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.

D. Michaels is at the Department of Environmental and Occupational Health, George Washington University School of Public Health and Health Services, Washington, DC, 20052, USA. E-mail: eohdmm@gwumc.edu W. Wagner is at the University of Texas School of Law, Austin, TX 78705, USA. E-mail: wwagner@mail.law.utexas.edu

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