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The Funding Effect in Science and its Implications for the Judiciary

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THE FUNDING EFFECT IN SCIENCE AND ITS IMPLICATIONS FOR THE JUDICIARY

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INTRODUCTION

Public policies and legal decisions implemented during the 1980s have created new incentives for universities, publicly-supported nonprofit institutes, and their faculties to commercialize scientific and medical research. Academic-industry and nonprofit-for-profit collaborations have led to the development of revised institutional norms that accommodate new organizational relationships. Among the most pronounced changes, which have been documented in a number of research studies, are that secrecy has replaced openness, privatization of knowledge has replaced communitarian values, and the commodification of discovery has replaced the norm that university-generated knowledge is a free good that is part of the intellectual commons.[1]

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[1] *See* David Blumenthal et al., *University-Industry Research Relationships in Biotechnology: Implications for the University,* 232 SCIENCE 1361 (June 13, 1986) (discussing study of research university faculty and the effect of industry support for research on several issues, including secrecy); Eric G. Campbell et al., *Data Withholding in Academic Genetics: Evidence From a National Survey,* 287 JAMA 473, 473 (Jan. 23, 2002) (discussing study of trend among geneticists of withholding data from other scientists and the effects of such behavior on research); Thomas Bodenheimer, *Uneasy Alliance: Clinical Investigators and the Pharmaceutical Industry*, 342 NEW ENG. J. MED. 1539 (May 18, 2000).

The rapid growth of academic entrepreneurship has given rise to new concerns about scientific conflict of interest, especially in areas such as public health and medicine, in which the public has a direct personal stake.[2] Conflicts of interest among scientists, rarely discussed prior to 1980, have been linked to research bias as well as the loss of a socially valuable norm among academic researchers, namely "disinterestedness."[3]

It should be noted, however, that academic entrepreneurship is not without precedent. As early as 1968, James Ridgeway described the growth of new consulting enterprises in his book *The Closed Corporation.* Ridgeway wrote that, in recent years, professors have started a number of new kinds of companies involved in social problem solving, so the idea that the university is a community of scholars is a myth. Ridgeway elaborated:

> Professors are a new priesthood . . . whose ideas are the drive wheels of the Great Society; shaping our defenses, guiding our foreign policy, redesigning our cities, reorganizing our schools, deciding what our dollar is worth. As power brokers, the professors act with one hand on the university and the other on a big corporation; they move in and out using their prestige as scholars to advance interests of the company.[4]

Whereas older academic entrepreneurship concentrated on faculty-formed consulting enterprises and startup companies in decision sciences and electronics, newer academic enterprise zones have concentrated in the biomedical sciences and medicine, where the stakes are higher and the public's concern about scientific integrity is greater.[5]

Mainstream science is now beginning to question how conflicts

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[2] Marcia Angell, *Is Academic Medicine for Sale?,* 342 NEW ENG. J. MED. 1516 (May 18, 2000).

[3] JOHN ZIMAN, REAL SCIENCE 161 (2000).

[4] JAMES RIDGEWAY, THE CLOSED CORPORATION 84 (1968).

[5] Susan Ehringhaus & David Korn, *Conflicts of Interest in Human Subjects Research, in* ISSUES IN SCIENCE AND TECHNOLOGY ONLINE, Winter 2002, *available at* www.issues.org/issues/19.2/ehringhaus.htm; *See also* COMM. ON GOV'T OPERATIONS, ARE SCIENTIFIC 'MISCONDUCT' AND CONFLICTS OF INTEREST HAZARDOUS TO OUR HEALTH?, H.R. REP. NO. 101-688 (1990).

of interest enter into professional activities, including publication, peer review, government advisory committees, federal science agencies, clinical trials, and expert testimony in the courts. Leaders in the scientific community are not ready to jettison the idea of "disinterested science" and "objectivity." Donald Kennedy, editor-in-chief of *Science,* recently wrote about the public's growing interest in the integrity of science: "Society is now concerned with possible sources of bias and seeks assurance through disclosure that the data or opinions presented are those of a disinterested party."[6] In December 2003, the *Los Angeles Times* ran a series of stories about conflicts of interest at the National Institutes of Health (NIH) and the National Science Foundation, where high-level scientific laboratory and program supervisors were cashing in on patents and business connections with drug companies.[7] The *L.A. Times* editorial criticized NIH for becoming "an arm of commerce."[8] The editorial described the NIH as "a place where objective science is being trampled in a stampede for market share" and where "scientists brazenly collect paychecks and stock options from biomedical companies, and do so with the blessing of their leaders."[9]

These comments hardly penetrate the surface of the public ire that has been directed at the commercialization of academic science. Public outcry has led to litigation, congressional hearings, dozens of investigative reports in the media, books, editorials in science journals, and new federal policies for addressing conflicts

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[6] Donald Kennedy, *Disclosure and Disinterest*, 303 SCIENCE 14 (Jan. 2, 2004) (noting that "society is now concerned with possible sources of bias and seeks assurance through disclosure that the data or opinions presented are those of a disinterested party").

[7] *See, e.g.,* David Willman, *Records of Payments to NIH Staff Sought,* L.A. TIMES, Dec. 9, 2003, at A12, *available at* 2003 WL 68903373; David Willman, *Stealth Merger: Drug Companies and Government Medical Research,* L.A. TIMES, Dec. 7, 2003 at A1, *available at* 2003 WL 68902911; Editorial, *Subverting U.S. Health,* L.A. TIMES, Dec. 7, 2003 at M4, *available at* 2003 WL 68903050 [hereinafter Editorial, *Subverting U.S. Health*]; Alan Zarembo, *Funding Studies to Suit Need,* L.A. TIMES, Dec. 3, 2003 at A1, *available at* 2003 WL 68902206..

[8] Editorial, *Subverting U.S. Health*, *supra* note 7, at M4.

