

BY-LINED ARTICLE

Judge Corporate-Funded Studies on Their Merits

By Kenneth M. Argentieri and Gerald J. Schirato Jr.

August 16, 2011

National Law Journal



During the past decade, the drumbeat against corporate-funded science has sounded in major journals, books and the news media. The backlash against this research has seeped into the judicial system, appearing to influence judges and juries to believe that "buying science" is a corporate phenomenon. Perhaps no greater example of this trend is the U.S. Supreme Court decision in *Exxon Shipping Co. v. Baker*, 554 U.S. 471 (2008), in which Justice David Souter — writing for a 5-3 majority — declined to rely on a body of jury research examining the predictability of punitive damage awards, simply because the "research was funded in part by Exxon," the corporate defendant. The criticisms of corporate-funded scientific research, specifically in litigation, will likely continue affecting corporations and various industries for decades. From recently instituted climate-change litigation (specifically *Connecticut v. American Electric Power Co.*, 406 F. Supp. 2d 265 (S.D.N.Y. 2005) and *Comer v. Murphy Oil USA*, 2009 WL 3321493, 17 (5th Cir. Oct. 16, 2009)) to pharmaceutical, mass-tort and other products liability cases, as well as potential litigation resulting from the 2010 BP Gulf oil disaster, corporations may continue to face a no-win situation when relying on self-funded scientific research. If they invest in scientific research that may answer questions raised in litigation, a court may ignore the findings because of their financial support. If they do not make such investments, they may then face criticism for failing to adequately evaluate the hazards and consequences resulting from a product, drug or business operation.

Souter's dismissal of scientific research solely because of its financial backing may raise a red flag for corporations funding such research. Nonetheless, corporations should continue to finance properly conducted research, for both their own benefit and the benefit of society.

Criticisms of Industry-Based Funding

Industry-funded research and scientific studies have often faced challenges from the public, government and other organizations because of claimed bias in results compared with neutral studies, industry control over the publication of negative results and failure to disclose funding and any apparent conflicts of interest.

The history of alleged research-tampering by certain sponsors has created an atmosphere of distrust of all industry-based scientific funding, specifically in litigation. For example, between 1971 and 1993, when the tobacco industry faced litigation, it contributed almost \$30 million to study the link between smoking and health concerns, including lung cancer and heart

disease, according to the report "Tobacco Industry Manipulation of Research," published in 2005 by Lisa A. Bero in *Public Health Reports*. Bero's report also showed that the results skewed in favor of the tobacco industry, even though neutral research led to opposite conclusions.

In the mid-1990s, studies conducted by the U.S. government concluded that secondhand smoke led to increased risks of lung cancer, while articles funded by the tobacco industry concluded that passive smoking presented no health concerns. Researchers led by Deborah E. Barnes concluded that "the tobacco industry may be attempting to influence scientific opinion by flooding the scientific literature with large numbers of review articles supporting its position that passive smoking is not harmful to health." See Deborah E. Barnes, "Why Review Articles on the Health Effects of Passive Smoking Reach Different Conclusions," *Journal of the American Medical Association (JAMA)* (May 1998).

Industries that retain control over trial design, data availability and publication of results of studies have also faced condemnation. The pharmaceutical industry has been criticized for industry-funded studies because some drug manufacturers have withheld negative information from clinical trials demonstrating harm or lack of efficacy of their product, even when they were aware of the risks to consumers.

Some industry-funded studies have also been noted for failing to disclose the amount and source of their funding. As one researcher noted, "[t]he need for transparency in reporting the financial conflicts of interest of authors and the relationships between investigators and funding sources has never been greater and is essential to help maintain confidence and trust in the integrity of medical research studies." Phil B. Fontanarosa, "Reporting Conflicts of Interest, Financial Aspects of Research, and Role of Sponsors in Funded Studies," *JAMA* (July 2005).

The Admissibility of Studies

Science and law are both at their very core a search for the truth. Both disciplines have mechanisms and procedures in place to help reach that goal. An essential feature of the scientific community is its members' acceptance of a code that outlines desirable behavior and specifies their obligations to one another and to the public before accepting the reliability and authority of a scientific study or other conclusion. Scientific studies are peer reviewed — subject to scrutiny of theory, method and procedure — and must often be duplicated under the same circumstances before the scientific community will widely accept their conclusions.

