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Conflicts of Interest in Scientific Expert Testimony

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CONFLICTS OF INTEREST IN SCIENTIFIC EXPERT TESTIMONY

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INTRODUCTION

Bias in privately funded scientific research has been much in the news recently.[1] Research bias causes problems in various contexts, from medical decisionmaking[2] to regulatory evalua-

1. The most prominent example is in tobacco research. Tobacco industry documents indicate both that the industry's criteria for research projects discouraged those that might have shown risks from smoking, *see* Diana Henriques, *Tobacco Lawyers' Role Is Questioned*, N.Y. TIMES, Apr. 23, 1998, at A18, and that the industry suppressed the results of studies that did detect health risks, *see* Milo Geyelin, *R.J. Reynolds' 60s Data Removal Cited*, WALL ST. J., Apr. 15, 1998, at B15; Milo Geyelin, *Tobacco Papers Show Lawyers' Control of Data*, WALL ST. J., Apr. 22, 1998, at A3 [hereinafter, Geyelin, *Tobacco Papers*]. Another example that recently received much press coverage is the suppression by Boots Pharmaceuticals, for several years, of the results of research it had funded that unexpectedly showed that a drug it sold was no more effective than drugs of its competitors. *See infra* text accompanying notes 118-24.

2. *See, e.g.*, Thomas M. Burton, *Urodollars: A Prostate Researcher Tested Firm's Product—And Sat on Its Board*, WALL ST. J., Mar. 19, 1998, at A1; Laura Johannes, *Medical Editorialists May Have Failed To Disclose Ties to Obesity-Drug Firms*, WALL ST. J., Aug. 28, 1996, at B3. For further discussion of the incident discussed in the

tions,[3] but the problems it presents are particularly acute in litigation. Scientific evidence is difficult for lay fact finders to assess under the best of circumstances. Bias exacerbates this difficulty because the same unfamiliarity with the practice of science that makes it difficult for laypersons to assess scientific evidence also makes it difficult for them to appreciate how bias can corrupt that evidence. Therefore, even though bias in general is a problem with which the adversary process is familiar, bias in scientific research may require an approach tailored to the particular difficulties that arise in that context.

Of course, the problem of bias in scientific evidence has not gone unnoticed by courts and commentators.[4] But most efforts to address the problem have focused on biased witnesses rather than on biased researchers.[5] These efforts, in other words, have focused on bias introduced in the process of testifying and have assumed that the underlying research record itself is unbiased.[6] An important example, because of its influence, is the Ninth Circuit's opinion in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*[7] In that opinion—to which this Article will refer as *Daubert II*—the court asked "whether the experts are proposing to testify about matters growing naturally and directly out of research they have conducted independent of the litigation, or whether they have developed their opinions expressly for purposes of testifying."[8] The court then went on to treat research conducted

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latter article, involving research into the effects of one-half of the weight control drug combination known as "fen-phen," see *infra* text accompanying notes 45-51.

3. *See* Philip J. Hilts, *F.D.A. Seeks Financial Disclosure by Researchers*, N.Y. TIMES, Sept. 24, 1994, at 7.

4. *See, e.g.*, Daubert v. Merrell Dow Pharms., Inc., 43 F.3d 1311, 1317 (9th Cir. 1995); KENNETH R. FOSTER & PETER W. HUBER, JUDGING SCIENCE: SCIENTIFIC KNOWLEDGE AND THE FEDERAL COURTS 207-24 (1997).

5. Although many experts are both witness and researcher, many other expert witnesses testify regarding the work of researchers who are not themselves before the court. *See infra* text accompanying notes 218-27.

6. *See* FOSTER & HUBER, *supra* note 4, at 209-17; *infra* text accompanying notes 28-36.

7. 43 F.3d 1311 (9th Cir. 1995). The Ninth Circuit considered this case on remand from the United States Supreme Court's decision in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993).

8. *Daubert*, 43 F.3d at 1317.

independent of litigation as reliable, ignoring the many other, nonlitigation sources of research bias.[9]

The weakness in this approach is apparent when one considers that a court would admit, apparently without further scrutiny, testimony regarding research funded by parties to litigation, so long as the research was not conducted in connection with the litigation. For example, in a suit challenging the safety of a drug, it would admit—again, without further scrutiny—research on the safety of the drug that was funded by its manufacturer, if the research predated the litigation. Yet the scientist conducting that research would be no less aware of the result desired by the manufacturer than would a scientist conducting similar research in connection with the litigation. Hence, *Daubert II*'s litigation-based test does not draw an appropriate line for admissibility.

Daubert II is surely correct, though, in treating bias as part of the more general problem of evidentiary reliability that was the focus of the Supreme Court in its *Daubert* opinion.[10] In *Daubert*, the Court held that, when considering scientific evidence, "*evidentiary reliability* will be based on *scientific validity*."[11] Bias certainly is an element of reliability; therefore, although *Daubert* did not discuss bias problems specifically, the opinion at least suggested that the Court would have bias issues decided in court as science decides them. Indeed, science has adopted procedures for dealing with bias that are in some respects similar to other scientific practices—such as peer review—to which the Court directed judges to defer.[12]

This Article argues, however, that a reading of *Daubert* that requires a scientific approach to conflicts would be inappropri-

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9. *See id.* (noting "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" (citing PETER W. HUBER, GALILEO'S REVENGE: JUNK SCIENCE IN THE COURTROOM 206-09 (1991))). Under *Daubert II*, only if the proffered testimony is *not* based on independent research must its proponent support it with other indicia of reliability. *See id.* at 1317-18.

10. *See id.* at 1316-18 (discussing the problem of bias in the context of reliability criteria set out in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 593-95 (1993)).

11. *Daubert*, 509 U.S. at 590 n.9.

12. *See id.* at 593-94.

ate. Bias is no more a valid part of scientific fact finding than it is of legal fact finding. The approaches of scientists to managing conflicts of interest therefore are not themselves scientific, but are simply efforts to preserve the objectivity of science. There is no particular reason to think that the same methods would be appropriate for ensuring objectivity in litigation, which is a very different discipline.

Moreover, even in litigation, different sorts of conflicts present different problems. The focus of *Daubert II* was on conflicts introduced by the litigation process. These conflicts may indeed be serious ones, but it is not clear that they are difficult ones for fact finders to appreciate. They are, after all, the same sorts of conflicts that are presented by the testimony of interested fact witnesses. The conflicts of scientists whose pre-litigation research is the subject of testimony are very different. Those conflicts may be reflected in subtle research choices whose implications will be very difficult for legal fact finders to assess. Hence, it may be that in making admissibility decisions courts should be more careful regarding purely "scientific" conflicts than they are regarding litigation-related ones.[13]

Part I of this Article outlines the holding and rationale of *Daubert*, noting that the reasoning of the Court in that case generally applies to conflicts of interest as well as to the specific aspects of scientific practice the Court discussed. Part II then reviews current treatment of the conflicts of scientific expert witnesses in the lower courts and shows that it is inconsistent in several respects with scientific treatment of such conflicts. Part III argues, as suggested above, that the courts are nevertheless correct in developing their own approach to conflicts because conflicts pose different dangers in legal fact finding than they do in science. Finally, Part IV proposes an approach to conflicts of interest in scientific expert testimony that not only takes into account the different contexts of law and science, but also recog-

13. In his recent philosophical examination of scientific expert testimony, Professor Scott Brewer draws a similar distinction between witnesses and testimony, though not in the context of conflicts of interest. *See* Scott Brewer, *Scientific Expert Testimony and Intellectual Due Process*, 107 YALE L.J. 1535, 1582-85 (1998).

nizes the distinction between the conflicts of scientific expert witnesses and those of scientific researchers.