[9] *Id.*

of interest.[10] In this paper, I discuss the effects of the academic funding structure and financial conflicts of interest on the integrity of scientific research. Additionally, I examine the influence of conflicts of interest on the courtroom testimony of experts and suggest ways in which judicial and scientific methodologies can look to each other to enhance objectivity. The central issues underlying this analysis include whether scientific conflicts of interests make a difference in the quality of science, whether objectivity is threatened by the growth of scientific entrepreneurship, whether judicial proceedings should be attentive to conflicts of interest in expert testimony, whether disclosure is a sufficient antidote, and whether objectivity can prevail when all interests are transparent.

I. LAW AND SCIENCE: TWO MODELS OF EPISTEMOLOGY

It is fair to say that the judicial system and the scientific system are both about getting to the truth. Sheila Jasanoff notes: "[T]he ways in which truth is found in each location is through establishing a direct correspondence with some exogenous reality: with a legally significant event in the case of law, and with a phenomenon of nature in the case of science."[11] However, science and law take quite distinct structural paths to arrive at their respective truths.

The judicial path is organized around a system of legal advocacy. Each advocate builds an evidentiary edifice intended to falsify or validate a causal story or a truth claim within that story. The advocate lawyer is not expected to be balanced, self-critical, or inclusive of all evidence, but rather to serve his or her client in the best way possible. When a legal brief cites evidence that does not support a client's claim, it is usually to dispute, invalidate, or provide a different interpretation of that evidence. The public

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[10] *See, e.g.*, Eyal Press & Jennifer Washburn, *The Kept University*, ATLANTIC MONTHLY, March 2000, at 39-54; Kennedy, *supra* note 6, at 14; Ehringhaus & Korn, *supra* note 5.

[11] Sheila Jasanoff, Contested Science in Legal Settings, Remarks at the Coronado Conference "Scientific Knowledge and Public Policy" (San Diego, CA) (March 13, 2003) (transcript available from author).

expects that lawyers are paid by their clients to advocate for a particular truth narrative. In fact, professional norms prohibit lawyers from simultaneously representing competing interests.[12] There are, however, important groundrules in legal epistemology. For example, lawyers and forensic investigators cannot destroy or manufacture evidence.[13] Additionally, they must make evidence available to others for analysis and interpretation.

The judicial model creates a decision space for an objective review of evidence by disinterested observers who are neither forensic investigators nor the creators of the causal narratives. Since *Daubert v. Merrell Dow Pharmaceuticals,* federal judges have played a more critical role in ascertaining the reliability of scientists and the science presented to interpret relevant evidence.[14] Within the judicial model, either the judge or jury renders a determination regarding the truth or probability of a given causal narrative through the use of evidentiary standards that are determined by the nature of the litigation. Undoubtedly, financial resources can play a role in the court's truth determination. After a decision has been rendered, legal advocates may pursue a reversal of the court's truth narrative by introducing new evidence or by questioning the methodology or process under which the inquiry took place.[15]

In science, by contrast, the operative methodological norm is

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[12] *See* MODEL RULES OF PROF'L CONDUCT R. 1.8(a) (2002).

[13] Jasanoff, *supra* note 11.

[14] 509 U.S. 579 (1993) (holding that the general acceptance of a scientific technique is not a precondition for admission of expert testimony based upon that technique so long as the standards of reliability and relevance under the Federal Rules of Evidence are met). The Court, in *Daubert*, listed several factors that federal judges should consider when determining the admissibility of expert testimony. *Id.* at 590-97. These factors, often referred to as the *Daubert* test, include whether the expert's theory is capable of being tested; whether the theory "has been subjected to peer review and publication"; the "known or potential rate of error and the existence and maintenance of standards controlling the technique's operation"; and whether the theory has been generally accepted by the relevant scientific community. *Id.* at 593-94 (internal citations omitted).

[15] FED. R. CIV. P. 59.

not advocacy but "organized skepticism."[16] As early as 1937, Robert Merton highlighted this norm as an essential component of scientific inquiry: "Organized skepticism [sic] involves a latent questioning of certain bases of established routine, authority, vested procedures and the realm of the 'sacred' generally . . . . Most institutions demand unqualified faith; but the institution of science makes skepticism a virtue."[17] Scientists as a community are expected to approach new truth claims with a critical eye toward the limitations of evidence and the falsifiability of the causal hypothesis. Scientists who fail to cite data that are unfavorable to their hypotheses are viewed as negligent or biased. Protecting the integrity of good evidence is valued, while harsh penalties are meted out for "cooking" or tampering with data.[18]

In keeping with this structure of skeptical independence, scientists who receive private funds for their work, unlike lawyers, are not supposed to speak *solo voce* for the values and interests of their sponsors. However, when private funders contract with academic scientists, hidden covenants sometimes demand greater fidelity to sponsors than professional standards would permit. Consider the case of Professor Betty Dong, a pharmacologist at the University of California at San Francisco.[19] A pharmaceutical company contacted Dong after a letter she had co-authored appeared in a medical journal.[20] The letter reported differences in the effectiveness of various pharmaceutical drugs in treating hypothyroidism and cited two brand name preparations as having greater benefits than the generic drugs, which had been gaining

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[16] Robert Merton, *Science in the Social Order*, *in* SOCIAL THEORY AND SOCIAL STRUCTURE 547 (Robert Merton ed., 1957).

[17] *Id.*

[18] THE NATIONAL ACADEMIES, RESPONSIBLE SCIENCE: ENSURING THE INTEGRITY OF THE RESEARCH PROCESS 2, 3 (NATIONAL ACADEMY PRESS 1992).

[19] This case is discussed fully in SHELDON KRIMSKY, SCIENCE IN THE PRIVATE INTEREST 14-18 (2003). *See also* Ralph T. King, Jr., *Bitter Pill: How a Drug Firm Paid for University Study, Then Undermined It,* WALL ST. J., Apr. 25, 1996 at A1; Lawrence K. Altman, *Drug Firm, Relenting, Allows Unflattering Study to Appear*, N.Y. TIMES, Apr. 16, 1997, at Al.

