

**Statement of
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**Oversight Hearing:
The Impact of Science on Public Policy**

**The House of Representatives
Subcommittee on Energy and Mineral Resources**

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Chairman Cubin, Distinguished Members of This Committee. My name is David Michaels. I am honored that the Committee invited me to provide testimony here today.

I am a Research Professor of Environmental and Occupational Health at The George Washington University School of Public Health and Health Services. I served as Assistant Secretary of Energy for Environment, Safety and Health from 1998 to January 2001. The nuclear weapons complex is self-regulated. As Assistant Secretary, I had chief responsibility for protecting the health of workers, communities and the environment around the nation's nuclear facilities. I also ran a nuclear safety enforcement program, and had a fairly significant research portfolio.

I am also an epidemiologist. I've served on federal science advisory panels and I've peer reviewed a number of journal submissions. I have experience in the use of science in policy, from perspectives of both the scientist and the policy maker.

I am here to tell you that prescriptive proposals that attempt to manage the way government policy-makers use and interpret scientific data have the potential to damage the leading source of scientific information the world has ever seen: the US system of science research and education the American scientific enterprise.

I am going to briefly address two of these proposals: HR 1662¹, Congressman Walden's proposed legislation, and the White House's "Proposed Bulletin on Peer Review and Information Quality."² I will conclude with a proposal to improve the quality of science used in regulation.

Both are based on the flawed premise that peer review is the mechanism through which the validity of scientific information is assured. The scientific enterprise involves observation, experimentation, publication, dissemination and application, in repeated cycles. Peer review is but one component of this. Peer review used by scientific journals is not the same as the scientific reviews conducted by many agencies, and this is how it should be. There are substantial differences between science that is investigator-driven and regulatory science. As Sheila Jasanoff, one of the nation's leading thinkers on the use of science in public policy (and author of *The Fifth Branch: Science Advisors as Policymakers*) notes, there are significant differences between regulatory science and research science.

"The reliability and success of regulatory, or policy-relevant, science cannot and should not necessarily be measured according to the same criteria as the reliability and credibility of ordinary research science, which is investigator-initiated or 'curiosity-driven.' ...[T]he success of regulatory science includes its capacity to provide timely answers to pressing policy questions; research science operates under no comparable time pressures. Correspondingly, the procedures used to ensure the reliability and credibility may reasonably differ from one scientific context to another."³

The authors of HR 1662 and the White House Peer Review proposal are seeking to impose a science audit, and are erroneously calling it peer review.

I have deep concerns about HR 1662. This bill attempts to legislate what is good science, mandating, for example, that greater weight be given to certain types of data – “scientific or commercial data that is empirical or has been field-tested or peer-reviewed.” This bill’s definition of the “best” available scientific data mixes apples and orangutans – the three categories – empirical, field tested, or peer reviewed – are a meaningless taxonomy. But more importantly, legislating how a science policy maker weighs evidence is antithetical (and probably damaging) to the science enterprise itself. The freedom America allows its scientific enterprise is in direct contrast to the failed science of the former Soviet Union, where the politburo decided the definition of the best available science.

An example recently in the news may help illustrate my point. One case of mad cow disease is an example of field-tested, empirical data. In developing national policy around mad cow disease, should this one empirical case report outweigh a model that is not empirical, not field-tested, has not been formally validated, and in fact cannot be formally validated?

Secretary of Agriculture Anne Veneman has been very reassuring – telling us she was putting beef on her family’s Christmas dinner table. She has based much of her reasoning, both for what she feeds her family and for policy protective of both the American consumer and the beef industry, on a Harvard Center for Risk Analysis study entitled “Evaluating the Risk of Bovine Spongiform Encephalopathy in the United States.”⁴ Legislation like HR 1662 would require her to give less weight to this model, rather than letting her rely on the weight of all the best available science.

We all agree that scientific policy should be based on the best scientific data available. The Congress of the United States is infinitely wise in many ways, but it is scientists, not legislators, who should determine what the best scientific data are.

