less intrusive approaches that might not be obvious to nonscientists.

Creating a Safety Zone

Scientists who conduct research that has potentially adverse implications for regulated industries should be protected in a "safety zone" that effectively immunizes them from the host of legal tools used to harass them and dismember their work. Safety zones would have the goal of placing scientists and their research "off limits" for those intent on mounting unsubstantiated or meritless attacks.

The best way to accomplish this essential outcome is to increase the burden on those seeking to subpoena data from independent researchers, foreclose accusations of scientific misconduct except in the most egregious cases, and prohibit complaints that request correction of data when the requesters have other opportunities to explain their positions to decision makers. "Raising the burden" means more than simply asking for more evidence while allowing the attack to run its course. To deter the harassment of scientists who produce inconvenient findings, the law should impose stiff sanctions on meritless or unsubstantiated attacks.

Scientists should have the right to go to court to seek damages for harassment, including not only compensation for their time and expenses, but also punitive damages when the delays caused by the attack have undermined the progress of their research. To ensure that such challenges are not defeated by the high costs of litigation, the law should include the availability of attorneys' fees and costs for the prevailing party.

In addition, scientific organizations like the American Association for the Advancement of Science or the National Academy of Sciences could provide an invaluable public service by establishing a balanced committee of scientists to investigate complaints and defend innocent researchers, much as the American Association of University Professors investigates complaints of infringements on academic freedom. These panels could conduct full examinations of the legitimacy of "junk science" allegations and issue a public report that would be available to the decision making body. More vigorous defense of harassed researchers will raise the costs to interest groups of exaggerating flaws in good research.

These recommendations will provoke controversy. Some will argue that they attempt to change fundamental characteristics of the legal system that are designed to ensure fairness for all of its participants. Among other things, they will charge that subpoenas and similar legal tools may be the only way to "discover" adverse information in order to prevent questionable research from causing grave and unjustified economic damage. Others will contend that these proposals are hypocritical: while we express great admiration for the scientific tradition of engaging in robust debate regarding the merits of research, we now seek to forestall such debate within the legal system, where it counts the most.

Greater government support of research is among the most important reforms needed to prevent science from being captured by special interests. Such support would solve several problems at once: It will avoid the suppression and bias that plague private research while simultaneously producing much needed knowledge on scientific questions that are fundamental to environmental and public health regulation.

far more damage than good. Scientists themselves have created ample opportunities for vetting the accuracy of research. More intractable scientific controversies can even be reviewed by high-level scientists under the auspices of the National Academy of Sciences or agency-specific scientific advisory boards, giving those wishing to challenge data or conclusions additional opportunity to make sophisticated arguments to their peers.

Lastly, if other reforms presented in greater detail below are adopted, the use of science by the legislative, judicial, and regulatory systems will become considerably more transparent, with underlying data disclosed as a matter of

> course by those hoping to influence decision making. As a result, participants in such debates should have no lingering concerns that their only recourse is against individual scientists.

Preventing Unfair Attacks

A greater role for public science also depends on more effective protections to keep publicly funded research from unfair, special interest attacks. The current regulatory system allows participants to abuse, with impunity, a variety of judicial and administrative mechanisms in order to delay regulation and harass and discredit public scientists. The Data Quality Act (also known as the Information Quality Act), the Data Access Act, third-party subpoenas,

There are several responses to these concerns. First and foremost, all science is not equal in terms of its significance for public policy. Scientists doing research that has important policy ramifications, especially when economic stakes are high, deserve extraordinary protection lest such fields of inquiry become a "no-man's land" for the best minds among us.

Second, the proposals are not designed to chill debate, but rather to prohibit extraordinarily destructive and highly personal attacks on individuals who can defend themselves only through significant sacrifice. Far from depriving potentially injured parties of a fair opportunity to counter the merits of research, these proposals are carefully aimed at eliminating additional, duplicative alternatives that cause scientific misconduct charges, and state public records statutes have all been used strategically to intimidate researchers and delay or halt their research. In fact, most of these legal tools arguably invite abuse, because even if the underlying petition is ultimately determined to be unfounded, such challenges are effective in wearing down researchers and delaying their research. Few sanctions are in place to deter abuse of any of these procedures.

