


**COVER  
STORY**

## Bad Science

*EPA's industry critics urge Congress and the new administrator to upgrade the science used in regulatory decisionmaking. They are right that science at the agency needs improvement — largely because these same self-interested critics overwhelmingly dominate research agendas and peer review*

LINDA GREER and RENA STEINZOR

*"The right to search for truth implies also a duty: one must not conceal any part of what one has recognized to be true." —ALBERT EINSTEIN*

**I**n Washington circles, "sound science" has become the remedy of choice for most of what ails the regulatory system. Whether it's arsenic in drinking water or particulates in the air, proponents of this seemingly simple solution argue that if the Environmental Protection Agency would only get more scientists on board and listen carefully to their sage advice, we could eliminate or at least reduce those excessive health and safety regulations that squander public funds, freeing scarce resources to address far more urgent problems.

EPA indeed practices a great deal of "bad science," but not in the sense asserted by its industry critics. What really upsets regulated industry is not the agency's supposed failure to consider "good science." Instead, the business community is driven to distraction by the fact that EPA must make most decisions on the basis of incomplete or uncertain science. However, as we explain below, Congress and EPA administrators have long recognized that the agency must act in the face of uncertainty to achieve its mission. While it is important to debate the issue of how to operate in the face of scientific uncertainty, it is unhealthy to allow that debate to obscure far more profound and troubling problems with scientific practice at EPA.

Although agency scientists do many tasks, one of their most important responsibilities is to select the salient developments among various research methodologies and findings. It is critical that they perform this function with objectivity. If their analyses are infected with bias, their scientific practice, by definition, is unsound. Unfortunately, bias and secrecy increasingly compromise not

only the work of EPA's in-house scientists, but also the ultimate failsafe intended to guarantee the soundness of agency science: peer review by the ostensibly independent and objective Science Advisory Board.

EPA science is dominated by self-interested industry research and peer reviewed by self-interested industry experts. The impact of these influences on the agency's rules is magnified by a lack of transparency about what pieces of research were used as the basis for important policy conclusions and why others were rejected. These problems are compounded by the fact that "science" at the agency is increasingly thrust into the role of final arbiter of all decisionmaking. Science cannot serve this purpose because the evidence on most issues considered by EPA is not definitive.

Two case studies support our diagnosis and suggest prescriptions for a cure. The first involves the inexplicable decision by EPA's Office of Research and Development (the primary location of in-house research and analysis) to revisit the toxicity profile of vinyl chloride and downgrade its estimate of the chemical's carcinogenic effects. The second involves a misguided opinion issued by the Science Advisory Board challenging an EPA staff conclusion that dioxin is significantly more toxic than first supposed. In both cases, experts working for chemical manufacturers dominated the process, managing to manipulate the pace, content, and final outcome of those deliberations.

At this point, readers may well wonder why, if the state of EPA science is as bad as we say it is, we don't agree with the critics who call for "sound science" — or "more science" or "better science," etc. Many reputable people, including several generations of EPA administrators, have recommended the expansion and elevation of science within



the agency, arguing that it is the crucial, missing element of wise decisionmaking. In fact, this spring Congress may consider a bill by Representative Vernon Ehlers (R-Michigan) that would establish a deputy administrator for science, to centralize administration and evaluation of the agency's research. (See "A View from the Hill," page 30.) But, as we indicate at the top of this article, the call for sound science collapses two separate issues into one.

The first of these issues is the appropriate role of science in EPA decisionmaking: should scientific evidence serve as the sole determinant — or gate-keeper — of agency decisions whether to regulate? The second issue concerns the fundamentals of what we would call "sound" science: when EPA evaluates available technical information, what core principles must govern its deliberations to ensure scientifically valid results? An explication of where we stand on the first issue will make it clearer why we are so concerned about the second.

**T**he unavoidable reality is that, despite widespread demands that EPA employ more science, the scientific information available to the agency rarely gives definitive answers to the difficult questions that confront it. Toxicology, epidemiology, conservation biology, ecology — these and related fields have yet to produce research results that map a straightforward path to uncontroversial policy solutions. In many, if not most, cases EPA faces the conundrum of implementing environmental statutes that command it to protect public health and the environment from risks that are unknowable, understudied, or poorly understood from a scientific perspective.

Congress appreciated this problem when it passed the statutes that define EPA's mission. Look at the language of the basic laws that protect the air we breathe and the water we drink. The Clean Air Act commands the agency to protect public health with an "adequate margin of safety." The Safe Drinking

Water Act requires the EPA administrator to regulate contaminants that "may have an adverse effect on the health of persons" where "there is a substantial likelihood" that the contaminant will be "of public concern" and present "a meaningful opportunity for health risk reduction." The Clean Water Act's central purpose is to "restore and maintain the chemical, physical, and biological integrity of the nation's waters," a phrase that has no defined meaning in science and requires human judgment.

As recently as last year, in *American Trucking Associations v. Whitman*, a unanimous decision authored by no less a regulatory skeptic than Justice Antonin Scalia, the Supreme Court reaffirmed Congress's Clean Air Act mandate that EPA protect public health with an adequate margin of safety and without regard to costs. Recognizing that this and similar mandates mean acting in the face of scientific uncertainty, Governor Christine Todd Whitman told the National Academy of Sciences in a speech delivered in 2000: "The absence of certainty is not an excuse to do nothing. . . . Environmental policy should always be based on the soundest information available at the time." The Earth Summit's action plan, Agenda 21, used similar language, admonishing all signatories (including the United States): "Where there are threats of serious or irreversible damage, lack of full scientific certainty

shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation." Under all these formulations, the crucial challenge is to ensure that the available science is factually correct and appropriately interpreted, and is then weighed with other factors in making final decisions.

Consider EPA's efforts to reduce cancers caused by exposure to toxic chemicals. Despite decades of research, cancer remains a mysterious disease. Because we do not understand how it is triggered in the body, no scientist can tell how many people will suffer cancer following exposure to a given level of a suspected carcinogen. Given these and other gaps in our understanding of the toxi-

***EPA mismanages  
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relied upon  
to be either  
objective or fair***

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## A VIEW FROM THE HILL

**Both Sides Are Right: EPA Needs To Improve Science Function**

The public discourse over how Environmental Protection Agency decisionmakers use science when determining controversial regulatory action or inaction always seems to fall into two camps. One view comes from the regulated community, who claim a controversial decision ignores the underlying science, which, in their view, shows the decision does more harm than good. Another view comes from environmental and public advocacy communities, who claim that the agency ignores the underlying science while letting the regulated community unduly influence the process. While these constituencies may forever diverge on the merits and effectiveness of a controversial decision, one theme is common to both camps — that science does not adequately imbue the regulatory decisionmaking process at the EPA.