The White House Peer Review Proposal: Code Red in the Science Community

Similar warnings are being raised by many in the science community about the White House’s Peer Review proposal. If this proposal is implemented, all federal agencies would have to institute a cumbersome system of peer review. The proposal is problematic for the following reasons:

- There is no evidence that the guidelines are needed; the White House has failed to identify a single regulation that would have been improved if the proposed bulletin had been implemented;
- It is misleading to call the proposed procedures “peer review,” since they differ markedly from accepted practices of peer review in the scientific community;

- The proposed procedures are unlikely to improve the quality of regulatory science; and
- The proposal centralizes power over science-driven federal policies in the White House’s Office of Management and Budget, an agency with little scientific expertise, is likely to constrain public health officials from reacting quickly in times of national emergency; and result in delays in protecting the nation’s health, safety and environment;

Traditionally, the organizations that represent mainstream scientists and their research institutions have focused their Washington political efforts on research funding, avoiding involvement in policy fights which might be perceived as partisan. The peer review proposal has generated a remarkable level of opposition, which appears to be growing steadily. The American Association of Medical Colleges (AAMC), representing the nation’s schools of medicine, and the Federation of American Societies for Experimental Biology (FASEB) a federation of 22 scientific societies, sent a scathing letter of opposition to the White House, as did the Council on Government Relations, representing more than 150 leading US research universities.

Perhaps most surprising is the unusually harsh language used by NAS President Bruce Alberts. As the nation’s pre-eminent arbiter of science, the National Academy of Sciences chooses its battles carefully, and rarely joins the open opposition to major White House initiatives. Alberts warned that “the highly prescriptive type of peer review that OMB is proposing differs from accepted practices of peer review in the scientific community, and if enacted in its present form is likely to be counterproductive.”⁵

According to Donald Kennedy, the editor of Science Magazine, the White House peer review proposal is problematic in another way: it is fueling an “epidemic of doubt” – an erosion of public trust in science and scientists.⁶ Kennedy is not someone to raise this concern lightly: he is a giant in the scientific community, having held major posts in academia (Stanford University President) and government (FDA Commissioner).

It appears that the White House and other opponents of certain federal regulatory programs are trying to stack the deck, to shape the science to fit the desired outcome, under the plea for “Sound Science”. But the Science community sees through this, and recognizes this isn’t an argument over science; it is an argument over policy.

Manufactured Uncertainty: Taking the Tobacco Road

The production and use of scientific data in public policy has become an adversarial process, with unfortunate results both for science and for society. An entire industry has emerged to lend support to the generic statement – used with great frequency by opponents of regulation -- “The science is uncertain – we can’t proceed until more data are collected.”

For almost half a century, the tobacco companies hired scientists to deny first that smokers were at greater risk of dying of lung cancer, then heart disease and other tobacco-related illnesses, and finally to refute the evidence that environmental tobacco smoke increased disease risk in non-smokers. In each case, the scientific community eventually reached the consensus that tobacco smoke caused these conditions.^{7,8,9} Despite the overwhelming scientific evidence and the smoking-related deaths of millions of smokers, the tobacco industry was able to wage a campaign that successfully delayed regulation and victim compensation for decades.^{10,11}

It is useful I believe to review how this was done. Following a strategic plan developed in the mid-1950s by Hill and Knowlton, one of the nation's leading public relations (PR) firms, the tobacco industry hired scientists and commissioned research to challenge the growing scientific consensus linking cigarette smoking with lung cancer and other adverse health effects. In one confidential memorandum, Hill and Knowlton consultants boast that after 5 ½ years of effort, they successfully created "...an awareness of the doubts and uncertainties about the cigarette charges." Hill and Knowlton credit tobacco-funded research that "...forced a recognition that the cigarette theory of lung cancer causation is not established scientifically..." and "...raised many cogent questions concerning the validity of the cigarette theory..."¹²

The Tobacco Institute even had its own scientific journal, *Tobacco and Health Research*. The criteria for selecting articles for *Tobacco and Health Research* was straightforward: "the most important type of story is that which casts doubt on the cause and effect theory of disease and smoking." As illustrated in the memo attached to this testimony, the PR firm advised that, in order to ensure that the message is clearly communicated, headlines "should strongly call out the point – Controversy! Contradiction! Other Factors! Unknowns!"¹³

The same message was communicated to the public. According to one tobacco industry executive: "*Doubt is our product* since it is the best means of competing with the 'body of fact' that exists in the minds of the general public. It is also the means of establishing a controversy (emphasis added)."¹⁴

Following tobacco's example, polluters and manufacturers of other dangerous materials have increasingly adopted the strategy of manufacturing uncertainty in the face of proposed governmental action. In virtually every instance in which a federal regulatory agency proposes protecting the public's health by reducing the allowable exposure to a toxic product, for example, the regulated industry hires scientists to dispute the science on which the proposal is based. It would be laughable if it weren't so dangerous. The Indoor Tanning Association, for example, has used this approach to challenge the science behind the government's designation of ultraviolet radiation as a cause of skin cancer.