In some cases, the best recourse may simply be to repeal these tools altogether. In other cases, the courts or administrators who preside over challenges to public science must be aware of the incentives and potential for abuse and become more suspicious of misconduct charges, subpoenas, and open records challenges when a special interest is bringing the claim and stands to profit from the delay and other interference the request might cause. Safety zones that protect disinterested scientists from harassment, as discussed earlier, may also be necessary to ensure that researchers do not find their research activities halted or diverted as a result of these attacks.

At the very least, hefty sanctions should be levied for abuse of these processes, similar to the sanctions levied for violations of the ethical rules now imposed on other professions. Individual scientists should be entitled to recover both compensatory and punitive damages for harassment. Complainants should also be required to pay for the agency costs associated with responding to challenges ultimately judged not to be meritorious. In the process of developing implementing regulations for the Data Access Act, the scientific community convinced the White House Office of Management and Budget (OMB) to include a provision requiring the requestor to reimburse nongovernmental scientists and other researchers for outof-pocket costs incurred in responding to data requests. Similarly, the Freedom of Information Act requires requesters to pay search fees and copying costs. This internalization of processing costs could provide a further disincentive for wasteful requests.

Expanded Public Funding for Scientific Research

Greater government support of research is among the most important reforms needed to prevent science from being captured by special interests. Such support would solve several problems at once: It will avoid the suppression and bias that plague private research while simultaneously producing much needed knowledge on scientific questions that are fundamental to environmental and public health regulation. Conversely, without a strong federal presence, the Environmental Protection Agency (EPA) and other regulatory agencies assigned to protect public health, safety, and the environment will remain dependent on the private sector for much of the science that informs regulation. This source of information is far from reliable.

The most critical area for government investment is greater support of research that advances our understanding of how chemicals and activities affect health and the environment, such as mechanistic research. This type of research serves as the foundation for regulation. Because it entails considerable scientific discretion, it should be performed by disinterested government or federally funded academic scientists who are not influenced by sponsors or financial incentives. Moreover, this type of research often informs a number of overlapping regulatory programs and is not tied specifically to one regulated party's product or activity. Since mechanistic research is dedicated to better understanding the extent of harm caused by industrial products and pollutants, however, it is only fair that industry help finance it. To support expanded research, those who produce potentially risky products or engage in polluting activities should to pay a fee or tax to support basic environmental and health research.

Proposals to increase government support for regulatory research and to fund a portion of this work through a fee or tax on industry will undoubtedly encounter fervent political opposition. The fact that urgent calls for increased government support for environmental and health research from prominent scientists has not led to changes in funding reinforces the possibility that the scientific community alone cannot accomplish reform in this important area. Such resistance arises in part from the perception that scientists who lobby for increased funding of environmental and health sciences are self-serving. Regulated parties may also lack enthusiasm for increased funding of regulatory science because the research could lead to increased liability and regulatory requirements if it suggests that harms are worse than supposed. In relation to the status quo, pervasive uncertainties are likely far better than what increased research might reveal.

More Aggressive Government Oversight of Private Research

Even with greater government financing and corresponding protection of public science, private sector research will remain an important source of information for regulation. The private sector possesses basic information about their products and processes and can conduct tests at an early stage in production more cheaply than their public sector counterparts. More vigilant government oversight would ensure that private sector research is shared promptly with regulators and is not subject to sponsor control that intrudes on scientific independence. Several additional reforms are needed to make such oversight effective.