[20] *See* Miriam Shuchman, *Consequences of Blowing the Whistle in Medical Research*, 132 ANNALS INTERNAL MED. 1013-14 (2000).

market share from the major brands.[21] A manufacturer of one of the leading brand name drugs signed a contract with Dong to undertake a bioequivalency study, which the company hoped would demonstrate that its formulation was superior to the generic drugs on the market.[22]

Dong completed a double-blind study in 1990 and sent the results to the company that sponsored it.[23] Dong's results showed that, for the four drugs she studied, there was no difference in the therapeutic effectiveness of the generics and the brand name drug.[24] When Dong notified the company that funded the study of her findings, it disputed her results and indicated that her study was flawed.[25] Dong submitted a paper describing her study to the *Journal of the American Medical Association.*[26] It was peer reviewed by five individuals, revised, and accepted for publication.[27] Prior to publication, Dong's corporate sponsor warned her that she could not publish the results of the study without its permission because of a restrictive covenant in her contract.[28] In relevant part, the covenant stated:

> All information contained in this protocol is confidential and is to be used by the investigator only for the conduct of this study. Data obtained by the investigator while carrying out this study is also considered confidential and is not to be published or otherwise released without written consent from Flint Laboratories, Inc.[29]

Fearing costly litigation, Dong withdrew the article after the

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[21] *Id.*

[22] Drummond Rennie, Editorial, *Thyroid Storm,* 277 JAMA 1238 (1997).

[23] A double-blind study in this case means that neither the subjects nor the researchers know which subjects received the drug and which received the placebos and in what order the drugs were administered. Double-blind studies are the gold standard for medical research.

[24] Rennie, *supra* note 22, at 1238.

[25] *Id.*

[26] *Id.* at 1239-43.

[27] *Id.*

[28] *Id.*

[29] Rennie, *supra* note 22, at 1239.

journal had already prepared galleys of the work.[30]

Dong's case attracted international attention to the question of control over the scientific data of sponsored studies. The attorneys general of thirty-seven states filed a class action suit against Flint Laboratories, claiming that the company had withheld information from the Food and Drug Administration and disseminated misleading information about its product.[31] The company agreed to pay approximately $98 million to users of its drug.[32]

To date, universities continue to sign contracts with restrictive covenants regarding the control of data and publication. A small group of journals associated with the International Committee for Medical Journal Editors (ICJME) has agreed that articles submitted to the journals on the results of clinical trials should have signed statements by authors stating that they, not the sponsors, have control over the data.[33] The editors of the ICJME journals were quite explicit about their disapproval of restrictive covenants in sponsored drug studies:

> Such arrangements 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 contact of a study that bears their names. [34]

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[30] The paper was published years later. *See* Betty Dong et al., *Bioequivalence of Generic and Brand-Name Levothyroxine Products in the Treatment of Hypothyroidism*, 277 JAMA 1205 (1997).

[31] KRIMSKY, *supra* note 19, at 18.

[32] *Id.*

[33] Frank Davidoff et al., *Sponsorship, Authorship, and Accountability*, 345 NEW ENG. J. MED. 825, 825 (2001) ("As editors, we strongly oppose contractual agreements that deny investigators the right to examine the data independently or to submit a manuscript for publication without first obtaining the consent of the sponsor.").

[34] *Id.* at 825-26. (stating "[w]e will not 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").

II. THE ROLE OF DISINTERESTEDNESS IN SCIENCE

The rejection of bias and advocacy in science is longstanding. Sir Karl Popper, one of the leading philosophers of science of the twentieth century, wrote that the logic of scientific discovery and the growth of science are based on the falsification of hypotheses.[35] Scientists should not be in the business of trying to confirm their hypotheses by consciously seeking data to support them in the way that a prosecutor might gather evidence to prove that a defendant is guilty. Instead, Popper argues, scientists should hold their hypotheses to the most rigorous examination, as if the hypothesis were a combatant and the scientist's role was to expose its vulnerability.[36]

The culture of science, however, does not generally conform to Popper's description of its proper role. The tension that builds within science is not between a scientist and his hypothesis, but among scientists as a community of skeptics who choose to interpret the evidence differently, see flaws in a theory, or question a methodology. The social systems of science have built incentives for doing what Popper rails against, namely demonstrating the truth of a hypothesis or getting positive results from an experiment. Journals typically do not publish negative results; grants are not usually awarded because someone failed to get a positive outcome in an experiment; and scientific review panels do not seek out negative results. From a psychosocial perspective, the gratification

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[35] KARL POPPER, THE LOGIC OF SCIENTIFIC DISCOVERY 280 (2d ed. 1968). Popper explains:

> The advance of science is not due to the fact that more and more perpetual experiences accumulate in the course of time . . . Bold ideas, unjustified anticipations, and speculative thought, are our only means for interpreting nature: our only organon, our only instrument, for grasping her. And we must hazard them to win our prize. Those among us who are unwilling to expose their ideas to the hazard of refutation do not take part in the scientific game.

Id.

[36] *Id.* at 279. According to Popper, hypotheses are not to be "dogmatically upheld. On the contrary, we try to overthrow them . . . in order to put forward, in their stead, new unjustified and unjustifiable" hypotheses. *Id.*

and rewards in science will not be the same for someone who destroys theories and hypotheses as for someone who builds them.