I. CONFLICTS OF INTEREST AND THE *DAUBERT* FRAMEWORK

The starting point in considering the admissibility of scientific evidence is *Daubert v. Merrell Dow Pharmaceuticals, Inc.*,[14] in which the Supreme Court set out criteria for trial judges to use in making admissibility decisions.[15] Although the Court did not explicitly consider the issue of bias,[16] its rationale for directing judges to apply scientific standards in making admissibility decisions appears as applicable in the context of bias as in other aspects of evidentiary reliability.

A. Daubert

Federal Rule of Evidence 702 provides that an expert may testify to "scientific . . . knowledge" that "will assist the trier of fact."[17] In *Daubert*, the Supreme Court read these two quoted phrases to impose two more or less independent criteria for admissibility: reliability and "fit," or relevance.[18] It is the former

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14. 509 U.S. 579 (1993).

15. *See id.* at 592-95.

16. The questions presented in *Daubert* were:

> 1. Whether, in light of the Federal Rules of Evidence, federal courts may apply the rule of *Frye v. United States*, 293 F. 1013 (D.C. Cir. 1923), and hold expert scientific testimony inadmissible unless it has attained general acceptance in the relevant scientific field.
>
> 2. Whether the *Frye* rule (assuming its applicability) is properly construed to make the admissibility of expert scientific testimony depend upon prior publication in a peer-reviewed journal.

Brief for Petitioners, Daubert v. Merrell Dow Pharms., Inc., 509 U.S. 579 (1993) (No. 92-102).

17. FED. R. EVID. 702. In its entirety, Rule 702 provides: "If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise." *Id. Daubert* did not consider the additional requirement of Rule 702 that the witness be "qualified as an expert by knowledge, skill, experience, training, or education," *id.*, but that requirement will be considered below. *See infra* text accompanying notes 189-91.

18. The Court wrote that "the requirement that an expert's testimony pertain to 'scientific knowledge' establishes a standard of evidentiary reliability," and that the

criterion that applies to the issues addressed in this Article; the latter asks only whether the proffered scientific evidence "properly can be applied to the facts in issue."[19]

In articulating a reliability requirement, the Supreme Court began from the reference in Rule 702 to "scientific knowledge": "The adjective scientific implies a grounding in the methods and procedures of science. Similarly, the word knowledge connotes more than subjective belief or unsupported speculation."[20] The Court then provided a set of five factors that it held were relevant to determining whether proffered testimony is both "scientific" and sufficiently well supported to constitute "knowledge."[21] The factors are: (1) whether the expert's "theory or technique" can be, and has been, tested; (2) whether it has been subjected to peer review and publication; (3) whether, if the expert's testimony is the product of a "particular scientific technique," the technique has an acceptable known or potential rate of error; (4) whether, again if a particular technique is involved, the application of that technique complies with any standards governing its operation; and, finally, (5) whether the testimony is generally accepted in the scientific community.[22] Each of these factors—except perhaps the third: error rate—is a reference to scientific theory or practice.

Notably absent from this list is any mention of the possible biases or conflicts of interest of the expert. The Court made clear, however, that its list of factors is not exhaustive.[23] This

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rule "further requires that the evidence or testimony 'assist the trier of fact to understand the evidence or to determine a fact in issue,'" a "condition [that] goes primarily to relevance." *Daubert*, 509 U.S. at 590-91.

19. *Id.* at 593.

20. *Id.* at 590.

21. *See Daubert*, 509 U.S. at 592-95. Some authors describe the case as setting out only four factors, presumably because the Court discussed both error rates and professional standards in the context of application of "particular scientific techniques." *See, e.g.*, Margaret A. Berger, *Evidentiary Framework, in* FEDERAL JUDICIAL CENTER, REFERENCE MANUAL ON SCIENTIFIC EVIDENCE 37, 71-72 (1994); Bert Black et al., *The Law of Expert Testimony—A Post-*Daubert *Analysis, in* EXPERT EVIDENCE: A PRACTITIONER'S GUIDE TO LAW, SCIENCE, AND THE FJC MANUAL 9, 15 (Bert Black & Patrick W. Lee eds., 1997). *But see* Daniel J. Capra, *The* Daubert *Puzzle*, 32 GA. L. REV. 699, 702 (1998) (referring to five factors).

22. *See Daubert*, 509 U.S. at 592-95.

23. *See id.* at 593 ("Many factors will bear on the inquiry, and we do not presume

caveat suggests that conflicts would be a legitimate factor to consider, at least to the extent that they affect evidentiary reliability. The manner in which courts would take conflicts into account is unclear, though. The Court indicated that other approaches to the reliability issues it addressed could "have merit," but apparently only "[t]o the extent that they focus on the reliability of evidence as ensured by the scientific validity of its underlying principles."[24] This statement seems to suggest that conflicts, like other issues of reliability, should be assessed based on their scientific significance, but this is not the approach the lower federal courts have taken.

B. Conflicts of Interest and Evidentiary Reliability

Conflicts of interest—or, more generally, biases—can affect evidentiary reliability. Courts generally handle biases of expert witnesses in the same way they handle biases of fact witnesses, by permitting cross-examination about the biases and allowing the fact finder to assess the overall credibility of the witnesses.[25] As suggested above, though, conflicts of interest may present particular problems for scientists and for laypersons assessing their testimony. Perhaps, therefore, courts should treat biases in scientific expert testimony differently than biases in other expert testimony.[26] It is, of course, exactly that sort of distinct treatment of scientific expert testimony that the Supreme Court established in *Daubert* when it wrote that, in regard to such testimony, "*evidentiary reliability* will be based on *scientific validity*."[27]

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to set out a definitive checklist or test.").

24. *Id.* at 594 n.12.

25. The Federal Rules of Evidence do not explicitly provide for impeachment of witnesses on the basis of interestedness, but the Supreme Court has held that such impeachment is permissible. *See* United States v. Abel, 469 U.S. 45, 51 (1984) ("We think the lesson to be drawn from all of this is that it is permissible to impeach a witness by showing his bias under the Federal Rules of Evidence just as it was permissible to do so before their adoption."); *see also* 3 JACK B. WEINSTEIN ET AL., WEINSTEIN'S EVIDENCE ¶ 607[03] (1996) (discussing impeachment for bias). Impeachment is appropriate for experts as well as fact witnesses. *See* Ford v. Wainwright, 477 U.S. 399, 415 (1986); Samuel R. Gross, *Expert Evidence*, 1991 WIS. L. REV. 1113, 1168.

26. *See supra* text accompanying note 3.

27. *Daubert*, 509 U.S. at 590 n.9.

Some lower courts, however, have taken a different, and perhaps inconsistent, approach.[28] These courts have considered issues of bias in the admissibility decision, as the unique characteristics of scientific evidence suggest might be appropriate. But instead of focusing on the broad range of conflicts that affect scientific validity and then considering those conflicts in the admissibility decision, the courts have looked at conflicts from what appears to be a narrower legal perspective and have then held that those (legal) conflicts make the expert's testimony unscientific.[29] The most prominent example of this approach—both in its explicitness and in the extent to which it has been followed by other courts—is the Ninth Circuit's opinion on remand in *Daubert II*. Delivering the opinion for a three-judge panel, Judge Kozinski wrote that "the most persuasive basis" for concluding that the expert proposes to testify to "scientific knowledge" is that the proffered testimony is based on the expert's preexisting research, primarily because that reduces the danger that the testimony is influenced by bias:

> 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; when an expert prepares reports and findings before being hired as a witness, that record will limit the degree to which he can tailor his testimony to serve a party's interests. Then, too, independent research carries its own indicia of reliability, as it is conducted, so to speak, in the usual course of business and must normally satisfy a variety of standards to attract funding and institutional support. Finally, there is usually a limited number of scientists actively conducting research on the very subject that is germane to a particular case, which provides a natural constraint on parties' ability to shop for experts who will come to the desired conclusion.[30]

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28. Some of these lower-court decisions are discussed in Part II of this Article. *See infra* text accompanying notes 54-174.