Preserving Disinterestedness through Conflict Disclosure

Most agencies fail to require conflict disclosures from researchers funded by private sponsors when their research is submitted for regulatory purposes. This laissez faire approach to research can be corrected, in part, by requiring researchers to provide conflict disclosures similar to those used by the best international biomedical journals. Specifically, scientists providing research or analyses to regulatory agencies and other decision-making bodies should be required to sign a conflict form specifying the extent of financial and sponsor influence on the research. In these forms, researchers should disclose financial and other conflicts of interest that might bias their work, as well as contractual provisions limiting their rights to publish their findings without the influence or consent of the sponsor. When scientists conduct research under the promise that sponsors will have the opportunity to review and even censor potential publications in advance, that fact should be disclosed as well.

These mandatory disclosures will benefit the public, policy makers, and the media by making it easier for them to assess the objectivity of individual research projects. Requiring standardized disclosures would also assist scientific colleagues in evaluating studies when they serve on advisory boards or are otherwise involved in reviewing regulatory science. Finally, mandatory conflict disclosures would reward sponsors who relinquish control over the design and reporting of their sponsored research, distinguishing them from sponsors who insist on controlling the design, methods, and reporting of research results.

Greater Access to Private Data

The Data Access Act requires publicly funded researchers to make available all of their underlying data, including lab notebooks. There is no equivalent requirement that applies to privately sponsored research. This double standard erects unwarranted barriers to the public's evaluation of their research. These barriers should be eliminated so that the science supporting regulation is accessible to other experts and the public at large, regardless of whether it is publicly or privately produced.

The first and most obvious reform is to extend the Data Access Act apply to all research supporting regulation, not just research that is publicly funded. As mentioned earlier, the Data Access Act exempts privately funded research from these public access provisions. Second, to limit the opportunities for actors to conceal adverse information through nondisclosure contracts, by sealing litigation records, or by claiming various legal privileges, Congress or public health agencies should require mandatory disclosures of health and safety information used to formulate public policy. Already, four separate statutory provisions require actors to report adverse effects under relatively narrow circumstances. By providing broader and more specific requirements for reporting under these same provisions, the federal government could minimize opportunities for actors to dodge or delay adverse information reporting, while simultaneously enlarging the circle of actors covered by reporting requirements.

To ensure that all private research that has a bearing on regulation is shared with regulators in a timely way, a registry of safety-related studies is also necessary. This registry would include, at a minimum: every study that is initiated to test safety or efficacy; the findings of that study, whether preliminary or final; and an explanation of the protocol used to conduct the research. Despite disagreements on the precise requirements, there is widespread consensus on the need for such a public registry of private regulatory research.

Preserving Scientific Honesty and Transparency

The overriding problems with scientific honesty and transparency are produced by understandable but counterproductive efforts by agency staff and affected parties to obscure controversial value choices by making them appear scientifically ordained. Both natural resources and public health agencies face a number of overlapping reasons to present science as the main determinant for policy decisions when in reality science can provide only partial guidance.

In the short term, the most effective antidote to the transparency problem is for policy-makers to develop a more sophisticated understanding of the thin but essential lines that divide scientific analysis and policy, especially with respect to difficult decisions involved in taking action in spite of pervasive scientific uncertainty. Scientists, for their part, must resist strong temptations to blur and cross those lines, achieving influence at the expense of independence. Regulators must also resist the strong, even overpowering, temptation to insulate their decisions from attack by pretending that, in effect, the science "made me do it." Finally, the judiciary has a role to play in reversing agency decisions that are misleading about where science ends and policy-making begins. Some courts have already interpreted administrative law to require agencies to be clear about the justifications for their regulatory choices. This approach to judicial review could be advanced more generally. There are countervailing dangers with such an approach, however, since courts are likely to vary markedly in the criteria they apply in determining whether agency statements of basis and purpose are sufficiently clear. Indeed, some courts might use this basis for reversal as an excuse to hold up

regulatory projects with which they do not agree. Therefore, the role of the courts needs to be reserved for the worst examples of agencies overstating the role of science in supporting policy outcomes.