The next stop for this debate is usually the halls of Congress and the judiciary, where these decisions are thoroughly scrutinized. Time and again I have heard my colleagues say, “What I really want is the use of sound science at the EPA.” Time and again I have seen court decisions overturn a regulation because it did not have a proper scientific foundation. That science is not infused throughout EPA’s regulatory process becomes a credible argument to wage both just and unjust legislative and legal battles over EPA action or inaction. Members of Congress and the judiciary do not have confidence that the agency uses science appropriately in its decisions. Science should not be used as a cudgel to win a battle, or as an afterthought to the regulatory process; rather it should serve as a decision’s foundation.

Congressional and judicial doubt about EPA’s process is borne out of both right and wrong motivations. However, it is not unfounded. Several independent reviews commis-

sioned by Congress and EPA have concluded that there are significant problems with how science is used within the agency’s decisionmaking structure. It is worth noting that these studies, for the most part, did not quarrel over the quality of the scientific research at EPA, but how it is used as proposed regulations move through the agency’s bureaucracy.

In 2000, the National Academy of Sciences concluded a series of four reports collectively titled *Strengthening Science at the U.S. Environmental Protection Agency*. The NAS reviewed how science was conducted at EPA and incorporated into the regulatory decisionmaking process. The report concluded that while the use of sound science is one of the agency’s avowed major goals, both intramural and extramural science should be more fully integrated into its management and decisionmaking structure.

The NAS concluded with this important statement: “The importance of science in EPA decisionmaking process should be no less than that afforded to legal considerations. Just as the advice of the agency’s general counsel is relied upon by the administrator to determine whether a proposed action is legal, an appropriately qualified and adequately empowered scientific official is needed to attest to the administrator and the nation that the proposed action is scientific.”

In a 1998 science policy report, approved by the House Science Committee and the full House, titled *Unlocking our Future: Toward a New National Science Policy Study*, I had reached similar conclusions about the use of science in decisionmaking — that science should not be used as a mere adjunct to the regulatory system; rather, it should be used at the beginning, middle, and end of an agency’s decisionmaking process — and about its proper place in an agency’s bureaucracy.

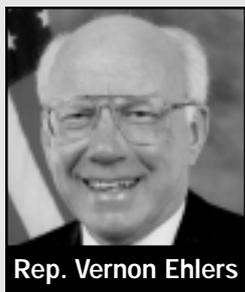
I introduced H.R. 64, The Strengthening Science at the Environmental

Protection Agency Act, to capture the two primary recommendations of the NAS report and meet the goal I laid out in the science policy report. First, the legislation would establish a new Deputy Administrator for Science and Technology to serve as an advocate for and reviewer of science at the most senior levels of the agency. Second, the legislation would convert the position of the Assistant Administrator of the Office of Research and Development to a set term and give that position the title of the agency’s Chief Scientist.

The Deputy Administrator position will bring a much needed change to the culture of the EPA and ensure that science has a higher profile in the agency’s decisionmaking process. This person would not only be accountable to the administrator for improving and overseeing science at the agency, but would also be accountable to Congress. This relationship would bolster Congress’s confidence in the appropriate role of science at EPA, and therefore in regulatory decisions.

The Deputy Administrator is also needed to coordinate research between the regulatory and scientific arms of the agency. A common problem with trying to ensure that science is involved throughout the regulatory process is that the head of the scientific arm of the agency, the Assistant Administrator for ORD, shares the same rank as the heads of the regulatory offices. The authors of the NAS report argued that since the new Deputy would rank higher than the existing AAs, this person could foster research relationships between ORD and the regulatory offices.

Furthermore, the Deputy Administrator could develop and oversee an agency-wide inventory of scientific activities. Various efforts to do this inventory have all died after fits and starts because there is no central science policy authority to administer this work. The Deputy Administrator would have the appropriate authority to ensure that the best possible peer-review and research-plan-



Rep. Vernon Ehlers

ning practices are used for all of the agency's scientific endeavors.

While the first recommendation of the legislation and the academy report is intended to increase the political clout that science has at the agency, the second recommendation, to establish a set term for the AA of ORD, seeks to decrease political pressures on this office. The report notes, "Although the political aspect of the Assistant Administrator's job often receives considerable attention, the most important aspects of the job are not political." Since the Deputy Administrator could bear many of the political pressures inside the agency, the AA for ORD could re-focus on his or her role as the agency's Chief Scientist and running a world-class scientific organization.

The tenure of an AA for ORD averages two to three years and is typically a lower priority appointment in new administrations. Under the current political appointment model, this position changes at least as often as the administration changes. The NAS noted that frequently changing goals, priorities, practices, structure, or funding are particularly disruptive to research organizations because of the long-term nature of research activities. Research endeavors cannot be easily stopped and then started again without significantly hurting productivity. A longer tenure for the AA would help insulate the office during changes in the administration, thereby providing more continuity for research conducted at the agency.

The NAS report captured the challenge that EPA's science mission faces in the future and the need to strengthen science at the agency by saying, "In the three decades since the U.S. Environmental Protection Agency was created, great progress has been achieved in cleaning the nation's worst and most obvious environmental pollution problems. Belching smokestacks and raw-sewage discharges are now scarce, and air pollution alerts and beach closings are more rare. EPA deserves a significant share of the credit for the accomplishments, but some of the most difficult and challenging tasks remain. Many past illusions about simple and easy solutions to environmental problems have been replaced by greater realization that environmental protection is a complicated and challenging mission." It is time that Congress and EPA rise up to meet this challenge by passing and implementing the provisions of H.R. 64.

*Vernon Elhers (R-Michigan) is Chairman of the House Science Subcommittee on Environment, Technology, and Standards.*

cology of common chemicals, EPA must act in advance of definitive scientific evidence in order to fulfill its statutory mandate to protect human health. If scientific evidence is called upon to resolve policy disputes where definitive answers are unavailable, science will lose the unique value it has to policymakers, converting the interpretations of scientific findings into an exercise in advocacy rather than an ongoing quest for truth.