29. The differences between the scientific and legal contexts are discussed in Part III of this Article. *See infra* text accompanying notes 175-84.

30. *Daubert v. Merrell Dow Pharms., Inc.*, 43 F.3d 1311, 1317 (9th Cir. 1995)

This test is discussed further below,[31] but the focus of this section is on the basic assumption underlying it: that "independent research carries its own indicia of reliability."[32] This claim seems to reflect an idealized view of the research enterprise, apparently presupposing that no scientific research conducted independent of litigation is subject to the sort of result-oriented biases that can be problematic in litigation. This idealized view has two specific problems.

First, scientific research is not conducted in a vacuum. Even when such research is conducted independent of "litigation," it is not necessarily conducted free of conflicts of interest. For example, is research funded by the tobacco companies research conducted "independent of litigation"?[33] More generally, is research on a product that is funded by the product's manufacturer, as much drug research is,[34] conducted "independent of litigation"? This problem is especially important because the relevant question in considering the admissibility of scientific testimony is not whether research conducted in connection with litigation is as reliable as *all* research conducted independent of litigation. Courts are only called upon to consider the admissibility of research proffered in litigation, so the relevant question is whether research conducted in connection with litigation—and proffered there—is as reliable as the subset of independent research that is proffered in litigation. As much of the latter class of research is conducted or funded by interested parties, it potentially is subject to the same biases as research related to litigation.

Second, it is not clear that the Ninth Circuit's basic assumption, even as it is stated, is correct; that is, it is not clear that research conducted independent of litigation is more reliable, as presented in court, than research conducted in connection with litigation. The assumption seems facially plausible, but it is less

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(citation omitted).

31. *See infra* text accompanying notes 95-100.

32. *Daubert*, 43 F.3d at 1317.

33. *See supra* note 1.

34. *See* PhRMA, *Domestic U.S. R&D and U.S. R&D Abroad, Ethical Pharmaceuticals, Research-Based Pharmaceutical Companies, 1994-1998* (visited Jan. 28, 1999) <http://www.phrma.org/pdf/publications/industrypdf98/tables.pdf>.

convincing when one realizes that even if the sponsors and researchers that create "independent" research are subject to no conflicts of interest, their research often will be presented in court by an expert employed by a party to the litigation, not by an unbiased source who might present its flaws as well as its strengths. One might even wonder whether research that is conducted in connection with litigation, and that is therefore conducted with the knowledge that it will be subject to the scrutiny of an opposing party, might be *more* reliable than that performed independent of litigation. Scientists in fact bemoan the lack of scrutiny that is applied to most published research.[35] To some extent, litigation can remedy this lack of scrutiny, but the underlying data that would allow a careful review is not always available, and actually it often will be more available when research is conducted for litigation.[36]

In any case, the Supreme Court's *Daubert* decision rests on the view that courts should look to scientific standards to deter-

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35. *See e.g.*, FOSTER & HUBER, *supra* note 4, at 175-82.

36. *See, e.g.*, Symposium, *Court-Ordered Disclosure of Academic Research: A Clash of Values of Science and Law*, LAW & CONTEMP. PROBS., Summer 1996, at 1-191.

This situation recently, though perhaps temporarily, changed for federally funded research. The omnibus appropriations act for fiscal year 1999 included a provision directing the Office of Management and Budget (OMB) "to require Federal awarding agencies to ensure that all data produced under an award will be made available to the public through the procedures established under the Freedom of Information Act," upon payment of a "reasonable user fee." Omnibus Consolidated and Emergency Supplemental Appropriations Act, 1999, Pub. L. No. 105-277, § 117(d), 112 Stat. 2681 (1998). The OMB has not yet implemented this requirement, however, and a bill has been introduced in the current Congress to repeal it. *See* H.R. 88, 106th Cong. (1999).

This disclosure provision, if it survives, will probably do little to address the problem discussed in this Article. The conflicts discussed here arise most frequently in privately funded, not federally funded, research. The provision would provide disclosure in some circumstances of potential conflict, however, as when scientists receive federal funding for research on a topic with which they have some other financial connection. For example, a scientist might receive federal funding for research on a drug produced by a company with which the scientist has an ongoing financial relationship. In such a case, disclosure might be valuable in allowing the detection of choices in conducting the research that might bias its results. When a potential conflict like this exists, however, it is more appropriate to require the party using the research in litigation to provide the underlying data rather than to require the party opposing the research to use FOIA to gain access to the data. *See infra* text accompanying notes 221-22.

mine whether proffered testimony is "good science."[37] It does not support the *Daubert II* position that all "independent" science is reliable; that is, it does not support the view that pure science is good science. *Daubert* provided a list of science-based criteria for telling good science from bad science precisely because the issue is not so simple.[38] When weighing the implications of conflicts of interest in the admissibility calculus, courts therefore should consider all conflicts, not just those connected with litigation.

C. Conflicts of Interest and Scientific Validity

Scientists do many things. As *Daubert II* noted, one of those things is research.[39] Contrary to the apparent suggestion of *Daubert II*,[40] though, scientists also assess and evaluate the research of their colleagues, much as expert witnesses do when testifying on the basis of research that they themselves did not conduct.[41] In doing this, scientists share the concerns of *Daubert II* about conflicts of interest in the interpretation of research, as the following comments from *The Lancet*, a leading medical journal, indicate:

> [W]hen interpretation does prove difficult, we turn to an "expert", which is why medical journals publish editorials, commentaries, and reviews. Editors select writers according to their reputation, academic performance, and independence. In truth, such criteria are vague and entirely subjective—the skill, or bias, of the editor in making these selections is critical.
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> Yet editors find it increasingly difficult to identify academic experts who have not crossed over to the commercial world in some way. . . . So, should the opinions of researchers who

37. *See* Daubert v. Merrell Dow Pharms., Inc., 509 U.S. 579, 592-95 (1993) (discussing the factors courts must use to determine "scientific validity").

38. *See id.* at 593-94.

39. *See* Daubert v. Merrell Dow Pharms., Inc., 43 F.3d 1311, 1317 (9th Cir. 1995).

40. *See id.* ("[A] scientist's workplace is the lab or the field, not the courtroom or the lawyer's office.").

41. In addition to the review articles and editorials discussed here, scientists also assess the work of their colleagues in the peer review process. *See* FOSTER & HUBER, *supra* note 4, at 163-205 (describing the process of peer review of scientific research).

> have collaborated with industry be disqualified from the pages of journals?[42]

These comments suggest a concern almost opposite that of *Daubert II*. Whereas *Daubert II* expressed skepticism regarding the testimony of those who have not conducted research on the subject of their testimony prior to offering their opinions,[43] the editors of *The Lancet* expressed concern about accepting the opinions of those who *have* done research for, or otherwise "collaborated with," an interested party.[44]

In fact, the *Lancet* editorial was prompted by a dispute among scientists over the significance of conflicts that would not have been a concern under *Daubert II*. Specifically, it was prompted by an editorial in the *New England Journal of Medicine* (*NEJM*) that appeared in the same issue as a study showing risks from the use of weight-loss drugs such as fenfluramine derivatives.[45] The *NEJM* editorial contended that these risks "appear[] to be outweighed" by the benefits of the weight loss that they produce.[46] It subsequently was revealed, however, that the authors of the editorial had been paid consultants to a manufacturer and some distributors of dexfenfluramine.[47] The authors had not disclosed these consulting arrangements to *NEJM* because they did not believe that the terms of *NEJM*'s disclosure requirement covered the arrangements.[48] The policy requires that editorial writers "'not have ongoing financial associations (including eq-

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42. *The Politics of Disclosure*, 348 LANCET 627, 627 (1996).

