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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 1662[1], 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 Graham 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 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, the NMA'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 the NMA make such a demand? It was very easy. The NMA had hired the scientist under a contract requiring the investigator to get the NMA'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. The NMA relented. The paper was published without the NMA'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 Proposal[21]

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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HILL AND KNOWLTON, INC.

October 18, 1968

MEMORANDUM TO: William Kloepfer, Jr.
The Tobacco Institute, Inc.

SUBJECT: Tobacco and Health Research Procedural Memo 7 T

Here, as requested, is a memo on the writing and production of Tobacco and Health Research.

I. AUDIENCE

The primary audience is comprised of doctors and scientists. This determines format, content and style. Secondary audience is the news media for which a press release is prepared summarizing contents. A third audience is the "tobacco interested" groups -- companies, organizations, etc. This third audience gets little consideration in the selection and writing of material. However, at one time a special insert was prepared for this group which consisted (usually) of a one-sheet, two-page reproduction of news clippings reporting more simply on some stories included in the publication.

II. SELECTION OF MATERIAL

A. Sources: The inflexible rule is that material should come from primary sources, that is, from accredited medical and scientific journals (sometimes an unpublished paper delivered at a scientific meeting is used). Secondary sources (such as Medical World News, Medical Tribune) are subject to errors and biases of the reporters. Because accuracy is the most important quality that can be given to T&HR, our policy has been to exlude them entirely.

Most papers used in T&HR come from the Council for Tobacco Research library, through the advance distribution of Ken Austin of CTR. Candidates for T&HR are xeroxed and kept for the next issue of T&HR. Other sources should, of course, be watched.

B. Criteria for Selection: First, the reports should be on new research, if possible. It need not always deal with some aspect of tobacco; for example, a report indicating some factor or factors other than smoking may be involved in one of the diseases with which smoking has been associated. Other examples:

-- a report in which the statistics of a smoking-associated disease are questioned

-- one in which death certificates or classifications of such a disease are questioned

-- one showing that many lung cancers may be metastatic from some other organ.

-- one indicating that a virus may cause human cancer, whether or not that cancer is associated with smoking

-- one on research with animals, indicating that some other factor may be involved with carcinogenesis or ciliostasis

The most important type of story is that which casts doubt on the cause and effect theory of disease and smoking.

A second major category is medical opinion. The best of this type is the report based on extensive review of the literature (such as Seltzer's 1967 review of heart disease). Second best are those in which a doctor of stature challenges the findings or conclusions of another (Garland doubting Auerbach's interpretations of his lung slides, for example).

Occasionally, a favorable editorial from a medical journal may be used, but these must be chosen with care. An editorial from JAMA or The Lancet is obviously important.

A third major category is CTR-USA news. TH&R has announced annual grants, summarized annual reports, and summarized important papers delivered by Dr. Hockett and Dr. Little. (Usually, the stories were accompanied by a boxed offer to supply complete texts on request.)

III. WRITING

A. Structure: The usual newspaper practice of leading off with the most important finding is used. This finding may be the most important finding to tobacco, rather than the one considered most important by the author. If there is a second important finding, this is usually placed in the second paragraph. This is followed by detail of who conducted the work and where, and how it was done. The article ends with direct quotations, if the paper contains any good ones. If not, the quotes are paraphrased.

Citations are footnoted at first opportunity in the story. This footnoting has two purposes: It gives a scientific journal aura to the story, and it prevents cluttering up the story with space-consuming identification.

IMPORTANT: If the paper contains any conclusions or findings unfavorable to tobacco, these are reported scrupulously. The account of these findings may be terse and placed at the end of the story, but it must be there.

B. Headlines: These should be very carefully written on the premise that doctors and scientists, like other readers, often grab information from the headlines and nothing more. Thus, the headline should strongly call out the point -- Controversy! Contradiction! Other factors! Unknowns!