Since such a broad and authoritative range of policymakers, over the course of several decades, have recognized that scientific uncertainty is inevitable, why is it so difficult to resolve the equally inevitable question of how much uncertainty is too much? Recent developments suggest that regulated industries use routine scientific data gaps opportunistically, by insisting that until EPA has "better science," it should not act. The infamous case of how much arsenic should be allowed in drinking water illustrates this phenomenon perfectly. In 1996, a unanimous Congress told EPA to change the 50-year-old standard that scientists conceded was not adequate to protect public health. The agency's in-house scientists worked diligently over a period of several years, supplemented with expert panels convened by the National Academy of Sciences. EPA conducted an exhaustive rulemaking that gave affected constituencies ample time to submit information. Cumulatively, the research demonstrated that EPA should lower the standard dramatically to avoid unacceptable adverse health effects, although the scientists could not reach a consensus on the appropriate numerical level. As is usually the case, there was no science that indicated precisely when exposure levels stop being "safe."

Operating competently in the face of remaining uncertainties, EPA Administrator Carol Browner was close to making a new standard final late in the Clinton administration when congressional appropriators invoked the specter of incomplete — and therefore "bad" — science in order to delay promulgation of the rule into the new administration. Browner nonetheless published the standard as final right before George W. Bush took office as president. Then, as the appropriators and their allies, mining interests and drinking water system operators in the West, had hoped, Whitman moved to delay the rule's effective date, declaring that she wanted to review the adequacy of the underlying science. Subsequently confronted

with consistent support from NAS experts for an even tougher standard, Whitman ultimately was forced to reverse her decision and allow the promulgated standard to go into effect. The arsenic episode is a powerful example of how, even when the National Academy of Sciences concludes that there is sufficient basis to lower allowed exposures to a toxic chemical, enough is never enough for those whose true intent is to hold back government intervention to protect public health.

Scientists are comfortable with data gaps and uncertainties. They view them not as “problems” but as future research agendas. It is policymakers who are plagued by these realities because they must make decisions in the face of uncertainty or stop trying to protect public health until some indefinite, far-off day. As the arsenic example reveals, the call for “more science” heard in the halls of Congress and from regulated industries often serves as nothing more than a ruse for indefinite delay on a rule, sometimes for decades. Given the political muscle of those who have mounted this campaign, scientists watching these developments from the sidelines would do well to take note: the fruitless quests for more and more definitive evidence from environmental policymakers unwilling to suffer political consequences for restricting pollution will inevitably make scientists the whipping boys for the consequences of regulatory gridlock. Unless we recognize that “science” cannot determine all that EPA is required by law to do, the agency will never have the breathing room it needs to craft wise policy.

As important as the issue of what role science can and should play at EPA is the issue of the fundamental principles that should govern the agency’s on-going scientific deliberations. In this long-overlooked area, we have found problems that would shock most traditional, academic scientists. The remainder of this article is devoted to demonstrating our case that too much of the science used by EPA is intrinsically unsound, straying far from the principles that have long served as the ground

rules of the discipline. Too often, EPA deems scientific evidence supporting more rigorous standards to be marginal and more readily accepts research suggesting that standards can be loosened. We begin with a review of the principles that define *truly* sound science and then apply those standards to the recent vinyl chloride and dioxin reassessments.

Science enjoys a unique reputation as an objective and dispassionate human endeavor. Because we consider it to be inherently unbiased, science is accorded a privileged role in deliberations about the organization of human affairs. Unlike many other human endeavors, scientists preserve the integrity of the scientific process exclusively through self-regulation. Although there are isolated examples of outside, lay investigations challenging the credibility of scientific research, the repetition of experiments by fellow scientists and objective peer review are the routine methods for uncovering mistakes and assessing when progress in understanding a topic has been made.

For centuries, scientists have engaged in their search for the truth by circulating the results of original research among their colleagues, first for informal discussion and then for formal, outside peer review. Colleagues first repeat work accomplished by others and then extend the experiments into additional areas. By exposing all of the underlying elements of one’s work to inspection by dispassionate peers, and revealing details sufficient to replicate results, researchers build on others’ successes and avoid others’ failures.

The transparency of results and the impartiality of conclusions derived from

those results are the indispensable foundation of science. Peer review and replication are the only reliable methods to ensure that experiments are conducted in a scientifically appropriate manner and that the results and conclusions presented by the researchers are supportable by the data generated. The peer-

***Congress and EPA administrators have long recognized that, as required by its core statutes, the agency must act in the face of uncertainty to achieve its mission***

review process is often challenging and difficult. But without it, results and conclusions cannot be accepted as valid.

The public trust in science depends on its unique reputation for objectivity. Scientists are expected to have opinions, but are also expected to resist bias. They are expected to reach careful conclusions and limit their conclusions to those supported by data. Or, to put this central principle more crassly, a scientist's quest for the truth and expression of opinion at the end of the quest should not be for sale or subject to control by self-interested sponsors, supervisors, the government, or any other entity with control over the scientist's career. Once financial considerations and legal constraints interfere with a quest for scientific truth, the public trust is broken, and science loses its power and authority.

Unfortunately, funding for the replication of experimental results and peer review of scientific research is most abundant in the context of topics that have captured public attention or, to put it another way, where the results of the research are of widespread economic or social importance. Claims that a scientific team had created cold fusion were immediately dissected because of the potentially monumental implications of such a discovery on the world's need for safer and cheaper energy. Similarly, discovery of a wonder drug to treat such widespread ailments as diabetes or stroke would inspire careful and extensive inspection — by the discoverer's competitors, potential allies, the larger medical community, and the government.

In a modern world overwhelmed by information and disinformation, extensive peer review or replication of certain other types of scientific findings is difficult to instigate, especially in the private sector. So, for example, efforts by a chemical manufacturer to prove that a given substance is not as toxic as EPA had originally assumed are unlikely to be scrutinized, much less validated, by other private sector scientists. Competitors have a low interest in refuting such results because they typically manufacture the same

chemical and like the way the results came out. Only producers of an arguably safer alternative have an economic incentive to second-guess, and they would likely place a higher priority on testing their own compounds.