43. *See Daubert*, 43 F.3d at 1317.

44. *The Politics of Disclosure*, *supra* note 42, at 627.

45. *See* JoAnn E. Manson & Gerald A. Faich, *Pharmacotherapy for Obesity—Do the Benefits Outweigh The Risks?*, 335 NEW ENG. J. MED. 659, 659 (1996) (editorial); Lucien Abenheim et al., *Appetite-Suppressant Drugs and the Risk of Primary Pulmonary Hypertension*, 335 NEW ENG. J. MED. 609, 610-14 (1996) (study). Fenfluramine is one-half of the "fen-phen" diet drug combination, and it was recently withdrawn from the market in response to a request by the Food and Drug Administration. *See* John Schwartz, *2 Diet Drugs Are Pulled Off Market: Health Concerns Grow After FDA Links Pills to Rare Heart Problem*, WASH. POST, Sept. 16, 1997, at A1.

46. *See* Manson & Faich, *supra* note 45, at 660.

47. *See* Marcia Angell & Jerome P. Kassirer, *Editorials and Conflicts of Interest*, 335 NEW ENG. J. MED. 1055, 1055-56 (1996).

48. *See* JoAnn E. Manson & Gerald A. Faich, *Conflicts of Interest—Editorialists Respond*, 335 NEW ENG. J. MED. 1064, 1064 (1996); *see also* JoAnn E. Manson, *Adventures in Scientific Discourse*, 8 EPIDEMIOLOGY 324 (1997).

uity interest, regular consultancies, or major research support) with a company that produces a product (or its competitor) discussed in the editorial.'"[49] Because the authors believed that their consulting arrangements were neither "ongoing" nor "regular," they did not report them.[50] The *NEJM* editorial staff, however, believed that the arrangements should have been disclosed.[51]

For present purposes, the important point is not which of these views is correct; it is that the *NEJM* considers these consulting arrangements, and others like them, sufficiently problematic to require a policy governing them. The *NEJM* is not alone in this respect. Scientific institutions have adopted a variety of policies governing conflicts of interest in a wide range of scientific activities, including research itself, peer review, and, as in this example, the publication of reviews and editorials.[52] These policies presumably reflect the views of the scientific community concerning the ways that conflicts can affect scientific validity and, hence, under *Daubert*, evidentiary reliability.[53]

II. THE TREATMENT OF CONFLICTS OF INTEREST BY COURTS AND SCIENTIFIC INSTITUTIONS

Sources of bias in scientific expert testimony can be divided into three categories. The first does not, strictly speaking, involve conflicts of interest on the part of the experts, but it is nevertheless a source of bias: parties to litigation control both the testimony presented and, often, the scientific research that is the basis of that testimony. For example, an interested party might select experts who will present testimony favorable to the party's point of view rather than purely objective testimony, or it might choose to fund only research that it believes will reach

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49. Angell & Kassirer, *supra* note 47, at 1056 (quoting letter allegedly sent to "accused" editorialists by *NEJM* editors prior to publication).

50. *See* Manson & Faich, *supra* note 48, at 1064.

51. *See* Angell & Kassirer, *supra* note 47, at 1056.

52. *See* FOSTER & HUBER, *supra* note 4, at 86-87 (quoting Eliot Marshall, *When Does Intellectual Passion Become Conflict of Interest?*, SCIENCE, July 31, 1992, at 620); *infra* text accompanying notes 71, 91-93, 103-09, 111-14, 129-34, 156-68.

53. *See* Daubert v. Merrell Dow Pharms., Inc., 509 U.S. 579, 590 n.9 (1993) (stating that "*evidentiary reliability* will be based on *scientific validity*").

results favorable to its position. The second problem is a more traditional conflict of interest: the inclination of experts to give testimony that favors a party or position in which the experts have a financial interest. The third problem is the possibility that the underlying research record itself may be distorted by conflicts of interest.

A. Bias in the Selection of the Expert

The most obvious potential bias in expert testimony is that presented by an expert who says what his client—or his client's lawyer—wants him to say, simply because the client is paying for the expert's services. This sort of bias can take two forms. The first is the problem presented when an expert whose true views are *A* testifies to *B* in an effort to curry favor with his client or to influence the outcome of the case for some other reason. This is a true conflict of interest, and it will be discussed in a later section.[54] The other problem, discussed immediately below, involves the expert who is not misrepresenting his actual opinion—perhaps he has none—but is simply providing whatever testimony his client desires.

From reading judicial opinions, one might think that this problem is the primary source of bias in scientific expert testimony. The courts regularly say that an expert should not be a "professional witness,"[55] a "hired gun,"[56] or an "advocate[] for a cause."[57] To the extent that these labels refer to distinct phe-

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54. *See infra* text accompanying notes 94-114.

55. *See* Lust v. Merrell Dow Pharms., Inc., 89 F.3d 594, 597 (9th Cir. 1996) ("professional plaintiff's witness"); Thomas J. Kline, Inc. v. Lorillard, Inc., 878 F.2d 791, 800 (4th Cir. 1989) ("professional expert"); Eymard v. Pan Am. World Airways (*In re* Air Crash Disaster), 795 F.2d 1230, 1234 (5th Cir. 1986) ("professional expert"); Tokio Marine & Fire Ins. Co. v. Grove Mfg. Co., 762 F. Supp. 1016, 1018 (D.P.R. 1991) ("professional witness"), *aff'd*, 958 F.2d 1169 (1st Cir. 1992).

56. Watkins v. Telsmith, Inc., 121 F.3d 984, 991 (5th Cir. 1997) (noting that the "application of the *Daubert* factors is germane to evaluating whether the expert is a hired gun or a person whose opinion in the courtroom will withstand the same scrutiny that it would among his professional peers").

57. Johnston v. United States, 597 F. Supp. 374, 411 (D. Kan. 1984) ("[T]his Court must reject the testimony of Dr. Morgan and Dr. Gofman because they have become advocates for a cause and have therefore departed from the ranks of objective expert witnesses."); *see* Rubinstein v. Marsh, No. CV-80-0177, 1987 WL 30608,

nomena, in the end these phenomena are not as corrupting as the labels would suggest, but derive simply from the fact that experts must be paid and selected by their clients.[58]

1. The "Professional Witness"

An expert who is a "professional witness" is not necessarily biased. Courts most often use this term to describe an expert who "spends substantially all of his time consulting with attorneys and testifying."[59] Independent of any bias such an expert might have, spending all of his time testifying will inevitably erode his scientific skills and knowledge, and he will become less qualified to opine on the subject of his (former) expertise. A court rightly might refuse to admit the testimony of such a witness because "he is more a professional witness than an expert."[60] Strictly speaking, though, the court would not be rejecting the witness's testimony itself; the court instead would be deciding that the proposed witness is not qualified as an expert at all.