C. Editorial Comment: The policy has been to allow almost no editorial comment. Very occasionally, comment to the extent is permitted:

1. Explanation of a scientific term which is likely to be outside the average physician's experience (in an item on free radicals or some other area of physics, for example).

2. Notation that a carcinogen being discussed in an animal experiment has not been found in cigarette smoke.

3. Citation of an earlier study, if the present article confirms and/or extends the earlier one, particularly if TH&R has reported the earlier paper.

WINNING THE GLOBAL WARMING DEBATE – AN OVERVIEW

Please keep in mind the following communication recommendations as you address global warming in general, particularly as Democrats and opinion leaders attack President Bush over Kyoto.

1. ***The scientific debate remains open.*** 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***, and defer to scientists and other experts in the field.

2. ***Americans want a free and open discussion.*** Even though Democrats savaged President Bush for formally withdrawing from the Kyoto accord, the truth is that none of them would have actually voted to ratify the treaty, and they were all glad to see it die. Emphasize the importance of ***"acting only with all the facts in hand"*** and ***"making the right decision, not the quick decision."***

3. ***Technology and innovation are the key in arguments on both sides.*** Global warming alarmists use American superiority in technology and innovation quite effectively in responding to accusations that international agreements such as the Kyoto accord could cost the United States billions. Rather than condemning corporate America the way most environmentalists have done in the past, they attack their us for lacking faith in our collective ability to meet any economic challenges presented by environmental changes we make. This should be our argument. ***We*** need to emphasize how ***voluntary*** innovation and experimentation are preferable to bureaucratic or international intervention and regulation.

4. ***The "international fairness" issue is the emotional home run.*** Given the chance, Americans will demand that all nations be part of any international global warming treaty. Nations such as China, Mexico and India would have to sign such an agreement for the majority of Americans to support it.

5. ***The economic argument should be secondary.*** Many of you will want to focus on the higher prices and lost jobs that would result from complying with Kyoto, but you can do better. Yes, when put in specific terms (food and fuel prices, for example) on an individual-by-individual basis, this argument does resonate. Yes, the fact that Kyoto would hurt the economic well being of seniors and the poor is of particular concern. However, the economic argument is less effective than each of the arguments listed above.

The most important principle in any discussion of global warming is your commitment to sound science. Americans unanimously believe all environmental rules and regulations should be based on sound science and common sense. Similarly, our confidence in the ability of science and technology to solve our nation's ills is second to none. Both perceptions will work in your favor if properly cultivated.

The scientific debate is closing [against us] but not yet closed. There is still a window of opportunity to challenge the science. Americans believe that all the strange weather that was associated with El Nino had something to do with global warming, and there is little you can do to convince them otherwise. However, only a handful of people believes the science of global warming is a closed question. Most Americans want more information so that they can make an informed decision. It is our job to provide that information.

LANGUAGE THAT WORKS

"We must not rush to judgment before all the facts are in. We need to ask more questions. We deserve more answers. And until we learn more, we should not commit America to any international document that handcuffs us either now or into the future."

You need to be even more active in recruiting experts who are sympathetic to your view, and much more active in making them part of your message. People are willing to trust scientists, engineers, and other leading research professionals, and less willing to trust politicians. If you wish to challenge the prevailing wisdom about global warming, it is more effective to have professionals making the case than politicians. When you do enter the fray, keep your message short, concise, and refer to the source of the material you use. Back up your points with a limited number of facts and figures – but then explain why they matter.

One final science note: Americans have little trust in arguments relying on short-term data, such as mentioning that year *X* was the hottest on record or year *Y* was the coldest on record, etc. Even 15 years of satellite records, or modeling that shows rising sea levels is not enough.

WORDS THAT WORK

"Scientists can extrapolate all kinds of things from today's data, but that doesn't tell us anything about tomorrow's world. You can't look back a million years and say that proves that we're heating the globe now hotter than it's ever been. After all, just 20 years ago scientists were worried about a new Ice Age."