For better or worse, these economic incentives mean that the government must play an active, rigorous role in reviewing and challenging scientific research developed by self-interested private parties. The National Academy of Sciences, the National Institutes of Health, and the Centers for Disease Control, to name just a few, have erected infrastructures of in-house scientists and external peer-review panels to undertake these functions. Unfortunately, these outside institutions have limited resources and too rarely are able to double check EPA's work.

Science at EPA supports decisionmaking through two main activities. In-house scientists assigned to the Office of Research and Development analyze the outside studies that are relevant to the issues at stake. They maintain the Integrated Risk Information System, or IRIS, an internationally influential compendium of "toxicological profiles" that describe the characteristics of

specific chemicals and set quantitative levels for safe exposures to them. Our case studies involve reassessments of long-standing toxicological profiles. The second activity is peer review, performed by panels of outside experts convened by the EPA Science Advisory Board and several other, smaller boards, such as the Science Advisory Panel, which focuses on pesticides. The SAB receives inquiries from agency staff working on regulatory issues and responds with advice based on its assessments of relevant scientific research. Our dioxin case study concerns an SAB peer review.

Many of EPA's in-house scientists and SAB experts serve the agency and the public with distinction, laboring diligently to produce informative and dispassionate science to guide policymaking. Too often, however,

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both enterprises flout the fundamental precepts of scientific research: first, the disclosure of methods, data, and calculations sufficient for appropriate experts to review the work or evaluate whether the conclusions reached were adequately supported by the study's findings and, second, conducting peer-review that is free of conflicts of interest.

Even a cursory look at the science EPA has practiced over the past decade shows that it has strayed far from the mandates of transparency and impartiality. Much of the science that EPA uses as a basis for decisions with far-reaching implications for public health is not peer-reviewed, and it is often based on confidential information or analysis. As a result, it would not be considered credible by disinterested researchers.

At the root of this crisis in credibility is the dominance of industry funding as the source of support for environmental health research. The vast majority of research on the toxicological properties of common chemicals occurs outside of the government (or sometimes in other agencies). EPA's toxicological profiles are based on this outside work. Corporate sponsorship does not, in and of itself, render such research invalid. But it does unquestionably put industry in the driver's seat for both the pace and focus of data development to support EPA rulemaking. More insidiously, it also puts industry in charge of deciding what information it would like to disclose and what analyses it would like to do, presenting ample opportunities for industry-funded researchers to keep underlying data and discrepancies confidential and to make strategic decisions as to whether to submit research studies for EPA's consideration.

**F**or several decades, the scientific community has achieved a rare consensus that three substances — lead, asbestos, and vinyl chloride — are not just extraordinarily toxic but produce well-characterized consequences of exposure, known colloquially as “finger-

print diseases.” Vinyl chloride, a volatile industrial chemical used since the 1930s to make plastics, is notorious for causing a rare and serious tumor, angiosarcoma of the liver, primarily among workers manufacturing and handling the compound. Studies have also linked vinyl chloride to a number of other cancers, including brain cancer.

In 1975, following a series of animal and epidemiological studies demonstrating the chemical's hazards, the Occupational Safety and Health Administration used the evidence on liver cancer as the basis for tough regulations limiting workplace exposure. These regulations resulted in sharp reductions in the prevalence of the chemical in the workplace and, as a result, the environment.

So it was a surprise when, in May 2000, EPA completed a 20-fold downgrading of the toxicological profile for vinyl chloride. EPA's decision to review vinyl chloride's toxicity was especially startling because the OSHA regulations, among other factors, have had their desired effect. At the same time that worker exposures have plummeted in the last decade and public exposure to the chemical has been minimal, industry has been able to continue using it, producing such goods as upholstery and waterpipes from its polymerized form. Given the demonstrated benefits of the regulations to both workers and industry, and the greatly lowered risk to the public, vinyl chloride should be off the list of chemicals requiring toxicological review, leaving the agency free to pursue more prevalent, less understood chemicals.

The decision to revisit the well-trodden ground of vinyl chloride toxicity appears especially irrational because EPA has faced extensive criticism for failing to assess the toxicity of many other chemicals produced and used in large amounts annually. EPA has *no* toxicity information on 43 percent of the nearly 3,000 organic chemicals produced or imported in amounts above one million pounds annually, and a full set of basic toxicity information is available for only 7 percent. Toxicological studies of these chemicals should be its overriding priority.

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Further, little new technical information on vinyl chloride's toxicity has become available since the agency's last review of the chemical, in 1994. Instead, EPA staff based the reassessment on animal studies completed in 1991 and earlier. Only one unpublished epidemiological study update was new, and it reached conclusions similar to previous analyses.

Although no changes in existing regulations were made when EPA made its decision, the revised characterization of the hazards posed by vinyl chloride exposure will prove very valuable to manufacturers of the chemical now engaged in toxic tort litigation with workers who contracted brain cancer following exposure on the job, as well as companies still facing liability at Superfund sites contaminated by the chemical. (Vinyl chloride has been found at one-third of the sites on the National Priorities List.) The decision will have these effects because EPA's toxicological profiles play the crucial role of informing regulatory and judicial decisions — not just domestically but internationally. Regretfully, given the potential implications of this change, the details of EPA's reevaluation of the science reveal biased technical judgment that resulted in poor selection of evidence practices and disproportionate reliance on information generated by self-interested parties.

EPA made two fundamentally flawed decisions in justifying the downgrade. First, the agency decided to confine its reassessment to statistically significant liver tumors, ignoring the various other cancers that frequently appear in both animal and epidemiological reports. Second, although the reassessment continued to rely on animal data, EPA decided to abandon certain default "safety factors" it has historically used when applying animal data to humans. Instead, the agency relied on a newly developed, "pharmacokinetic" model designed to predict an internal concentration of vinyl chloride in the human body.

Epidemiological studies of vinyl chloride

workers have generally reported the occurrence of many cancers besides liver angiosarcomas, including cancer in the lung, lymphatic and blood tissue, and the brain, with the last of particular concern. Richard Monson first found an excess of brain cancers in his study of Swedish workers in 1974, as did Irving Tabershaw and William Gaffey in 1974 and Richard Waxweiler in 1976. In 1981, W. Clark Cooper enlarged the Tabershaw and Gaffey study and found statistically significant increases in brain and

central nervous system malignancies. In a 1991 update of the Cooper study, Otto Wong confirmed statistically significant brain cancers. The evidence concerning brain cancers is sufficiently convincing that in 1989 the Vinyl Institute, an industry-funded advocacy group, acknowledged brain tumors as a valid concern in a letter to the California Air Resources Board: "For brain cancer, three out of five studies demonstrate statistically significant findings, although the results were somewhat variable. Positive findings occurred in studies with the greatest statistical power."