Scientists are not disinterested ideal observers when it comes to their own contributions, but rather are people with personal interests outside of science. They may, for example, be concerned about overpopulation or globalization. As John Ziman notes in *Real Science,* "[t]here is no denying that scientific facts and theories are produced by human beings, whose minds cannot be completely cleansed of individual interests."[37] According to Ziman, because science is a collective process, subjective elements are filtered out first by the socialization of researchers and then by the peer review process. Ultimately, it is the self-correcting function of science that serves as a balancing force because "the particular bias of each individual is neutralized in the collective outcome."[38]

It surely cannot be said that scientists are indifferent to the outcome of their work on intellectual or personal grounds. After all, science is a social system. Thus, the term "disinterestedness" must be viewed in this context. An individual scientist might be passionate about and even personally biased toward his theory. However, the system of science has no special interest in a particular theory being true or false; it only has an interest in pursuing the truth. Individual scientists may refuse to give up their hypotheses in light of falsifying evidence, but the social system of science is always prepared to jettison a theory that does not account for empirical evidence. Ziman believes that science's "ethos" and "established practice" help to transform scientists' personal conflicts of interest "into a shared collective interest in the production of reliable knowledge and in the anonymous, institutionalized credibility of that knowledge."[39]

For this transformation to occur, members of the scientific community must ascertain the biases that enter into a scientific investigation. They must be able to debate and reach consensus on controversial issues of data reliability and interpretation.

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[37] ZIMAN, *supra* note 3, at 155.

[38] *Id.* at 159.

[39] *Id.* at 161.

Intellectual interests of scientists are part of the published record and consequently, can be debated in the open literature. When a scientist has a financial interest in his or her work, however, the instrumental value of the conflict is not part of the scientific record and is not subject to debate. Instead, it falls outside the zone of "organized skepticism" that is generally placed on scientific findings. Scientists do not typically debate whether the entrepreneurial interests of a researcher could influence the objectivity of his published research. In many cases, these interests are not even known to the scientific community. Thus, the norm of "organized skepticism" does not operate on financial conflicts of interest.

Importantly, a scientist's entrepreneurial interests need not affect the objectivity of his or her research. Most scientists bristle at the allegation that their equity holdings in a company or a patent related to the subject matter of their research affect their objectivity, but this is an open empirical question. It is generally understood that certain fields of academic science have been heavily commercialized. John Ziman refers to these fields as "post-academic science" because they have much closer ties to industry.[40] In "post-academic science," Ziman writes, "what cannot be denied is that the academic norm of disinterestedness no longer operates."[41] Ziman goes on to argue that the loss of individual disinterestedness will not derail the attainment of objectivity when the other norms are protected.[42]

Ziman distinguishes between cognitive objectivity and social objectivity.[43] The former refers to the true nature of physical reality, which science is supposed to reveal. Social objectivity, by contrast, is the public's belief in the credibility of the knowledge

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[40] *Id.* at 67; *See also* John Ziman, *No Conflict,* NEW SCIENTIST, Oct. 4, 2003, at 34.

[41] ZIMAN, *supra* note 3, at 174.

[42] *Id.* Ziman explains: *"*The production of objective knowledge thus depends less on genuine personal 'disinterestedness' than on the effective operation of the other norms, especially the norms of communalism, universalism and skepticism. So long as post-academic science abides by these norms, its long-term cognitive objectivity is not in serious doubt." *Id.*

[43] Ziman, *No Conflict*, *supra* note 40, at 34.

claims. As long as "organized skepticism" is well and functioning (for example, through peer review, the self-correcting function of science, the replication of results, etc.), a scientist's financial interests will not affect "cognitive objectivity."[44] However, science's "reputation for short-term social objectivity" and its "hard-won reputation for a reasonable degree of impartiality, political neutrality and fairness" suffer when scientists fail to maintain disinterestedness.[45]

While the legal advocacy system has long dealt with the effect of private, moneyed interests, the scientific epistemology is only recently coming to terms with this factor. Of course, there are many occasions in which company sponsors of research work closely with academic researchers on mutually agreed upon protocols. Companies frequently hire their own scientists who are often very knowledgeable in the fields of pharmacology, biochemistry, toxicology, and medicine, and who may also understand the regulatory process for getting a drug to market better than academic scientists. Although corporate funding may influence research outcomes in some cases, a scientist's financial interest may prove irrelevant if the scientist follows the dictates of responsible research.

The universally held norms of scientific inquiry in pursuit of the truth make other relationships inconsequential so long as scientists are totally and uncompromisingly invested in that pursuit. One could argue that scientists who violate the canons of their discipline would soon become pariahs—outcasts in their professional circles. Whatever a scientist might gain in financial reward, for example, is hardly worth the loss of professional standing. If this is the case, then how do we explain tobacco science, which funded many academic researchers and produced volumes of questionable studies to counter the public health mobilization against tobacco use?[46]

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[44] Misleading or false science is not cognitively objective.

[45] ZIMAN, *supra* note 3, at 175; *See also* Ziman, *No Conflict*, *supra* note 40, at 34.

[46] Lisa A. Bero et al., *Publication Bias and Public Health Policy on Environmental Tobacco Smoke*, 272 JAMA 133, 133-36 (1994) (studying sixty-five symposium articles and forty-nine peer-reviewed articles concerning

A. Manufactured Tobacco Research

If there were a poster-child for "the best science money could buy," it would certainly be the tobacco industry. Through tobacco litigation and the discovery process, internal documents of cigarette manufacturers became public and revealed a systematic campaign to construct a science around tobacco safety while attempting to dismiss as "junk science" findings that connect tobacco use to excess morbidity and mortality.[47]

In July 2000, the World Health Organization (WHO) published a particularly comprehensive report detailing the strategies used by the tobacco industry to manufacture its own science.[48] The report was based largely on internal company documents released during litigation. It showed that the science produced by tobacco funding was the product of research by the industry's hired staff as well as "a variety of ostensibly independent quasi-academic, public policy, and business organizations whose tobacco industry funding was not disclosed."[49] The report also showed that tobacco companies attempted to undermine the WHO by "rel[ying] heavily on international and scientific experts with hidden financial ties to the industry."[50]

Some of the tactics used by the tobacco companies to support their claims included placing articles in the medical literature without revealing their support for the research; financing a large number of studies intended to show that studies by the International Agency for Research on Cancer (IARC) were flawed; planning a series of studies, literature reviews, and scientific conferences conducted by front organizations or consultants; and seeking to create an ostensibly independent coalition of scientists

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tobacco smoke and finding sponsorship can influence results).