Is This "Sound Science", Or Something That Just Sounds Like Science?

In parallel to their attempts to delay or prevent regulation through assertions of scientific uncertainty and pleas for "sound science", manufacturers of pollution and hazardous

products have promoted the “junk science” movement, which attempts to influence public opinion by ridiculing scientists whose research threatens powerful interests, irrespective of the quality of that scientist’s research. Advocates for this perspective allege that many of the scientific studies (and even scientific methods) used in the regulatory and legal arenas are fundamentally flawed, contradictory or incomplete, asserting it wrong or premature to regulate the exposure in question or to compensate the worker or community resident who may have been made sick by the exposure.

The strategy of creating uncertainty about scientific evidence about the risks associated with pharmaceuticals, chemical exposures or hazardous products has been remarkably successful. By raising the cry of “junk science,” questioning the validity or strength of scientific evidence, polluters and manufacturers of dangerous products have been able to delay, often for decades, regulations and other measures designed to protect the health and safety of individuals and communities.

It has been so successful, in fact, that this strategy has been used to constrain the ability of the federal judicial and regulatory system’s ability to address issues of public health and victim compensation. The U.S. Supreme Court’s 1993 *Daubert v. Merrell Dow Pharmaceuticals, Inc.* decision has enabled manufacturers of products alleged to have caused harm to exclude credible science and scientists from court cases.¹⁵ Similarly, the Data Quality Act, the authorizing legislation for the White House’s peer review proposal, provides a new mechanism for parties to magnify differences between scientists in order to avoid regulation and victim compensation.¹⁶

Further proof of the political, rather than scientific, basis for much of this dispute comes from a memo (portions appended to this testimony) written in early 2003 by political consultant Frank Luntz, who advised the leadership of the Republican Party that a rhetorical approach could be successfully employed to oppose regulations controlling greenhouse gases. Luntz wrote:

Voters believe that there is *no consensus* about global warming within the scientific community. Should the public come to believe that the scientific issues are settled, their views about global warming will change accordingly. Therefore, *you need to continue to make the lack of scientific certainty a primary issue in the debate...The scientific debate is closing [against us] but not yet closed. There is still a window of opportunity to challenge the science.*¹⁷ (emphasis in original).

In reality, there is a great deal of consensus among climate scientists about climate change.^{18,19,20} Luntz understands that it is possible to oppose (and delay) costly regulation without being branded as anti-environmental, by focusing on scientific uncertainty, and by manufacturing uncertainty if it does not exist.

Improving the Integrity of Science used in Regulation

There are, in fact, ways that to improve science used in important government programs that protect our health and environment, such as the Endangered Species Act. The adversarial nature of the science policy debate has resulted in a crisis in research integrity, which I believe needs to be addressed, and would not require additional legislation to do so.

I'll begin with a true story, involving research on a current regulatory issue, one of some interest to the members of this committee – control of diesel particulate exposure in underground mines. The Mine Safety and Health Administration has been moving toward issuing a rule limiting exposure, with the assistance of the National Institute for Occupational Safety and Health, which was developing a methodology for measuring underground exposure levels.

The Washington attorneys for the Methane Awareness Resource Group (MARG) Diesel Coalition, which I understand to be a consortium of mine operators who are members of the National Mining Association, hired a well-respected scientist to do a study evaluating NIOSH's exposure measurement methodology.

When the scientist was preparing to publish his study, MARG's attorney (not scientist, an attorney) did not like the scientist's interpretation of the results. The attorney demanded that the scientist change the study's conclusions before it could be submit for publication. How could MARG make such a demand? It was very easy. MARG had hired the scientist under a contract requiring the investigator to get MARG's permission before publishing.