Written correspondence included in the EPA docket on vinyl chloride reveals that the Chemical Manu-

facturers Association, the trade association that recently was renamed the American Chemistry Council, became quite upset with Wong for publishing his positive results on brain tumors without first submitting the study to its scientists for review. Wong did the work under a research contract with CMA that apparently included a "prior review" clause giving it the right to comment before publication.

In what was likely a response to the trouble that the Wong update caused industrial users of vinyl chloride, CMA commissioned yet another study of the same worker cohort, updating some data post-Wong but also re-analyzing some of Wong's data in a way that raised questions about his conclusions. This study was never published in a peer-reviewed journal, but it was submitted to EPA

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and became a primary basis for its 2000 reassessment.

In justifying its decision to focus exclusively on liver cancer in recalculating the vinyl chloride potency factor, EPA cites this unpublished work, as well as two peer-reviewed research review articles. The unpublished CMA study was not, by itself, a sufficient basis for EPA to eliminate brain cancers from its list of concerns. To the contrary, this study also reported statistically significant incidences of brain cancers.

As for the two articles reviewing available research (as opposed to reporting the results of original research), the first was written by Sir Richard Doll in 1988, two years before the publication of the Wong study. Without the benefit of the Wong or subsequent epidemiological updates of vinyl chloride workers, Doll had raised questions about the strength of the data supporting brain tumors, but had concluded with the relatively mild statement: "There is too little evidence either to confirm or refute the suggestion that vinyl chloride might cause melanoma or cancers of the thyroid, brain, and lymphatic and hematopoietic systems." This equivocal conclusion from an outdated paper hardly provided a reliable basis for ignoring the numerous studies in EPA's decisionmaking docket that found statistically significant incidences of brain tumors. Indeed, Doll has cautioned against using epidemiological results to dismiss chemical hazards in this and other publications.

The other cited research review article was authored by Jan Storm and Karl Rozman in 1997, but it does not address the issue of brain or other tumors caused by vinyl chloride exposure. Rather, the paper compares various risk assessment extrapolation models used and proposed by EPA. Given the weakness of Doll's conclusion, and the inappropriateness of the Storm and Rozman citation, EPA is left without evidence to support its decision to limit its reassessment of vinyl chloride's carcinogenicity only to tumors of the liver.

**E**PA's second technical misstep was the decision to abandon the conventional approach used to apply animal data to likely human health effects. When scientists conduct animal studies, they expose the animals to increasing doses of a chemical, and then perform an autopsy on the animal to see how many tumors were generated at each dose. Because chemicals may take a different course within the bodies of rats, mice, and other creatures than they do in the human body, and may be metabolized at different rates, animal studies using traditional dose measurements can either overstate or understate the consequences of comparable human exposures. Up until recently, the best way to eliminate such uncertainties would be — hypothetically, that is — to intentionally expose people to different amounts of a chemical and then track the "fate and transport" of the chemicals within their bodies by drawing samples, taking biopsies of organs, etc. Such studies should be unthinkable for obvious reasons.

Pharmacokinetic models are an emerging, as yet experimental, alternative method designed to bridge this gap. Such models estimate internal concentrations within the human body by using a computer program to predict how fast the chemical is absorbed in the bloodstream, whether it reaches the brain, etc. The models then derive an "effective" dose for a given organ over the time that the human body metabolizes the chemical. If doses of vinyl chloride at X levels caused Y incidences of tumors in rats, but pharmacokinetic models show that humans metabolize the chemical more effectively than rats, and therefore ex-

perience lower internal concentrations, the model provides support for downgrading estimates of the chemical's carcinogenic effects on people.

The catch here is that pharmacokinetic models are at the cutting edge of the already highly uncertain science of environmental modeling as a whole. It is certainly true that reputable scientists are working to refine

*In justifying its downgrade of vinyl chloride, EPA cites an unpublished review and two reviews of technical literature, one outdated, the other irrelevant*

such models in order to better predict effects of exposure. It is also likely that, once they are developed, such models should allow us to better understand the correlation between internal concentrations of toxic compounds and adverse health effects. But at this point in the evolution of scientific understanding, these models cannot be validated with respect to exposures at environmentally realistic concentrations. This uncertainty means that pharmacokinetic modeling unquestionably does not put EPA in a position to remove default safety factors.

Mindful of these concerns, when EPA staff considered the application of pharmacokinetic models in a proposed reassessment of the toxicological profile of trichloroethylene, they made a concerted effort to compare several versions of the models, as well as to quantify the level of uncertainties in each model's estimates of liver, lung, and kidney tumors in response to the modeled doses. This analysis quantified uncertainties so huge (as high as 20,000-fold) that EPA staff insisted on continuing to apply default safety factors, thereby sharply curtailing their reliance on any of the models. This carefully qualified application of an emerging scientific methodology stands in stark contrast to the wholesale reliance on pharmacokinetic modeling results in the context of the vinyl chloride reassessment. Such extraordinarily high rates of uncertainty raises obvious concerns about modeling accuracy, as well as concerns about "model shopping" by researchers trying to find a model that gives a desired outcome rather than one that predicts outcomes accurately.

The general problems of pharmacokinetic models are severely compounded in the case of vinyl chloride by EPA's decision to confine its consideration of modeling to a single version developed by Harvey J. Clewell. The Clewell model was not validated for exposures that occur routinely in the environment. It thus could not and was not validated for its intended purpose — to accurately predict effects in humans. The inadequate verification of the Clewell model makes it a very poor

policy choice as a basis for the reevaluation of vinyl chloride toxicity. Furthermore, the Clewell model was confined to liver tumors, ignoring all the other tumors of concern. Using such a limited model to justify dropping safety factors for cancers other than liver cancer added insult to injury.

The fatal blow to the technical credibility of EPA's vinyl chloride decision is that industry scientists drafted the final decision-making document. The revised toxicological profile, known formally as the 2001 Vinyl Chloride Toxicological Review, is known in the world of science as a "technical review paper," consisting of a literature collection, analysis, and interpretation. Vinyl chloride is but the first of four chemicals where industry is drafting the review. (The others are styrene, ethylene oxide, and toxaphene.)