SCIENCE AND GOVERNMENT

Disclosure in Regulatory Science

David Michaels and Wendy Wagner

There is substantial divergence between the scientific community's standards for ensuring research integrity and the ad hoc protections for researcher independence tolerated by federal regulatory agencies. The biomedical community's concern about potential conflicts of interest is addressed in the widespread (*1*, *2*) policy of journals to require that authors of submitted articles disclose financial relationships so that editors and readers can judge whether conclusions might have been influenced by those financial ties. The editors of 13 leading biomedical journals have gone further and declared that they will no longer publish articles based on studies done under contracts in which the investigators did not have the unfettered right to publish the findings (*1*).

With the increased involvement of universities in commercial enterprises and collaborations, conflicts-of-interest concerns at academic institutions have grown in importance. In response, many institutions have implemented policies that attempt to ensure independence and protect the ability of researchers to share data with fellow scientists and the public (*3*–*6*).

Research independence is also of great importance to regulators. Federal agencies charged with protecting the public's health rely out of necessity on scientific evidence submitted by private parties in determining the hazardous characteristics of products and wastes. At the same time, there is growing evidence of conflicts of interest in private research submitted for regulation. For example, there are reports of a "funding effect," with sponsorship associated with favorable findings (*3*, *7*, *8*). There are also accounts of improper sponsor control over the design and reporting of results, and sponsor suppression or termination of research showing adverse effects (*9*–*13*).

Except for limited prohibitions against the suppression of adverse effects, however, the quality and independence of private research used for regulation is subject to considerably less oversight than corresponding federally funded research. Most significantly, private research submitted for regulatory purposes escapes external scrutiny if the research or the chemical under study is claimed to be confidential business information (*14*). Most of the applications submitted to the U.S. Environmental Protection Agency (EPA) to market new chemicals, for example, contain science-relevant information that industry claims is confidential. Many of these trade secret claims do not appear to be justified (*15*). Yet without this information, it is not possible to evaluate the regulators' decisions.

Even when sponsored research is not protected as trade secrets, the data underlying privately submitted research used for regulation need not be made publicly available, as is required for its federally funded counterpart (*16*). Also in contrast to public research, private research is not subject to the scientific misconduct regulations promulgated by the U.S. Office of Research Integrity (*17*). Finally, even the "Data Quality Act", which ostensibly is an attempt to improve the quality of regulatory science through a formal complaint process, exempts a great deal of private research from its coverage (*18*).

Despite the evident value of transparency about sponsorship in regulatory science, the disclosure of sponsor influence is generally not required or even requested by federal regulatory agencies. The EPA, the Occupational Safety and Health Administration, the Mine Safety and Health Administration, the Consumer Product Safety Commission, and the National Highway Traffic Safety Administration have no formal mechanisms to identify potential conflicts of interest, nor do they provide any incentive to encourage the conduct of research that is free of sponsor control. The Food and Drug Administration (FDA) has instituted a conflict policy requiring financial disclosures for safety research conducted by private parties in support of a license to market a drug or food additive (*19*). These disclosures do not, however, distinguish between research where the sponsor controls the design or reporting of the research and research where sponsors have no control.

Regulatory agencies should adopt, at a minimum, requirements for research independence comparable to those of biomedical journals. Disclosure of conflicts of interest should be required for all research, regardless of whether it is federally or privately funded. Scientists should disclose whether they have a contractual right to publish their findings free of sponsor control and should identify the extent to which their work was reviewed by an affected party before publication or submission to the agency. Sponsors who submit data should similarly disclose if their investigators had the contractual right to publish without sponsor consent or influence. Finally, other parties (i.e., trade associations, unions, or public interest groups) who submit scientific results should disclose all known conflicts of interests of the scientists conducting the studies.

Regulators should not use conflict disclosures to exclude research; they have the obligation to consider all evidence, according greater importance to studies of higher quality and relevance. Federal agencies should, however, develop policies that strongly encourage clear disclosures that counteract the strong incentives for sponsors to influence research. Only then can agencies accurately weight studies and encourage research independence.

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