No issue of bias necessarily exists here, at least on the part of the witness. It is true that if a "professional witness" is one who lacks real scientific competence, he may be more likely to testify for the party whose position is less scientifically accepted, because that party will find it more difficult to hire competent experts. That does not show that the witness is biased, though, or that his testimony is false. It instead might be that "professional witnesses" can be found with a wide range of views,[61] so that the only bias in their use is in the universal selection by parties of witnesses that will support their positions.

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at *7 (E.D.N.Y. Dec. 10, 1987) ("When expert witnesses become partisans, objectivity is sacrificed to the need to win.").

58. The alternative, court-appointed experts, is discussed below. *See infra* text accompanying notes 197-217.

59. *Eymard*, 795 F.2d at 1234.

60. *Tokio Marine & Fire Ins. Co.*, 762 F. Supp. at 1018.

61. *See infra* notes 79-80 and accompanying text.

2. The "Hired Gun"

It is certainly true that the testimony of a "hired gun"—or, as some courts put it, an expert who is "available to the highest bidder"—is not "scientific knowledge" and therefore should be inadmissible under *Daubert*.[62] Given the frequency (and vehemence) with which this danger is invoked, especially in the popular press,[63] one might expect it to be a frequent focus of the courts. In fact, though, courts are seldom concerned about this issue, presumably because, as *Daubert II* recognized, "few experts appear in court merely as an eleemosynary gesture."[64] One cannot use the mere fact that an expert is paid by his client as a basis for inferring that his testimony is biased; one must look more carefully at the expert's testimony to determine if it is biased, and once one makes that further inquiry, one is not relying on the premise that the expert is a "hired gun."

Courts occasionally do claim to find the mere fact that an expert is paid to be a problem,[65] but comments along this line of-

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62. Even before *Daubert*, the *Eymard* court wrote that those "whose opinions are available to the highest bidder have no place testifying in a court of law, before a jury, and with the imprimatur of the trial judge's decision that he is an 'expert.'" *Eymard*, 795 F.2d at 1234.

63. *See* MARCIA ANGELL, SCIENCE ON TRIAL: THE CLASH OF MEDICAL EVIDENCE AND THE LAW IN THE BREAST IMPLANT CASE 133 (1996); Max Boot, *"Expert" for Hire*, WALL ST. J., Aug. 22, 1996, at A14.

64. Daubert v. Merrell Dow Pharms., Inc., 43 F.3d 1311, 1317 (9th Cir. 1995). The Ninth Circuit also wrote, however, that the fact "[t]hat an expert testifies for money does not *necessarily* cast doubt on the reliability of his testimony," *id.* (emphasis added), suggesting that being paid to testify might cause additional skepticism by the courts.

Of course, if an expert's testimony were really available "to the highest bidder," bias would be present. If this concern were interpreted broadly, it would include within its reach witnesses that critics of expert testimony probably do not intend to condemn. In the recent Microsoft antitrust litigation, Richard Schmalensee, the dean of the Sloan School of Management at the Massachusetts Institute of Technology, appeared as a witness for Microsoft and, when confronted with some earlier writings that contradicted his testimony, responded, "What could I have been thinking?" Transcript of Proceedings, United States v. Microsoft Corp., (Nos. 1:98cv1232, 1:98cv1233) (D.D.C. Jan. 14., 1999), *available in* 1999 WL 15436, at *37; *see also* John R. Wilke & Keith Perine, *Economist Testifies Microsoft Confronts Myriad Threats to Its Windows Software*, WALL ST. J., Jan. 15, 1999, at B6.

65. *See* Lust v. Merrell Dow Pharms., Inc., 89 F.3d 594, 597-98 (9th Cir. 1996) ("It is not unreasonable to presume that Done's opinion on Clomid was influenced by

ten do not appear to be well thought out. For example, in rejecting an expert's testimony, a federal district judge observed that "the fact that [the expert] was hired by [the plaintiff's] counsel further taints the validity of her findings."[66] This statement suggests that the court considered the testimony less reliable simply because the expert was "hired" by counsel to give it. To support the statement, though, the court quoted the Ninth Circuit's comment in *Daubert II* that "'a scientist's normal workplace is the lab or the field, not the courtroom or the lawyer's office.'"[67] To interpret this comment as support for the proposition that a scientist who is "hired" to "work" in the courtroom is thereby less reliable surely goes further than *Daubert II* intended. As noted above, *Daubert II* explicitly recognized that experts are frequently paid to testify, and it did not suggest that their testimony is less admissible as a result.[68]

Following *Daubert*, courts might look to the standards of the scientific community to determine the propriety of being paid to testify.[69] Scientists do not view payment for testimony as improper. For example, the American Medical Association (AMA) claims that "the physician has an ethical obligation to assist in the administration of justice"[70] and recognizes that payment is part of the process, condemning only payment of an expert on a contingency basis.[71] Other organizations also recognize that their

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a litigation-driven financial incentive."); Johnston v. United States, 597 F. Supp. 374, 411 (D. Kan. 1984) ("Indeed, given his $500.00 per day expert witness fee, one must wonder who is partisan!").

66. Washington v. Vogel, 880 F. Supp. 1545, 1548 (M.D. Fla. 1995).

67. *Id.* (quoting *Daubert*, 43 F.3d at 1317).

68. *See supra* text accompanying note 64; *see also* Eymard v. Pan Am. World Airways (*In re* Air Crash Disaster), 795 F.2d 1230, 1234 (5th Cir. 1986) ("That a person spends substantially all of his time consulting with attorneys and testifying is not a disqualification.").

69. *See* Daubert v. Merrell Dow Pharms., Inc., 509 U.S. 579, 589-90, 592-93 (1993) (noting that courts must make a preliminary assessment of whether evidence has "grounding in the methods and procedures of science").

70. COUNCIL ON ETHICAL & JUDICIAL AFFAIRS, AM. MED. ASS'N, CODE OF MEDICAL ETHICS: CURRENT OPINIONS WITH ANNOTATIONS § 9.07 (1997) [hereinafter AMA, CODE OF MEDICAL ETHICS].

71. *See id.* One could view an expert who testifies regularly as doing so on a contingency basis. *See* HUBER, *supra* note 9, at 18 ("A witness may not work directly for a contingent fee, but the expert is a contingent player anyway, and he knows it. His continued employment today, and reemployment tomorrow, depend critically on the

members will offer testimony,[72] and some even have no explicit ban on contingent-fee arrangements.[73]

Moreover, litigation is not the only context in which scientists are paid to express a particular scientific position. For example, some physicians and scientists are paid by drug companies to promote the drug companies' products.[74] Although some scien-

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strength of the support he can supply."). See *infra* text accompanying notes 95-100 for a discussion of this issue.

72. For example, the National Society of Professional Engineers (NSPE) recognizes that its members may provide testimony in requiring that "[e]ngineers shall be objective and truthful in professional reports, statements or testimony." NATIONAL SOC'Y OF PROF'L ENG'RS, CODE OF ETHICS FOR ENGINEERS § II.3.a (1996). The NSPE's *Code of Ethics* does not explicitly forbid contingent fees, but it does provide for disclosure of fee arrangements:

> Engineers shall issue no statements, criticisms, or arguments on technical matters that are inspired or paid for by interested parties, unless they have prefaced their comments by explicitly identifying the interested parties on whose behalf they are speaking, and by revealing the existence of any interest the engineers may have in the matters.

Id. § II.3.c.