In the scientific community, it is widely understood that technical reviews, like similar efforts in other disciplines, are heavily influenced by an author's subjective judgment regarding such issues as which studies to include, which studies to declare flawed or irrelevant, and which methodologies to favor. The danger of tainting a technical review with the unrestrained bias of its author provoked the prestigious *New England Journal of Medicine* to prohibit "editorialists and authors of review articles" from having "any financial connection with a company that benefits" from the subject of the article. The *Journal's* decision was announced in a lengthy editorial published in 1996 expressing mortification about its earlier publication of such a paper authored by two industry experts with obvious, but undisclosed, conflicts of interest.

**I**n theory, EPA's Science Advisory Board is where the buck stops on bad scientific practice within the agency, serving as a safety net to protect against the types of abuses that run rampant when the generation of scientific evidence and the

***The agency removed default safety factors in applying animal data by relying on an unproven computer program designed to model how a chemical behaves in the human body***

selection of salient research are both determined by industry. In reality, the SAB suffers from many of the same weaknesses that were manifest at the staff level in the vinyl chloride reassessment. Too often, the SAB operates in a context where self-interested research dominates the agenda of the outside experts recruited for peer review. The seriousness of these problems is exacerbated when studies important to EPA, such as those specifically delineating the potency of a certain carcinogen, have not been published in a peer-reviewed journal and therefore were never subject to an objective evaluation by a disinterested party.

Last June, a General Accounting Office report evaluating the SAB review process found that “to be effective, peer-review panels must be . . . free of any significant conflict of interest and uncompromised by bias.” In the report, “EPA’s Science Advisory Panels: Improved Policies and Procedures Needed to Ensure Independence and Balance,” GAO auditors examined the procedures employed by SAB staff to ensure panel effectiveness. GAO found that, despite the requirements of the Federal Advisory Committee Act, agency staff often failed to obtain conflict of interest disclosures from candidates and that EPA did not have either the information or processes in place that would preclude the appointment of panelists with direct conflicts of interest. The result of these omissions is the appointment of too many panels disproportionately influenced by industry experts motivated to clear chemicals of prior findings of toxicity. Many SAB panels escape this fate, but enough suffer from these ethical lapses to undermine the credibility of the entire EPA peer-review process.

One example of these problems is EPA’s star-crossed effort to strengthen public health standards for arsenic in drinking water, mentioned earlier. An SAB review panel took on no less an entity than the NAS arsenic panel. NAS experts typically spend two or more years reviewing available science on an issue, and this particular panel had clearly

mastered the data before it recommended tightening the standard. In contrast, SAB panels too often make recommendations within a period of a few months and with many fewer world-renowned experts. Only after an additional NAS panel took the SAB panelists to task for flaws in its analysis did the SAB panel back off its contention that EPA’s in-house scientists had erred. Although this episode had a happy ending, the SAB arsenic toxicity panel was part of the problem, not the solution, of this contentious public health debate.

**B**ut perhaps the best case study of the weaknesses that increasingly overwhelm the SAB is its participation in the reassessment of dioxin, which is released by incineration of chlorinated materials and also by paper bleaching. Starting in 1990, EPA staff spent a decade pursuing claims that dioxin was not as toxic as initially thought, producing a final report consisting of several thousand pages that concluded the opposite: that dioxin is even more toxic than the agency’s original estimates.

But an SAB panel appointed to peer review a draft of the study concluded in 2001 that in-house scientists had exaggerated the risks posed by exposure to the chemical. These assertions not only challenged the competence of the EPA staff who wrote the report, they erected a barrier to its release. During the public outcry that followed, it emerged that a large number of panel members had worked for — or received funding from — industries with a clear financial stake in the outcome of the deliberations.

For example, John Graham, a political scientist appointed to the panel, served as director of the Harvard Center of Risk Analysis, which receives extensive funding from companies facing liability for dioxin contamination of the environment. (Graham now serves as head of the White House’s Office of Information and Regulatory Affairs, which evaluates the

*After a decade of research pursuing claims that dioxin is not as toxic as initially thought, agency staff concluded that the chemical is in fact more toxic than original estimates*

costs and benefits of rules before they are published as final. The Natural Resources Defense Council opposed his nomination.) Appointment of a second panelist, Dennis Paustenbach, was questioned for similar reasons. Research by the Center for Health and Environmental Justice found that fully a third of the panel members received organizational support from 91 dioxin-producing companies. As a result, members of Congress accused EPA of setting up a panel dominated by industry bias. Witnesses at the public hearing on the results of the SAB peer review repeated these charges, questioning the credibility and the integrity of the panel.

Yet the clear appearance — and likely existence — of impropriety is only a threshold conclusion that should prompt further investigation. Regardless of the panelists' links to self-interested industries, the crucial point is the soundness of the SAB's assertion that EPA staff did not consider alternative scientific theories about dioxin's toxicity and, as a result, overstated the degree of scientific certainty regarding the overall toxicity of the compound. Stung by these attacks, William Farland, the acting deputy assistant administration in charge of the reassessment, took the unusual step of entering the fray. In defending the agency's work, Farland provided the SAB's Executive Committee, which must ratify all SAB panel reports, with nine pages of blistering comments on the panel's draft. He said that the review contained "numerous errors or distortions of fact" and that its major conclusions "defied logic." He added that the panel's report was internally inconsistent with the discussion of the science held in open session at prior review meetings; was inconsistent with advice provided by SAB panels on earlier versions of the reassessment; and was inconsistent with EPA's general risk assessment procedures.

Farland was particularly critical of the SAB's review of the dioxin risk assessment methodology, asserting that the panel had a poor understanding of both EPA guidance on risk assessment and the research available

on dioxin. For example, the panel had questioned whether a "linear dose response curve" for cancer was warranted because there is some evidence that dioxin is a promoter of the disease, rather than an initiator. A linear dose response curve is a line that runs all the way down to a dose of zero. It is used when evidence is inconclusive as to whether there is a threshold dose below which exposure does not cause cancer. In the

interest of safety, where data are inconclusive, a linear curve assumes that any dose — no matter how small — will lead to an adverse health effect.