[47] *See* THOMAS ZELTNER ET AL., WORLD HEALTH ORGANIZATION, TOBACCO COMPANY STRATEGIES TO UNDERMINE TOBACCO CONTROL ACTIVITIES AT THE WORLD HEALTH AT THE WORLD HEALTH ORGANIZATION: REPORT OF THE COMMITTEE OF EXPERTS ON TOBACCO INDUSTRY DOCUMENTS iii (2000), *available* at http://www.who.int/tobacco/en/who_inquiry.pdf.

[48] *Id.*

[49] *Id.* at 3.

[50] *Id.*

to criticize studies that linked tobacco to disease.[51] Tobacco companies also funded international seminars involving other industries to develop "good epidemiological practices"—a euphemism for changing the standards of scientific proof that would serve cigarette manufacturers when they lobbied to prevent increased restrictions on tobacco.[52]

Evidence shows that research funded by the tobacco industry was designed as advocacy science. The so-called independent centers created by tobacco companies to fund research on indoor air, including studies of environmental tobacco smoke, also were found to be producing advocacy science.[53] Similarly, studies supported by tobacco companies on the effects of nicotine or smoking on cognitive performance invariably reported positive effects.[54] Nonetheless, there was no dearth of academic scientists, including some at Harvard and Yale, willing to accept the funding of the tobacco industry for scientific research that would support

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[51] *Id.* at 49-52.

[52] Elisa K. Ong & Stanton A. Glantz, *Constructing "Sound Science" and "Good Epidemiology": Tobacco, Lawyers, and Public Relations Firms,* 91 AM. J. PUB. HEALTH 1749-57 (2001). Phillip-Morris seized on the Chemical Manufacturers Association (CMA) study annunciating principles for "sound science" practices, using the public relations firms Burson-Marsteller and APCO to legitimize their own scientific findings on the effects of tobacco. *Id.* at 1751-53. These efforts were undertaken in retaliation to the International Agency for Research on Cancer (IARC), and their efforts to spearhead smoking restrictions in Europe by questioning "junk-science" utilized by tobacco manufacturers. *Id; See also* CHEMICAL MFRS. ASSOC., DOCUMENT NO. 2024005575/5604, GUIDELINES FOR EPIDEMIOLOGY PRACTICES FOR OCCUPATIONAL AND ENVTL. EPIDEMIOLOGIC RESEARCH (1991), *available at* http://www.pmdocs.com.

[53] Deborah. E. Barnes & Lisa A. Bero, *Industry-Funded Research and Conflict of Interest: An Analysis of Research Sponsored by the Tobacco Industry Through the Center for Indoor Air Research*, 21 J. HEALTH POL. POL'Y & L. 515 (1996). Much of the industry-sponsored research on environmental tobacco smoke was later published in non-peer reviewed journals. *Id.* at 520-24. The quality of those articles proved to be inferior to articles published in peer-reviewed journals. *Id.* at 526-28.

[54] Christina Turner & George J. Spilich, *Research Into Smoking or Nicotine and Human Cognitive Performance: Does the Source of Funding Make a Difference?*, 92 ADDICTION 1423, 1426 (Nov. 1997).

tobacco's interests.[55]

Financial interest by scientists undoubtedly affects the popular culture's perception of scientific reliability. However, we must examine the effect of financial interests on science itself, not merely the perception of this impact. This question can be explored by investigating whether there is a funding effect in science. Clearly, such an effect is present in "tobacco science."[56] Still, we must consider whether the same effect appears in other sectors of science. More importantly, we must evaluate the possible implications of such a funding effect on the judiciary, which seeks independent scientific expertise to guide the administration of justice. If there is evidence that financial interests play a role in the outcome of science, then we must question whether "conflict of interest" is simply a problem of perception and its antidote is mere disclosure or transparency.

B. The Funding Effect in Drug Studies

The question of whether funding affects scientific outcomes had not been systematically studied prior to the 1990s. The reasons are rather complex. Those who questioned the legitimacy of science or its objectivity were largely from the new post-modernist field of literary scholarship or the new feminist critique of science. The former attacked the objective framework of science that claims to find a single "text" for explaining the nature of the universe, whereas the latter saw a gender bias in the epistemology of science.[57]

By the 1990s, publicity regarding conflicts of interest, especially in the biomedical sciences, prompted investigations into the relationship between commercial ties and research outcomes.[58] Among the most impressive of these investigations was a 1998

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[55] Derek Yach & Stella A. Bialous, *Junking Science to Promote Tobacco,* 91 AM. J. PUB. HEALTH 1745 (2001).

[56] *See infra* notes 45-46 and 52-55.

[57] *See, e.g.,* SANDRA HARDING, WHOSE SCIENCE? WHOSE KNOWLEDGE? (1991).

[58] *See e.g., infra* Table, at 67.

study performed by a team of Canadian researchers.[59] The Canadian team examined the degree to which industry support of medical education and sponsorship of research influenced the opinions and behaviors of clinicians and researchers. The team's study followed in the footsteps of a Canadian television documentary that highlighted a conflict of interest between the Health Protection Branch of Health and Welfare Canada and the manufacturers of calcium channel antagonists (CCAs), a new generation of drugs used for hypertension and cardiac problems. An ongoing controversy over the safety and efficacy of CCAs provided a natural experiment. The Canadian team sought to determine whether commercial ties to drug manufacturers played any role in explaining the attitudes of journal authors regarding the risks of the drugs.