73. *See supra* note 72. Paying witnesses on a contingent basis, however, generally runs contrary to legal rules of ethics. The *Model Code of Professional Responsibility* of the American Bar Association (ABA) provides that "[a] lawyer shall not pay, offer to pay, or acquiesce in the payment of compensation to a witness contingent upon the content of his testimony or the outcome of the case." MODEL CODE OF PROFESSIONAL RESPONSIBILITY DR 7-109(C) (1980). The ABA's *Model Rules of Professional Conduct* eliminate this prohibition, stating only that "[a] lawyer shall not . . . offer an inducement to a witness that is prohibited by law," MODEL RULES OF PROFESSIONAL CONDUCT Rule 3.4(b) (1983), but they note in a comment that "[t]he common law rule in most jurisdictions is . . . that it is improper to pay an expert witness a contingent fee." *Id.* at Rule 3.4 cmt.

Two bills have been introduced in Congress proposing to amend Federal Rule of Evidence 702 to make expert testimony inadmissible if the expert is paid on a contingent basis. House Bill 903, introduced in the 105th Congress, provides that "[t]estimony by a witness who is qualified as described in subdivision (a) is inadmissible in evidence if the witness is entitled to receive any compensation contingent on the legal disposition of any claim with respect to which the testimony is offered." H.R. 903, 105th Cong. § 4(2) (1997). A Senate bill was similar. *See* S. 79, 105th Cong. § 302(2) (1997).

74. *See* Elyse Tanouye, *Off the Label: Staffers of Drug Maker Say It Pushed Product for Unapproved Uses*, WALL ST. J., Sept. 15, 1997, at A1 (discussing the case of a "physician and professor of medicine" who "spends much of his time on speaking engagements" promoting the drugs of Rhone-Poulenc Rorer, which pays him "up to $1500" for each speech).

tists object to this practice,[75] it apparently violates no ethical rules.[76]

Thus, there is no indication that scientists question the "scientific validity" of an expert's testimony simply because the expert is paid by the litigant for whom she testifies. That is not to deny that some paid experts do offer testimony that cannot properly be called scientific and therefore should be excluded. Courts nevertheless should not exclude testimony simply because the expert proffering it is paid to do so. Those courts that use the "hired gun" epithet would do better to focus either on the merits of the proffered testimony or, as *Daubert* directs, on considerations that actually do affect scientific validity.

This, in fact, is the approach being taken by the AMA. In a recent report, the AMA's board of trustees observed that "[e]conomic incentives can color the nature of the physician expert's testimony."[77] The AMA is not addressing this problem by

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75. *See, e.g.*, Richard F. LeBlond, Letter to the Editor, 266 JAMA 61 (1991).

76. The AMA has established rules governing a physician's receipt of gifts, *see* AMA, CODE OF MEDICAL ETHICS, *supra* note 70, § 8.061, but these rules are aimed at gifts that might influence physicians' prescription practices, and they do not seem to cover paid marketing of drugs by physicians. *See id.* A letter written in response to AMA promulgation of these rules objected on exactly this point:

> Many university faculty members and prominent practicing physicians serve as paid consultants to major pharmaceutical houses and travel around the country giving seminars and educational conferences that are frequently, although not always, thinly veiled promotions for particular products. In doing so, they exercise their rights as individuals to contract for services, but they also abrogate their responsibilities as faculty members to pursue an impartial view of medical research and therapy.

LeBlond, *supra* note 75, at 61. The AMA's Council on Ethical and Judicial Affairs responded that it had addressed the issue of physicians serving as consultants to industry in another report. *See* Richard J. McMurray & David Orentlicher, *In Reply*, 266 JAMA 63, 63 (1991) (citing Council on Scientific Affairs and Council on Ethical and Judicial Affairs, American Medical Association, *Conflicts of Interest in Medical Center/Industry Research Relationships*, 263 JAMA 2790 (1990) [hereinafter AMA, *Conflicts of Interest*]). That report, however, did not in fact address the issue, or did so only superficially, recommending that in these cases "the researcher's remuneration is commensurate with his or her actual efforts on behalf of the company." *Id.* at 2793.

77. *Report of the AMA Board of Trustees 5-A-98* (visited Jan. 8, 1999) <http://www.ama-assn.org/meetings/public/annual98/reports/bot/bot05.htm> [hereinafter *AMA Report*].

focusing on these economic incentives, though. Instead, it is focusing on the substance of the testimony, by declaring false testimony "intolerable" and developing a peer-review system to discipline physicians who give such false testimony.[78]

3. The Advocate for a Cause

Although the courts sometimes invoke the dangers of the "professional witness" and the "hired gun," the real legal problems with expert testimony are more subtle. Even the most vehement critics of litigants' use of scientific expert testimony acknowledge that litigants usually do not *need* to influence their experts. On the contrary, a litigant usually can find an expert who will express the view that the litigant wants to have expressed.[79] Nor does this necessarily suggest that the expert is biased, even if the testimony is a minority view: "Some of these experts are undoubtedly motivated by financial concerns; others may simply possess eccentric viewpoints."[80]

The ability of a litigant to select an expert who already holds views favorable to the litigant's position presents difficult problems. Certainly courts should not exclude any and all testimony by an expert who has formed an opinion on a scientific issue. In fact, one might well think that such experts will provide the most objective—i.e., uninfluenced by litigation—testimony. As the court in *Daubert II* noted, "when an expert prepares reports and findings before being hired as a witness, that record will limit the degree to which he can tailor his testimony to serve a

78. *See id.*; Michael Higgins, *Docking Doctors?: AMA Eyes Discipline for Physicians Giving 'False' Testimony*, A.B.A. J., Sept. 1998, at 20.

79. As Judge Jack Weinstein puts it, experts "can be found to testify to the truth of almost any factual theory, no matter how frivolous." Jack B. Weinstein, *Improving Expert Testimony*, 20 U. RICH. L. REV. 473, 482 (1986); *see also* Peter Huber, *Safety and the Second Best: The Hazards of Public Risk Management in the Courts*, 85 COLUM. L. REV. 277, 333 (1985) ("The scientific community is large and heterogeneous, and a Ph.D. can be found to swear to almost any 'expert' proposition, no matter how false or foolish.").

80. David Bernstein, Note, *Out of the* Fryeing *Pan and into the Fire: The Expert Witness Problem in Toxic Tort Litigation*, 10 REV. LITIG. 117, 121 (1990).

party's interests."[81] This seems no less true when the position the expert is advocating is a minority one.

From the perspective of the scientific community, it is not "unscientific" to advocate a particular scientific position, even an unpopular one.[82] A scientist can advocate, strongly and over a long period of time, a minority point of view, and no one suggests that he is thereby made unscientific. A prominent example is Peter Duesberg, who for many years has claimed that the HIV retrovirus does not cause AIDS.[83] He published his views in several scientific journals, including *Cancer Research*[84] and the *Proceedings of the National Academy of Sciences*,[85] and they were debated in *Science*.[86] More importantly, perhaps, he expressed his views in traditional scientific terms, arguing, for example, that the HIV causation theory did not satisfy Koch's postulates,[87] probably the best-known and most widely accepted medical causation criteria. This does not mean that he is correct, of course, but it does indicate that an expert can hold a minority view regarding a scientific question—and hold it for a long time—without the expert (or the view) becoming unscientific.

It remains true, however, that "[w]orking scientists can and do readily identify peers whom they regard as having become advocates, no longer capable of reading evidence in an even-handed way."[88] Some scientific institutions seek to address the

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81. Daubert v. Merrell Dow Pharms., Inc., 43 F.3d 1311, 1317 (9th Cir. 1995).

82. In addition to the example discussed in the text, see *AMA Report*, *supra* note 77 ("Because medicine is both a science and an art with a dynamic body of knowledge, theories held by a minority of the medical community may not necessarily be 'junk science,' and instead could be an evolving scientific consensus.").