The SAB panel argued that exposure to dioxin exacerbates the growth of cancerous cells that have already begun to grow in the body as a result of another cause, but does not itself initiate the cancer. In other words, there is a threshold, the panel said, below which dioxin exposure is unimportant because some other factor is causing the disease. The panel further complained that use of a non-linear model would have resulted in a significant downgrade of the chemical's overall toxicological profile because it would have shown that small

doses of the chemical are not harmful. "Belief is one thing," Farland responded, "data is another." EPA policy commands the use of a linear model when use of alternative models cannot be justified from the available data, as was the case here. There were neither data nor policy justifications to diverge from a linear default model for dioxin's cancer effects.

Similarly, Farland was incredulous that the SAB panel gave credence to the possibility that very low doses of dioxin were actually beneficial, resulting in decreases in cancer rates. The panel had urged EPA to give this counter-intuitive possibility additional scrutiny. However, EPA's extensive data showed that dioxin could cause adverse health effects at the relatively low levels that already occur in the general population. Farland pointed out that animal data are unequivocal on this point and that human data, though limited, are also compelling.

***The SAB attacked the staff report. It said that dioxin does not initiate cancer but promotes existing cancers. And it said that low doses of dioxin might actually be beneficial***

Ultimately, the controversy triggered by the panel's report on dioxin compelled the SAB Executive Committee to substantially rewrite the summary and conclusions of the report, producing a credible outcome — but illustrating the perils of lax ethical rules in lower-profile proceedings. Recognizing that this incident and the GAO report threatened the credibility of the SAB itself, the Executive Committee agreed to set up a subcommittee that will recommend reform of SAB policies and procedures on bias and conflict of interest.

**A**s it crafts these policy and procedural guidelines for release later this year, the SAB will undoubtedly consider the approach taken by 12 medical journals that have faced equally serious challenges to their reputations as sources of credible life science in the context of pharmacology, a discipline that is the genesis of environmental toxicology. The crisis in the medical community started simmering in 1988 when the Boots Company, a British pharmaceutical manufacturer, hired Betty Dong, a researcher at the University of California in San Francisco, to do a research study designed to demonstrate the superiority of the company's bestselling thyroid medication, Synthroid, in comparison to generic versions. With Synthroid sales in the \$600 million range in the United States alone, Boots had a large stake in demonstrating that generic versions are not "bioequivalent," and therefore should not be substituted for its name brand. To Boots's horror, the study found that the generics were in fact bioequivalent. The company then spent four years working to discredit the research, raising a litany of technical objections to its protocols and their implementation. Despite this campaign, extensive investigation upheld the soundness of the study.

In 1994, in the midst of this maneuvering, Dong submitted an article based on the

study to the *New England Journal of Medicine*. The article, accepted for publication following peer review by five outside experts, explained that the finding of bioequivalence meant U.S. health care costs could be cut by \$356 million annually if patients substituted generic medications. The company immediately threatened to sue Dong, citing a provision in her research contract that required her to obtain the company's written consent before publishing. The University of California began to waver in its support, and Dong pulled the piece, triggering an intense investigation by the publication.

The *Journal* finally published the article in 1997, along with an article reporting that in a survey of 2,100 life science researchers, nearly 20 percent reported having delayed the publication of research results for more than six months. Of the 410 researchers willing to report such delays, 28 percent said the reason was "to slow dissemination of undesired results." A subsequent Carnegie Mellon University canvass of contracts at university-sponsored research centers

found that 35 percent of signed agreements allowed sponsors the right to delete information from publication; 53 percent allowed publication to be delayed; and 30 percent allowed both. To medical journal editors, these troubling findings were the unavoidable byproduct of sharp increases in industry funding and increased blending of business interests and science at both the individual researcher and university levels.

What are the implications of this all-pervasive industry funding of university research? In a recent article published in *Risk Policy Report*, David Clarke, a longtime observer of the controversies involved in toxic regula-

tion who now participates in the sound science debate on behalf of the American Chemistry Council, argued that the simple fact that a study is funded by industry does not mean that it is wrong, or even biased. Regardless of whether you accept this counter-intuitive argument that money does

***The agency must reserve for its staff the sensitive task of writing toxicological profiles and should never again delegate such work to self-interested industry scientists***

not buy influence, it is certainly true that industry-sponsored research will remain the primary source of information on toxics for the foreseeable future and that effective reform must be premised on that fact.

Empirical studies have documented the correlation between funding and results. For instance, one analysis found that 98 percent of industry-funded research reported positively on the efficacy of specific drugs, versus 79 percent of independent research. Because we cannot eliminate our dependence on such research, but suspect that funding may affect the outcome, all the other checks and balances — from disclosure of funding sources to peer review — become all the more important.

Last September, in reaction to stories and statistics like these, the editors of the world's leading medical journals announced that they would no longer "review or publish articles based on studies that are conducted under conditions that allow the sponsor to have sole control of the data or to withhold publication." The editors promised to release detailed guidelines on this prohibition, and on their intention to require authors to disclose conflicts of interest related to a study, in early 2002. "I am not against pharmaceutical companies," Catherine DeAngelis, editor of the *Journal of the American Medical Association*, told the *Washington Post*. "What I object to is the use of my journal as an advertisement mechanism rather than a vehicle for the distribution of sound medical science."

The journals' new policy is expected to have a profound effect on the way medical research is funded and conducted. The journals are crucial to the dissemination of pharmaceutical research among the practicing physicians who serve as purchasing agents for all prescription drug sales. Television and print advertising are poor seconds to the influence they wield. Although these same reforms are necessary in the arena of environmental research, they may prove much harder to accomplish, especially given the fundamentally different economic incen-

tives at work in investigations of the toxicological properties of common chemicals. In too many cases, chemical manufacturers have powerful incentives *not* to know whether their products are toxic; ignorance may help them sidestep liability and increased regulation. Unlike medicine, where publicizing efficacy is the quid pro quo for selling drugs, documenting the possible consequences of chemical exposure can only have a negative impact on sales.

In fact, the only kind of scientific inquiry with potentially substantial financial benefits is research that exonerates chemicals — such as the two examples featured in our case studies.

As Wong's experience with the American Chemistry Council shows, the corporate funders of investigations into chemical toxicity, like the pharmaceutical companies, impose restrictive arrangements on their grantees. Given the dearth of government funding for such basic research, and the fact that it is unlikely to bring prestige to any truly independent research institution, these restric-

tions are likely to persist in the absence of strong action by EPA and other regulatory agencies.