First, the Canadian research group collected journal articles and letters to the editor on CCAs that were published between March 1995 and September 1996.[60] The group compiled seventy usable published documents, including original research, reviews, and letters for its study.[61] Second, the group identified the authors listed in the documents and classified them by the content of their writings.[62] The authors were categorized as critical, neutral, or supportive of the use of CCAs.[63] Third, the research group sent out a survey to authors to learn whether they had any financial associations with any of the forty companies that manufacture CCAs or a competing product.[64]

The study confirmed the team's hypothesis that supporters of CCAs were more likely than others to have financial relationships with manufacturers of this class of drugs.[65] The study showed that 96 percent of authors identified as supportive had financial

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[59] Henry T. Stelfox et al., *Conflict of Interest in the Debate Over Calcium-Channel Antagonists,* 338 NEW ENG. J. MED. 101 (1998).

[60] *Id.* at 104-6.

[61] *Id.*

[62] *Id.*

[63] *Id.*

[64] *Id.* Financial associations include travel support, honorarium, educational funds, research grant, consultation, etc.

[65] Stelfox, *supra* note 59, at 104-6.

relationships with manufacturers of CCAs, while only 60 percent of neutral authors and 37 percent of critical authors had such affiliations.[66] The study also demonstrated that supporters of CCAs were more likely than other authors to have financial relationships with any pharmaceutical manufacturer. The investigators discovered that 100 percent of supportive authors, 67 percent of neutral authors, and 43 percent of critical authors had relationships with pharmaceutical manufacturers.[67] The team's hypothesis that critics of CCAs were more likely than others to have financial relationships with manufacturers of competing products proved false. In fact, authors critical of CCAs were much less likely to be financially associated with manufacturers of competing products.[68] The research group concluded that there was "a strong association between author published positions on the safety of calcium-channel antagonists and their financial relationships with pharmaceutical manufacturers."[69] The Canadian study is one of several studies published within the last decade that have identified a funding effect in the biomedical sciences that could have serious health effects on the consumer population.

One Yale University research team pooled all of the studies available in a type of meta-analysis on the impacts of financial conflicts of interest in biomedical research.[70] Based on eleven independent studies, the research team determined that "strong and consistent evidence shows that industry sponsored research tends to draw pro-industry conclusions."[71]

The data from the studies tells a convincing story that commercial affiliation of researchers has a biasing effect—not simply on each investigator, but also on the general population of investigators. It imposes a kind of evolutionary pressure that steers the research toward the interests of the sponsors. This bias can often be subtle and difficult to detect, even for veteran journal editors. Frank Davidoff, former editor of the *Annals of Internal*

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[66] *Id.*

[67] *Id.*

[68] *Id.*

[69] *Id.*

[70] *See* Bekelman, *supra* note 73, at 463.

[71] *Id.*

Medicine, believes the issue is one of transparency. Recalling an instance in which he and his staff questioned an author's overstated description of statistical evidence in a sponsored study, Davidoff explained:

> The problem for me was not that the trial sponsor had an interest in how the study was conducted and reported—that was natural enough, given its sizeable financial investment. The problem was that details of the sponsor's involvement in and control over research done by 'independent' investigators weren't being made known to editors, reviewers, and readers.[72]

In Davidoff's view, once the relationship between the researcher and the corporate funder of the study has been disclosed, the editor's responsibility ends.[73]

The response doubtlessly would be far different in another sector of our society, be it government, journalism, or law. Imagine if a judge prefaced his remarks during the sentencing phase of a trial by declaring that he would be sentencing the convicted felon to time in a for-profit prison in which he, the judge, had some

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[72] Frank Davidoff, *Between the Lines: Navigating the Uncharted Territory of Industry-Sponsored Research*, 21 HEALTH AFFAIRS 235, 236 (2002).

[73] *Id*. at 236. Davidoff writes:

> The title of the page of the study we received in 1995 made the fact of industry support quite clear; the trial was well conducted, and the drug it tested, potentially important. The problem lay buried in the text. It seemed to me, my fellow editors, and our statistician that the authors had gone well beyond the data in stating the drug's efficacy and safety. I suggested alternative wording that we felt was more appropriate, but the author's revision still contained the original wording. I tried again, but the second revision also came back unchanged. I then called the lead author to find out what was going on.
>
> He made no bones about the fact that the drug company sponsoring the research had reserved the right to review the manuscript before it was submitted—something that had not been disclosed to us. When I pushed him about how much control the company had over the paper's wording, things got a little murkier. The principal researchers had nominally retained control, he said, but the company's opinion did very likely influence the report's language.

Id.

personal equity. Moreover, the judge rationalized that, by augmenting his modest government salary in this way, he could better serve the public interest and act more objectively. With this scenario in mind, we must question whether the disclosure of financial involvement is sufficient to protect the interests of society and the public's investment in university science.

III. SCIENCE AND THE JUDICIARY

What implications do issues of scientific conflict of interest have on judicial processes? Trial lawyers choose their own experts who must pass the *Daubert* test in federal courts.[74] Generally, a scientist's financial relationship to the subject matter of his or her research is not a matter of material concern in a *Daubert* hearing. However, at trial and under cross examination, all factors affecting the scientist's credibility and objectivity are teased out for the jury, including whether the expert has more than an intellectual or professional interest in the field of knowledge he or she brings to the court.

In *Daubert v. Merrell Dow Pharmaceuticals*, the Ninth Circuit cited the objectivity of the expert witness as a relevant criterion pertaining to whether the testimony was based on pre-litigation or post-litigation science.[75] The court ruled that the timing of the research used in the testimony was relevant in applying the *Daubert* criteria:

> That an expert testifies based on research he has conducted independent of the litigation provides important, objective proof that the research comports with the dictates of good science. For one thing, experts whose findings flow from existing research are less likely to have been biased toward a particular conclusion by the promise of remuneration . . . .[76]

Still, there is no evidence that pre-litigation research is more

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[74] For an explanation of the *Daubert* test, *see supra* note 14.

[75] 43 F.3d. 1311 (9th Cir. 1995).