83. For a history of Duesberg's advocacy of this position and the responses of other scientists, see STEVEN EPSTEIN, IMPURE SCIENCE: AIDS, ACTIVISM, AND THE POLITICS OF KNOWLEDGE 105-78 (1996). For a complete discussion of Duesberg's position, see PETER DUESBERG, INVENTING THE AIDS VIRUS (1996).

84. *See* Peter H. Duesberg, *Retroviruses as Carcinogens and Pathogens: Expectations and Reality*, 47 CANCER RES. 1199 (1987).

85. *See* Peter H. Duesberg, *Human Immunodeficiency Virus and Acquired Immunodeficiency Syndrome: Correlation but not Causation*, 86 PROC. OF THE NAT'L ACAD. OF SCI. 755 (1989).

86. *See* Peter H. Duesberg, *HIV is Not the Cause of Aids*, 241 SCIENCE 514 (1988); Blattner et al., *Blattner and Colleagues Respond to Duesberg*, 241 SCIENCE 514 (1988).

87. *See* EPSTEIN, *supra* note 83, at 75, 137-38.

88. Marshall, *supra* note 52, at 620.

problems these sorts of "intellectual conflicts" create.[89] For example, the National Research Council notes that "[t]he conflicts of interest that arise most frequently concern individual points of view on especially contentious issues," and that it deals with the problem by "selecting a carefully balanced group so that all points of view can be represented."[90] Interestingly, this approach is similar to the adversary process of litigation, and it therefore suggests that intellectual conflicts should not disqualify a witness from testifying, at least if scientific standards are to control legal practice.

The approach science takes in another context supports this point of view. Studies have shown that industry support of Continuing Medical Education (CME) programs can influence the content of those programs.[91] Presumably due to concerns about such issues, the AMA and the Accreditation Council for Continuing Medical Education (ACCME) have decided that commercial CME sponsors should have no voice in determining which speakers appear at CME programs.[92] The difference between the AMA

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89. Several recent articles, however, have suggested that these problems are not easily solved. *See* Carl C. Seltzer, *"Conflicts of Interest" and "Political Science,"* 50 J. CLIN. EPIDEMIOLOGY 627, 627-28 (1997) (describing the NIH's objections to publication of research, based on data obtained in NIH-funded research, indicating that the consumption of moderate amounts of alcohol could reduce coronary heart disease); Gary Taubes, *The (Political) Science of Salt*, 281 SCIENCE 898, 898-907 (1988) (describing the federal government's history of advising citizens to avoid salt in order to reduce hypertension, despite many scientists' beliefs that the advice is not supported by scientific evidence).

90. *The National Research Council Process* (visited Oct. 10, 1998) <http://www.nas.edu/about/faq4.html>. The Council reports that "[c]onflicts stemming from financial interests arise less frequently." *Id.* Both kinds of conflicts must be disclosed: "At the time of appointment, each committee member is required to list all professional, consulting, and financial connections, as well as to describe pertinent intellectual positions and public statements by filling out a confidential form, 'Potential Sources of Bias and Conflict of Interest.'" National Research Council Institute of Medicine, *Getting to Know the Committee Process* (visited Oct. 6, 1998) <http://www2.nas.edu/bbhome/2122.html>.

91. *See* David S. Shimm et al., *Conflicts of Interest in Relationships Between Physicians and the Pharmaceutical Industry*, *in* CONFLICTS OF INTEREST IN CLINICAL PRACTICE AND RESEARCH 321, 326 (Roy G. Spece, Jr. et al. eds, 1996).

92. *See* AMA, CODE OF MEDICAL ETHICS, *supra* note 70, § 8.061 ("[W]hen companies underwrite medical conferences or lectures other than their own, responsibility for and control over the selection of content, faculty, educational methods, and materials should belong to the organizers of the conference or lectures."); Accreditation Council

position in this context and its position regarding expert witnesses—who *are* selected by those who pay them—presumably is related to the presentation of CME programs as objective information. In other words, it is precisely because a CME speaker is *not* clearly a hired gun that the speaker's possible bias presents a danger.[93]

In sum, the problems of the payment and selection of scientific expert witnesses are not unique to litigation. They also are present in science (and, indeed, throughout society). That does not mean that these problems can be dismissed, but it does suggest that they are not so subtle as to be beyond the capacity of legal fact finders to appreciate. It is the less obvious conflicts that are likely to present greater difficulty.

B. Conflicts for the Expert Testifying

In considering bias in expert testimony, the usual focus is the witnesses' conflicts of interest.[94] Most obviously, this sort of conflict of interest can arise when the expert has a financial inter-

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for Continuing Medical Education, *Standards for Commercial Support of Continuing Medical Education* (visited Oct. 6, 1998) <http://www.accme.org/essent/commerce.htm>.

The FDA recently issued a document providing guidance to the pharmaceutical industry on these matters. *See* Final Guidance on Industry-Supported Scientific and Educational Activities, 62 Fed. Reg. 64,073 (1997). The FDA does not regulate "truly independent and nonpromotional industry-supported [scientific and educational] activities" because those activities are not subject to its jurisdiction over labeling and advertising. *Id.* at 64,094. This limitation on its jurisdiction requires the FDA to determine whether an activity is independent:

> The agency will consider whether the provider has maintained full control over the content of the program, planning of the program's content, and over the selection of speakers and moderators. . . . In addition, the agency will consider if the company has suggested speakers who are or were actively involved in promoting the company's products or who have been the subject of complaints or objections with regard to presentations that were viewed as misleading or biased in favor of the company's products.

Id. at 64,097.

93. *See* Shimm et al., *supra* note 91, at 325 ("[U]nlike gift giving or advertising, CME usually takes place under the aegis of a legitimate and supposedly neutral academic or professional institution or organization, so that physicians listening to presentations are much less likely to suspect bias in the information.").

94. *See, e.g.*, Daubert v. Merrell Dow Pharms., Inc., 43 F.3d 1311, 1317 (9th Cir. 1995); FOSTER & HUBER, *supra* note 4, at 207-24; HUBER, *supra* note 9, at 198-209.

est either in the outcome of the case in which he is testifying or in the results of the research about which he testifies. This section describes the possibility of conflicts that arise when a witness has an expectation of future employment as an expert witness—the probable concern of *Daubert II*—and then focuses on other relationships that can cause an expert to skew his testimony, as well as the approach the scientific community takes in handling these relationships.

1. Testimony Distorted by an Expert's Expectation of Future Testimony

The conflict created by a witness's expectation of future testimony was probably the primary concern of the Ninth Circuit in *Daubert II*. When the court wrote of the "promise of remuneration" for the expert, it presumably was focusing on remuneration from being hired in future cases.[95] An expert's remuneration in a given case is not likely to depend on his testimony because experts generally are not paid with contingent fees,[96] but whether the expert is hired again indeed might depend on his testimony.

One might expect a test addressing this problem to focus on the ongoing relationships between experts and their clients or their clients' lawyers. Opposing lawyers routinely cross-examine expert witnesses on these relationships, and fact finders may consider the possibility that it is the relationship, and the expectation of its continuance, rather than the facts that more powerfully influences the expert's testimony. The problem is that, given the perceptions of laypersons that science is objective, cross-examination might not be enough.

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95. *Cf. supra* text accompanying notes 65-68 (discussing the inference of bias from the mere fact that an expert was paid).