**S**ix categories of reform are needed to restore the credibility of science at EPA. First, the agency must focus on encouraging research that will close the gap in our understanding of the toxicity of common chemicals, rather than spending scarce resources on efforts to exonerate chemicals with a proven track record. Second, EPA must refuse to consider, in any context, the results of research that does not satisfy the central tenets of sound science: full disclosure of underlying data and no sponsor interference with the design of the study or release of results. As with the medical journals, EPA should disclose the sponsor of the research for all the key articles it relies upon for its decisionmak-

***EPA should establish a peer review process that eliminates panels with actual or potential conflicts of interest and balances competing scientific views***

ing. Third, EPA must establish a peer review process that eliminates panelists with actual or potential conflicts of interest. Given the problems reported by the medical journals, it cannot rely exclusively on peer review by others, even peer-reviewed articles that have been published. Fourth, since many scientists are biased in the sense that they have strong opinions, peer-review panels must be balanced with regards to scientific view. To achieve the crucial objective of preventing the domination of peer review by one or another self-interested constituency, EPA must conduct expanded recruitment of experts who have no conflicts and represent a full range of scientific view. Fifth, EPA must reserve for its staff the sensitive task of writing toxicological profiles and should never again delegate such work to self-interested industry scientists. Last, increased government funding for basic research would go a long way toward making the first five reforms possible.

To implement the first reform, EPA scientists should make it their overriding priority to compile a research agenda based on such factors as the prevalence of a chemical in commerce and in the environment; the seriousness of its suspected adverse health or environmental effects; and the state of our ignorance of the chemical's toxicological properties. Once a list of priorities is developed, and the expense of further research can be estimated more accurately, the agency will be in the position to convince the executive branch and affected industries that further research is urgent.

Ending any consideration of studies that breach core principles of research ethics is the easiest reform to implement, and is most akin to the joint policy statement announced by the world's leading medical journals. Indeed, it is hard to imagine anyone arguing the converse of this proposition: namely, that EPA staff should rely on research findings to revise regulatory requirements even when they have never seen the underlying data that supports those conclusions. This principle is particularly important in the context of stud-

ies funded by entities with a financial stake in the regulatory decisions that the studies ostensibly inform, although it should by rights apply across the board to any piece of scientific evidence offered for EPA's consideration. It is worth noting that the government gives agencies specific powers in this regard for studies that they fund. Office of Management and Budget Circular A-110 specifies that an agency is entitled to unrestricted access to grantees' records related to the award, including research data. To accomplish this reform, EPA should require that authors of studies submitted for its consideration sign comprehensive statements regarding their funding sources and the limits imposed by their research contracts. EPA should publicize the sources of funding for each major study it relies upon for its decisions.

As for the troubled peer-review process, EPA should not recruit candidates with actual or potential conflicts of interest to serve on SAB advisory committees (including subcommittees) or any other panel of scientific experts convened to provide EPA with advice. Conflicts of interest should encompass any financial interest that would impair the individual's objectivity, including such characteristics as stock ownership or employment by an organization with a direct financial interest in the outcome of the review, such as the award of research grants. If the prohibition on nominees with conflicts of interest makes it impossible to convene a panel consisting of members with sufficient expertise to give EPA the advice it is seeking, the administrator should waive such conflicts in written, individualized determinations subject to public review. EPA may include candidates with actual or po-

tential bias regarding the issues to be addressed by the panel, provided that the panel's overall membership is balanced. In this context, bias should encompass any predisposition resulting from professional affiliation, previous work, social relationship, or conflict of interest that could influence the

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candidate's views of the information or policy alternatives at stake in the panel's deliberations.

At the moment, candidates for EPA peer-review panels and other scientific advisory functions are selected from an existing list kept by the SAB staff. The agency clearly needs to develop a larger pool of scientific experts qualified to serve on SAB committees and panels. Within legal constraints, the administrator should explore ways to compensate scientific experts at the prevailing market rate for their services, both to expand the pool of candidates and to eliminate the advantage of industry-funded scientists who are able to earn a living doing such work.

**T**he precautionary principle lies at the heart of the controversy over the role of science in the regulatory state. The principle means taking action to prevent harm to human health or the environment, even if the relationship between the cause and the effect is not fully established scientifically. As applied, it can mean taking preventive measures to reduce pollution; shifting the burden of proving the safety of polluting activities to those who wish to engage in them; or searching for safer alternatives to releasing the pollutant into the environment. Or, as Governor Whitman put it so well: "The absence of certainty is not an excuse to do nothing."

Some commentators have argued that application of the precautionary principle is essentially a policy choice, implicitly suggesting that scientists leave the room when such decisions are made. At the opposite end of the spectrum, conservative commentators argue that when science becomes uncertain, the only alternative is to work harder to make it better, forestalling regulatory action until a reasonable level of certainty can be achieved.

While both arguments are extreme, the second is transcendent at the moment and is likely to prove far more harmful to the cred-

ibility of science over the long run. By cloaking a decision not to act as a purely scientific judgment, scientists are saddled with the burden of being wrong, of failing to take protective action in the face of what emerges as a real threat. When the sources of financial support for additional research are obviously self-interested, the public will be left with the clear impression that science was sold to the highest bidder.

We cope with uncertainty in all aspects of modern human endeavor. The whole concept

of insurance is based on the proposition that we can try to predict the future on the basis of facts about the past, but in the end are willing to pay a fee to ameliorate the consequences if we end up among the injured. If we were certain what the future would bring, insurance would be unnecessary because we could either save funds to address the risk, or make plans to avoid the risk.

Similarly, as the United States becomes the world's dominant peacekeeper, we are constantly faced with the imperative of predicting the worst case scenarios that could occur in such situations and doing everything possible to ensure both the success and the safety of

our military forces. No public official would consciously decide to absorb more casualties in order to lower the costs of equipping our troops to cope with such scenarios, although those precautionary measures often are triggered by no more than an educated guess by experts.

Like insurance underwriting or defense, environmental regulation needs to encompass the best information available at the time a decision must be made. Suspending decisions until scientists tell us exactly what will happen makes no more sense than forcing people to self-insure or refusing to engage in long-term military planning. Only by acknowledging that it is the exceptional case where we will have definitive data can we hope to restore science to its rightful place in environmental decisionmaking. •

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