[76] *Id.* at 1317 (internal citations omitted).

dependable or objective than post-litigation research.[77] As previously indicated, however, evidence shows that private funding of research introduces bias and compromises objectivity.[78] Under *Daubert*, judges have a daunting task in deciding whether expert evidence is relevant and reliable. To add "objective" to that list would bring the court into a "hornet's nest" of issues related to conflict of interest and bias—forcing courts to grapple with the link between moral purity of research and scientific epistemology.

Litigation science has financial rewards and, as such, is considered a disclosable financial interest (except in the rare situation where the scientist does the work pro-bono or at no cost). However, non-litigation science may also be connected with financial interests.[79] Thus, the criterion of pre- or post-litigation science may be less relevant than the nature of the financial interests and the availability of evidence that such interests impair the objectivity of the scientist.

The government's own policies on conflicts of interest and scientific advisory committees have been less than exemplary. For example, consider that there are two rules that guide the appointment of experts to federal advisory committees: (1) scientists with substantial conflicts of interest in the subject matter of the advisory committee should not be allowed to serve; and (2) the first rule can be waived.[80] Waivers of conflict of interest issues can be significant, as demonstrated by a study carried out by *USA Today*.[81] Investigative journalists of *USA Today* examined eighteen expert advisory committees established by the Food and Drug

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[77] *See* Sheila Jasanoff, *Hidden Experts: Judging Science After Daubert, in* Trying Times: Science and Responsibilities After *Daubert* 30-47 (Vivian Weil ed., 2001). Jasanoff states: "[T]he assumption that science is more biased if it emerges from post-litigation than from pre-litigation remains, at the very least, more doubtful than Kosinski's opinion suggested." *Id.* at 34.

[78] *See infra* Table, at 67.

[79] *Id.*

[80] The Food and Drug Administration reportedly waves conflicts of interest of up to $100,000 for members of its advisory committees. *See* www.fda.gov/fda/special/newdrug/advice.html.

[81] *See, e.g.*, Anonymous, *How the Study was Done,* USA TODAY, Sept. 25, 2000.

Administration's Center for Drug Evaluation and Research between 1998 and 2000.[82] These committees make recommendations to the FDA on drug approval. There were 159 meetings during this study period.[83] At least one advisory committee member had a financial stake in the subject under review in 146 of the 159 meetings.[84] At 50 percent of the meetings, at least half of the advisory committee members had financial interests in the products being evaluated.[85] The study also reported that "more than half of the experts hired to advise the government on the safety and effectiveness of medicine have financial relationships with the pharmaceutical companies that will be helped or hurt by their decisions."[86]

Similarly, court-appointed panels of experts charged with advising the judiciary should also be vetted under conflict of interest guidelines. When Judge Sam Pointer of the U.S. District Court in Alabama accepted the appointment of Canadian rheumatologist Dr. Peter Tugwell to review scientific claims of disease causation in the breast implant litigation, he decided that the candidate's financial relationship and ongoing discussions with two of the defendants in the case did not disqualify Dr. Tugwell from serving on the panel.[87] In his deposition, the medical expert responded to the plaintiff's attorney regarding his relationship with a drug company:

> Attorney: So as I understand it . . . as of January 11, 1999, while serving on the science panel, you had entered into two contracts with Bristol-Myers Squibb, is that correct, the consulting contract and the contract relating to the clinical trial?
>
> Tugwell: Again, this connection you're making is, in my

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[82] *Id.*

[83] *Id.*

[84] *Id.*

[85] *Id*. *See also* Dennis Cauchon, *FDA Advisers Tied to Industry*, USA TODAY, Sept. 25, 2000, at A1.

[86] Dennis Cauchon, *FDA Advisers Tied to Industry*, USA TODAY, Sept. 25, 2000, at A1.

[87] This case is discussed in KRIMSKY, *supra* note 19, at 135-39.

> opinion, not relevant because my involvement in the breast silicone implant litigation is in no way related with any discussion I had with anyone else either in Bristol-Myers Squibb or any other company.[88]

In response to the plaintiff's motion to vacate Dr. Tugwell's appointment to the National Science Panel because of his conflicts of interest, Judge Pointer concluded that no conflict of interest existed and that Dr. Tugwell had acted neutrally, objectively, and impartially.[89] In cases such as these, it is worth questioning whether the standards for impartiality were as high for the selection of jurors as they were for the members of the expert panel.

The scientific community, government agencies, and scholarly journals have largely accepted the idea that transparency is the only meaningful and practical response to conflicts of interest. If we apply the same concept to the judiciary, we might again imagine a situation in which a sentencing judge discloses his equity interest in a for-profit prison. Of course, this scenario seems quite ridiculous and it is hard to imagine that judges, politicians, and journalists could redeem themselves of conflicting interests by simple disclosure.

CONCLUSION

Considering that the disclosure of conflicts of interest fails to provide an adequate solution in the judicial setting, it follows that mere disclosure may also prove insufficient to protect the integrity of scientific research. In fact, evidence shows that even though the norms and conduct of science are believed to conform to a set of universal and inviolable principles, they are not insulated from financial conflicts of interest. Thus, the judiciary could benefit from an understanding of the means by which advocacy science surreptitiously enters the courtroom and the ways in which this

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[88] Deposition of Dr. Peter Tugwell, Apr. 5, 1999, at 116, In re Silicone Gel Breast Implant Products Liability Litigation, 174 F. Supp. 2d 1242 (N.D Ala., 2001) (No. CV-92-N-10000-S).

[89] KRIMSKY, *supra* note 19, at 138.

science is distinct from science that is not designed to support a predetermined financial interest.