In the international trade arena, a comprehensive reform of the prevailing standards for resolving trade disputes should also be considered. International courts resolving trade disputes sometimes interpret trade agreements as requiring that countries abandon their own stringent health and environmental regulations unless they can demonstrate that those requirements are mandated by science. But in virtually all these cases, nations formulating such regulations have combined their understanding of the underlying science with strong policy choices.

Failure to recognize those justifications for regulatory decisions is offensive to the country and damaging to science. Therefore, the text of trade agreements should be amended to recognize that science alone does not determine the stringency of domestic health and environmental regulations. Once the country challenging the regulatory controls has explained its objections, courts should adopt explicit rules that recognize the limitations of science in resolving trade disputes, deferring to domestic policies and value choices where necessary.

Judicious Peer Review

Policy makers need to reconsider their at-times naïve expectation that additional peer review can only be a positive development. Requirements ostensibly designed to ensure adequate peer review of regulatory research are vulnerable to strategic deployment and politicization. Indeed, one of the most important downsides of regulatory peer review is its use in situations where it is likely to do more harm than good. As the scientific community indicated in their comments on the 2003 OMB proposal for peer review, indiscriminate peer review requirements can introduce bias and error into regulatory science. Given the politicization that can infiltrate peer review processes, the burden of demonstrating the need for additional layers of peer review should fall squarely on those advocating them.

The law gives agencies the opportunity to conduct peer review behind closed doors if they hire their reviewers as "consultants," undercutting transparency and public accountability. The law has also failed to require agencies to disclose when they have waived the requirement that a reviewer is free of conflicts of interest, giving agency officials the opportunity to create stacked or imbalanced panels. Finally, the law does not require agencies to document whether and how they have ensured that a peer review panel is adequately representative of the larger, disinterested scientific community.

Weighing All Evidence

A final and more extensive set of reforms is needed to encourage decision makers to take advantage of all available evidence using a "weight of the evidence" approach, in contrast to the corpuscularization and censoring of individual studies that has become increasingly prevalent in both the courts and the agencies. Several recent judicial rulings excluding expert testimony are fundamentally at odds with approaches that scientists themselves take to similar evidence. Lacking clear Supreme Court guidance on these issues, the lower courts' counterproductive approach to incorporating science into civil adjudications is likely to grow only more dysfunctional in the future. Viable solutions to these problems include a congressional amendment to the Federal Rules of Evidence to clarify the courts' role in screening expert testimony and more vigorous training of federal judges so they will better understand scientific practices, including methods of scientific inference.

The corpuscularization of science is less evident in the agencies, presumably because agencies enjoy more freedom in weighing all evidence without concerns about juror confusion or the diversion of scarce judicial resources. Nevertheless, recent efforts to use tools like the Data Quality Act to exclude or even censor research from public data bases and decision making processes has become a worrisome development. Particularly given the limited research available to inform regulation, the prospect that some of it might be singled out and excluded because of a flaw or weakness not only violates principles of good scientific practice, but further reduces the scant research that is available to inform regulatory decisions.

Conclusion

T is no small irony that just as public health and environmental decision makers need reliable science the most, the legal system continues to tolerate the suppression, deconstruction, and underproduction of valuable research that informs regulation. There are important reasons why regulatory proceedings must be designed to afford affected parties an opportunity to present their views. Yet as the issues involved in such proceedings become more complex and the financial stakes increase, these opportunities are being used strategically to

slow decision making. Scientists have become targets of attack because impugning their reputations and discrediting their research allows adversaries to argue that their findings should be ignored.

The principles of good scientific practice underscore just how counterproductive these assaults have become and provide a benchmark for distinguishing legitimate advocacy from illegitimate distortion. No one would argue that science should be dependent on special interests; no one would suggest that scientists should suffer attacks on their professional reputations simply because their research is threatening as an economic matter; and no one would urge that scientific research that advances the public interest should be suppressed. Yet the legal system permits, and often encourages, the violation of these principles with resultant harm to science and policy.