Like the scientific community, the judicial system has also implemented procedural mechanisms testing the efficacy of scientific studies and research before such evidence is permitted to even be heard in a court of law. Because of these pre-established safeguards, the Supreme Court's dismissal of corporate-funded research out-of-hand in *Exxon Shipping Co.* appears more perplexing. The Court did not observe principles it set forth in *Daubert v. Merrell Dow Pharmaceuticals*, 509 U.S. 579 (1993). In *Daubert*, the Supreme Court instituted guidelines for admitting expert testimony and related evidence in federal courts. Generally, evidence is admissible as scientifically reliable if a party can demonstrate that it is of sound methodology derived from the scientific method. The Supreme Court imposed a gatekeeping function on trial judges by charging them with preventing "junk science" from entering the courtroom as evidence. A fair reading of *Daubert* clarifies that the financial backing behind a scientific study should not be the litmus test for preventing the admission or consideration of the study by a court. *Daubert* itself stands for the principle that the validity of scientific research should be judged on its merits.

The Benefits

Souter's dismissal of corporate-funded research appears based on a false premise that such research is somehow inherently unreliable. This position does not recognize that corporate funding of research is invaluable to the scientific community. In an Oct. 30, 2008, *New York Times* article "'Misleading' Research from Industry?", John Tierney discussed the analysis of a 2008 study by a team led by Olivia Thomas in the *International Journal of Obesity* that found the quality of data and findings in industry-sponsored research to be better and more accurate than nonindustry-supported research. Tierney applauded the benefits of industry-funded research compared with noncorporate studies, noting the greater scrutiny, concern for training industry personnel and rigorous reporting standards found in industry-funded research. Moreover, experts and researchers who perform corporate-funded research are aware that the funding behind their research and studies will likely lead others to look upon such research with a keener eye.

Accordingly, one can argue that researchers who perform corporate-funded research, specifically in the litigation context, may be more careful and motivated to perform their research with impeccable standards in order to belie added criticism. These researchers can face intense scrutiny in litigation, including, but not limited to, cross-examining attorneys and opposing expert witnesses. Indeed, many industries seek world-renowned researchers to conduct their studies. Those researchers risk losing their standing in their scientific community and their credibility if they do not adhere to proper scientific methods to conduct their research.

Corporate-funded research is not the only type that has been proven to be flawed. Recently, three significant noncorporate-funded studies were retracted for their lack of credibility. Two of those were debunked by the scientific community. One linked the measles, mumps and rubella (MMR) vaccine to autism. Another linked an antibody to cancer-fighting properties. The third study involved the psychological effects of Accutane. Sponsored by plaintiff's counsel, it was rejected by New Jersey courts. See *Palazzolo v. Hoffman-La Roche Inc.*, No. A-3789-07T3, slip op. (N.J. Super. App. Div. Feb. 3, 2010).

The ardent criticism of industry-funded research and studies also disregards a dire need for corporate funding for such work. Government does not have the resources to fund all necessary research. In 1965, the federal government financed more than 60% of all research and development in the United States. Today, the balance has flipped, with 65% of research and development being funded by private interests, according to an October 2007 *Discover Magazine* article, "Science's Worst Enemy: Corporate Funding" by Jennifer Washburn. Industries often need to fund studies not only to address government regulatory activities, but also to address claims of various interest groups — both inside and outside of litigation.

How to Judge a Study

In addition to the standards set forth by the Supreme Court in *Daubert*, the merits of industry-funded (or any) research or study can be judged by various factors, including disclosure of any funding and potential conflicts of interest; the control/lack of control by the funder over the study design; the control/lack of control by the funder over the publication of results; peer review; consistency of results with other neutral studies; and the study's compliance with accepted scientific methodologies. A combination of these six factors not only addresses the current criticisms of industry-based research, but also provides a framework by which any research can be judged purely on its merits.

To potentially alleviate concerns and criticisms of corporate-funded research, researchers may be required to share data and support the study's reliability in regulatory and judicial proceedings. Such openness about funding, methodology and results can help curb common criticisms regarding lack of transparency. By increasing access to privately funded data with

appropriate safeguards, corporations can improve their standing with the public as well as in courtrooms across the United States.

Corporate-sponsored research has in many instances become an indispensable aid to the advancement of knowledge in the scientific community. The stigmatization of corporate-sponsored research should not dissuade corporations and industries from continuing to invest in research, both inside and outside of the litigation context. Corporate litigants should consider taking on courts and opposing parties directly and challenging the judicial system to evaluate the merits of the studies under the standards set forth by the Supreme Court in *Daubert* and its progeny — regardless of the financial backing.

Kenneth M. Argentieri is the co-chairman of the products liability group at Duane Morris and is based in the firm's Pittsburgh office. Gerald J. Schirato is a litigation associate in that office.

This article originally appeared in the National Law Journal and is republished here by permission of [law.com](http://www.law.com).