To his great credit, the scientist refused to alter his conclusions. He was sufficiently senior and well-regarded in the field that he did not need additional publications to advance his career. He could simply walk away from the study.

This story has a happy ending. MARG relented. The paper was published without MARG's changes. And the researcher learned his lesson. The next time he was hired, in this case by a major chemical company; he demanded, and received, the right to publish, no matter what the results.

There is a long ugly history of industries hiding or manipulating or disputing scientific data to avoid or regulation. Included in this are several of the major public health disasters of the 20th century – most notably tobacco, asbestos and lead. While these are hopefully long behind us, their shadows remain, and can't be ignored.

The potential for conflict of interest exists in the conduct and reporting of all research that is conducted to influence regulatory decision-making, be it endangered species determinations, underground diesel particulate levels, or new drug applications.

Following a series of alarming instances in which the sponsor of research used their financial control to the detriment of the public's health, the leading biomedical journals in the US and abroad have established policies that make their published articles transparent to commercial bias and that require authors to accept full control and responsibility for their work. The editors of thirteen of the world's leading biomedical journals, including *The New England Journal of Medicine* and *The Journal of the American Medical Association*, recently declared that they will only publish studies done under contracts in which the investigators had the right to publish the findings without the consent or control of the sponsor. In a joint statement, the editors of these journals asserted that contractual arrangements that allow sponsor control of publication "not only erode the fabric of intellectual inquiry that has fostered so much high-quality clinical research but also make medical journals party to potential misrepresentation, since the published manuscript may not reveal the extent to which the authors were powerless to control the conduct of a study that bears their names."

The academic community generally shares the biomedical community's commitment to research independence. With the increased involvement of universities in commercial enterprises and collaborations, many academic institutions require that faculty members who enter into contractual agreements for sponsored research retain full rights to publish and to otherwise disclose information developed in the research.

Federal regulatory agencies, charged with protecting the public's health and environment, have no requirements for "research integrity" comparable to those of medical journals. These agencies rely on scientific evidence to determine, for example, the allowable level of arsenic in drinking water, pesticide residue in food, and particulate matter in air. Given the central role science plays in shaping public health and environmental protection programs, regulatory science should be subject to quality controls at least as rigorous as those employed by biomedical journals. However, federal regulatory policies ensuring research integrity have not kept pace with developments in the academic and biomedical communities.

The need to ensure the integrity of research used for environmental and health regulation is made all the more imperative by the regulators' dependence on regulated parties for much of the scientific information used to formulate regulations, a dependence made necessary by limited federal research funding.

Compounding concerns about conflicts is the fact that much of this mandated private research is subject to considerably less oversight by the scientific community than federally-funded research and research published in biomedical journals. Once a sponsor claims that a study is protected as a trade secret, the data and research are immediately classified, unless a Freedom of Information Request is filed and the agency determines that the trade secret claim is unjustified.

Disclosure in Regulatory Science: A Proposal²¹

Under the current regulatory system, sponsors with clear conflicts of interest have no incentive to relinquish control over sponsored research governing their products and activities. Federal agencies should therefore adopt, at a minimum, requirements for “research integrity” comparable to those used by biomedical journals:

- Scientists who submit comments or other materials for consideration by government agencies should be required to disclose financial and other conflicts of interest that might bias their work. They should also disclose whether they had the contractual right to publish their findings without influence and without obtaining consent of the sponsor. If their work was reviewed by a party affected, prior to either publication or submission to the regulatory agency, that should be disclosed as well.
- Parties that submit data from research they have sponsored must disclose if the investigators had the contractual right to publish their findings without the consent or influence of the sponsor.
- Other parties (i.e. trade associations, unions, public interest groups) who submit scientific results to regulatory agencies should disclose all known financial and other conflicts of interests of the scientists conducting the studies.

Regulators should not use conflict disclosures to exclude research; regulators have the obligation to consider all evidence, according greater importance to those studies that are of higher quality and relevance. Federal agencies should, however, develop policies acknowledging that financial interests may influence the research submitted to agencies during the rulemaking process and, more importantly, develop policies that begin to counteract the strong incentives sponsors face to influence the research process. Only then can agencies provide an accurate weighting for the studies and encourage research free from sponsor influence.

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