Over the next several years, our society will be forced to confront the implications of evidence that human activities are causing the earth's climate to change, as well as dire predictions that oil will run out in less than a century. Debates will continue over the toxicity of ubiquitous pollutants such as mercury, the damage caused by nutrient loading of surface water, the use of scarce potable water resources, and the disruption of ecological patterns such as sharp decreases in the worldwide population of amphibians. It is difficult to think of a time in U.S. history when we have needed science more.

About the Center for Progressive Reform

Founded in 2002, the Center for Progressive Reform is a 501(c)(3) nonprofit research and educational organization dedicated to protecting health, safety, and the environment through analysis and commentary. CPR believes sensible safeguards in these areas serve important shared values, including doing the best we can to prevent harm to people and the environment, distributing environmental harms and benefits fairly, and protecting the earth for future generations. CPR rejects the view that the economic efficiency of private markets should be the only value used to guide government action. Rather, CPR supports thoughtful government action and reform to advance the well-being of human life and the environment. Additionally, CPR believes people play a crucial role in ensuring both private and public sector decisions that result in improved protection of consumers, public health and safety, and the environment. Accordingly, CPR supports ready public access to the courts, enhanced public participation and improved public access to information. Direct media inquiries to Matthew Freeman at mfreeman@progressivereform.org. For general information, email info@progressivereform.org. Visit CPR's website at www.progressivereform.org. The Center for Progressive Reform is grateful to the Beldon Fund and the Deer Creek Foundation for their generous support of its work.



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Wendy Wagner is the Joe A. Worsham Centennial Professor at the University of Texas School of Law, 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, and she clerked for the Honorable Judge Albert Engel, Chief Judge of the U.S. Court of Appeals for the Sixth Circuit. Before entering academia, Wagner served as an honors attorney with the Environmental Enforcement section of the Environment and Natural Resources Division of the U.S. Department of Justice, and as the pollution control coordinator in the Office of General Counsel of the U.S. Department of Agriculture. Wagner teaches courses in torts, environmental law and regulation. She is a member scholar of the Center for Progressive Reform.

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. Professor Steinzor joined the faculty in 1994 from the Washington, D.C. law firm of Spiegel and McDiarmid. Before joining the firm, from 1983 to 1987, she was staff counsel to the U.S. House of Representatives' Energy and Commerce Committee's subcommittee with primary jurisdiction over the nation's laws regulating hazardous substances. She is a board member of the Center for Progressive Reform.

Rescuing Science from Politics

"These are difficult times for science in the zone where it converges with public policy.... [S] cience 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."

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"This compendium by some of the nation's top philosophers and legal scholars provides a chilling portrait of the heavy burdens on the scientific enterprise that have evolved over the past decade. Science remains an exquisitely social institution, with human fragilities, strengths, and follies. The marketplace of ideas is fettered by competing political interests. Democracy rests on an informed public that freely consents to be governed. This book reveals the precarious nature of scientific information on which any democratic society must depend."

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Mark S. Frankel, Ph.D., Director, Scientific Freedom, Responsibility & Law Program, American Association for the Advancement of Science

"This book begins with a sobering prologue by Science magazine editor-in-chief and former FDA commissioner Donald Kennedy alerting us to the dangers posed by the increasingly ruthless tactics used by powerful opponents to health and environmental regulations. The book proceeds with detailed example after example showing how opponents to governmental protections have engaged in deliberate and pernicious efforts to subvert the legitimate scientific process for their interests or that of their client and illustrating the Orwellian manner in which the concept of 'sound science' has been corrupted by special interests. This book is a must-read for anyone who cares deeply about science or how it is being both used and abused in public policy."

Michael E. Mann, Director of the Earth System Science Center at Penn State University

Inside:

A Center for Progressive Reform White Paper

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

Excerpted from their new book by editors Wendy Wagner and Rena Steinzor

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