In his dissenting opinion in the Bendectin case in 2000, Justice Ronald Castille of the Pennsylvania Supreme Court noted that the accepted methodology for studying Bendectin's effects on the fetus was principally supported by a drug company.[90] He wrote that the pharmaceutical company "largely created the 'generally accepted orthodoxy' that would freeze out viewpoints contrary to their litigation interests . . . [and thus] subsidized or otherwise influenced most of the studies that concluded that Bendectin does not cause birth defects."[91]

Justice Castille correctly identified a corporate research strategy that has been used to fund core methodologies and develop standards of proof that support the long-term financial interests of companies. This strategy has been used to address a variety of scientific issues, including low dose effects, second-hand smoke, endocrine disrupting chemicals, ambient air quality, global warming, and even punitive damage awards by juries. For example, in 1994, an Alaskan federal jury awarded $5.3 billion in punitive damages to individuals who were adversely affected by the Exxon Valdez oil tanker spill.[92] Exxon funded studies by several academic social scientists who eventually published papers challenging the competence of juries to set punitive damages fairly.[93] Those papers were then used by Exxon to support its appeal of the damage award.[94] Several scientists who signed on with the company declared their independence.[95] According to the *L.A. Times,* however, one social scientist contacted by Exxon to

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[90] Blum v. Merrell Dow Pharm., Inc., 764 A.2d 1, 16-17 (Pa. 2000) (Castille, J., dissenting).

[91] *Id.* at 16. Judge Castille wrote: "There is something not a little offensive about an entity, creating a biased, litigation-driven scientific 'orthodoxy,' and then being permitted to silence any qualified expert holding a dissenting view on the grounds of 'unorthodoxy'." *Id.* at 17.

[92] Alan Zarembo, *Funding Studies to Suit Need*, L.A. TIMES, Dec. 3, 2003, at A1.

[93] *Id.*

[94] *Id.*

[95] *Id.*

write an article reported that the company explicitly told him it was looking for articles that could be used in court to argue that juries were not competent to make punitive awards.[96]

There are similar cases of corporate funding of research in risk analysis, toxicology, and epidemiology, in which financial support is aimed at establishing baseline principles that set a high burden of proof for demonstrating causal relationships in public and occupational health with the hope of defining standards that will be used in future litigation. Under *Daubert*, federal judges would benefit from not only being informed about the scientific standards of the specific disciplines from which expertise is drawn, but also about the ways in which corporate stakeholder interests may socially construct those standards. Given the growing evidence that advocacy science has a potentially distorting effect on scientific objectivity, the funding effect in science should be no less relevant to trial judges than considerations of whether a scientific analysis has been peer reviewed, whether a meta-analysis of data is reliable, or whether a technique has a known error rate.

[96] *Id.* at A1.

Table 1 ("The Funding Effect in Science")

Source Journal	Focus of the Study	Conclusion
Journal of General Internal Medicine	conflicts of interest and research results	"authors with COI were 10-20 times less likely to present negative findings than those without COI"[97]
Journal of General Internal Medicine	funding and the outcome of clinical trials	"in no case was a therapeutic agent manufactured by the sponsoring company found to be inferior to an alternative product manufactured by another company"[98]
Journal of the American Medical Association	effect of research funding in randomized drug trials	"conclusions of trials were significantly more likely to recommend the experimental drug as the treatment of choice if trials were funded by for-profit organizations"[99]
Journal of the American Medical Association	impact of financial conflicts of interest in biomedical research	"evidence suggests that financial ties that intertwine industry, investigators, and academic institutions can influence the research process"[100]

[97] Lee S. Friedman & Elihu D. Richter, *Relationship Between Conflicts of Interest and Research Results,* 19 J. GEN. INTERNAL MED. 51, 54 (2004). The study found this "relationship was strongest among studies investigating drug treatments." *Id.*

[98] R. A. Davidson, *Source of Funding and Outcome of Clinical Trials,* 1 J. GEN. INTERNAL MED. 155, 158 (1986) (concluding that studies sponsored by pharmaceutical companies were more likely to favor the new therapy).

[99] Bodil Als-Nielson et al., *Association of Funding and Conclusions in Randomized Drug Trials,* 290 JAMA 921, 925 (2003).

[100] Justin E. Bekelman et al., *Scope and Impact of Financial Conflicts of Interest in Biomedical Research*, 289 JAMA 454, 463 (2003) (finding that "industry-sponsored research tends to draw pro-industry conclusions").

Source Journal	Focus of the Study	Conclusion
Journal of the American Medical Association	potential conflict of interest in trials of new oncology drugs	"[s]tudies funded by pharmaceutical companies were nearly 8 times less likely to research unfavorable qualitative conclusions than nonprofit-funded studies and 1.4 times more likely to reach favorable qualitative conclusions"[101]
British Medical Journal	randomized clinical trials published in the British Medical Journal	"[a]uthors' conclusions . . . significantly favoured experimental interventions if financial competing interests were declared"[102]
Family Practice	randomized controlled drug trials	showing "an association between financial support of published RCTs by commercial interests and outcomes favouring the use of products being tested"[103]
Addiction	smoking or nicotine and human cognitive performance	"researchers acknowledging tobacco industry support were considerably more likely to arrive at a conclusion favorable to the tobacco industry than were researchers not acknowledging industry support"[104]

[101] Mark Friedberg et al., *Evaluation of Conflict of Interest in Economic Analyses of New Drugs Used in Oncology*, 282 JAMA 1453, 1455 (1999).

[102] Lisa L. Kjaergard et al., *Association Between Competing Interests and Authors' Conclusions: Epidemiological Study of Randomized Clinical Trials Published in the BMJ*, 325 BRIT. MED. J. 249, 249 (2002) (also noting that "[o]ther competing interests were not significantly associated with authors' conclusions").

[103] John Yaphe et al., *The Association Between Funding By Commercial Interests and Study Outcome in Randomized Controlled Drug Trials,* 18 FAMILY PRACTICE 565, 567 (2001).

[104] Christina Turner & George J. Spilich, *Research into Smoking or Nicotine and Human Cognitive Performance: Does the Source of Funding Make a Difference?,* 92 ADDICTION 1423, 1426 (1997).