96. *See supra* note 73. *But see* Paul D. Carrington & Traci L. Jones, *Reluctant Experts*, LAW & CONTEMP. PROBS., Summer 1996, at 51, 55-56 ("While expert witnesses cannot, consistently with lawyers' ethical duties, be employed on a contingent fee basis, more than a few such experts know that there is little prospect that their client will be able to pay their fees unless they prevail on the merits at trial." (footnote omitted)); Michelle M. Dillon, *Contingent Fees and Medical-Legal Consulting Services: Economical or Unethical?*, 11 J. LEGAL MED. 93, 97, 108 (1990) (discussing the payment of flat rates to expert witnesses by medical-legal consulting firms that are compensated on a contingent basis by parties to litigation).

Courts therefore reasonably might choose to rest admissibility on some criterion that reflects the likelihood that an expert's testimony is intended to promote his future employment as a witness. Courts, for example, might ask whether the expert has significant employment *outside* his role as a witness. If not, the expert presumably relies primarily on giving testimony for income and therefore might be motivated to provide testimony that would preserve that income. Such a test would be consistent with the reasoning in *Daubert II*, which focused on whether the expert is testifying about research conducted independent of litigation.[97] If an expert does little other than testify, any research he actually does conduct most likely would be done in connection with litigation.

The *Daubert II* test, however, also would cover legitimate scientists hired to conduct research in connection with litigation. Even if these scientists have no expectation of, or desire for, future employment as expert witnesses, they could be prevented from testifying by the *Daubert II* standard. This view that the *Daubert II* test is overbroad is consistent with scientific practice. For example, there is no requirement that the authors of editorials and review articles, the publications that most closely resemble expert testimony,[98] have themselves performed any of the research that they discuss.[99]

Even experts who do little research beyond their work in connection with litigation cannot always anticipate future employment if their testimony is satisfactory. For example, the case in which an expert testifies might be the only one in which the subject of the expert's testimony is at issue, or it might be a nationwide class action that will resolve all related claims. In ei-

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97. *See Daubert*, 43 F.3d at 1317.

98. The *New England Journal of Medicine* states that "the essence of reviews and editorials is selection and interpretation of the literature." *New England Journal of Medicine, Information for Authors* (visited Oct. 6, 1998) <http://www.nejm.org/general/text/InfoAuth.htm> [hereinafter *NEJM, Information for Authors*].

99. *See Journal of the American Medical Association*, JAMA *Instructions for Authors* (visited Oct. 6, 1998) <http://www.ama-assn.org/public/journals/jama/instruct.htm#-categories> [hereinafter JAMA *Instructions for Authors*] (discussing reviews); *Writing for* The Lancet (visited Oct. 15, 1998) <http://www.thelancet.com/newlancet/reg/author/writing1.html> [hereinafter *Writing for* The Lancet] (discussing commentaries and review articles).

ther case, because there would be no future opportunities to offer testimony on the same topic,[100] it is difficult to see why the expert would have an incentive to skew his testimony.

At the very least, then, a test that focuses on whether the expert testifying performed the research about which he testifies in connection with litigation also should incorporate some reference to the likelihood that the expert expects future employment as a witness. Only then will the test really address the sorts of conflicts that it presumably intends to reach. For example, a better-focused test might ask whether the expert's research, even if performed in connection with litigation, is related to non-litigation work that he has done and will continue to do. In that case, the court presumably could be more confident both that the expert had real expertise and that he might suffer costs from misusing that expertise. The test also might attempt to determine, as suggested above, whether the expert could reasonably anticipate future employment in offering similar testimony. Incorporating these questions into the test complicates it, of course, but that is the cost of fitting the test to the real problems in expert testimony.

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100. It is still possible that the expert could anticipate testifying in other cases on other topics. An extreme example was discussed in Tokio Marine & Fire Ins. Co. v. Grove Mfg. Co., 958 F.2d 1169, 1174 (1st Cir. 1992).

> Alterman admitted to having testified as a professed expert in an extraordinary array of dissimilar fields: construction safety, scaffolding, real estate appraisals on industrial facilities, fire protection systems, bulk oil terminals, cargo waterfront terminals, bridges, high rise construction, construction of highways, construction of race tracks, the field of construction management, the field of drainage projects, construction of containerized cargo facilities, the field of construction estimating, the field of waste treatment plants and water treatment plants, industrial buildings, wire ropes and wire cables, and opened wedged sockets.

Id. This, in fact, is one of the objections often raised to the testimony of "clinical ecologists," who have testified that environmental chemicals have caused a broad range of injuries. *See infra* note 291 and accompanying text. *Daubert II*, however, offers no evidence to suggest that all experts can expect future employment if their current testimony is satisfactory, so there does not seem to be a sufficient basis for adopting a test that relies on an assumption that such expectations exist.

2. Testimony Distorted by Other Conflicts of Interest

The *Daubert II* test is also underinclusive. Even if an expert has previously conducted research on the subject about which he testifies, he may have a financial interest in the results of the case, or in one of the parties to the case. In fact, it seems *more* likely that an expert who has previously conducted research on a subject will have a financial interest in it. This is the case, for example, when an employee testifies for his or her employer, yet *Daubert II* expresses no concern about this problem. A reason to ignore this problem, one might think, is that the future employment of a non-employee expert may depend more directly on his testimony than does that of an employee expert. The client has no need to employ a freelance expert who does not provide testimony favorable to his case, whereas an expert who is also an employee presumably provides other valuable services to his employer. The other side of the coin, though, is that the freelance expert may have other clients or potential clients, so that he might feel more free to provide testimony less favorable to a particular client than would an employee. Furthermore, as discussed below, the employee may be testifying about research that he did himself for the company, and that research itself may be biased.[101]

The existence of conflicts of interest in many circumstances beyond litigation is reflected in scientific practice. In some cases, as in the AMA ban on contingent fee arrangements for medical experts, scientists consider this problem in the specific context of expert testimony, but more often they focus on conflicts in other contexts. Nevertheless, because many of these contexts involve the reporting or evaluation of scientific evidence, as expert testimony does, the policies of scientific institutions in these instances may indicate how scientists would treat similar conflicts of scientific expert witnesses.

At the outset, it seems clear that scientists would view both employment relationships and continuing expert witness relationships as presenting similar problems.[102] The conflict of inter-

101. *See infra* text accompanying notes 155-74.

102. As of 1995, some journals apparently saw no problem at all with either type

est policies of most scientific journals and institutions require authors to disclose continuing financial relationships, without specifying what those relationships might be.[103] An employment relationship therefore presumably would be of as great a concern as would a continuing expert witness relationship. One journal, the *Journal of the American Medical Association* (*JAMA*), may view expert-witness relationships with particular concern. *JAMA* requires authors to disclose any "financial involvement," which it defines to include "expert testimony."[104] This might suggest that *any* expert witness relationship, not just a continuing one, would trigger concern about a conflict. This seems unlikely, though, and the policies of other journals suggest that only continuing relationships raise concerns.[105]

Of course, that a journal requires disclosure of a conflict does not mean that it uses the disclosed information in any way. In most cases, the policies of scientific journals do not suggest that

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of relationship, and did not require disclosure of such conflicts. *See* Sheldon Krimsky & L.S. Rothenberg, *Financial Interest and Its Disclosure in Scientific Publications*, 280 JAMA 225, 226 (1998) (citing a survey of North American medical journal editors). The leading medical journals have disclosure requirements, though. *See* JAMA *Instructions for Authors*, *supra* note 99; *NEJM, Information for Authors*, *supra* note 98; *Writing for* The Lancet, *supra* note 99. The voluntary Uniform Requirements for Manuscripts Submitted to Biomedical Journals also recommends such disclosure. *See Uniform Requirements for Manuscripts Submitted to Biomedical Journals* (visited Oct. 15, 1998) <http://www.thelancet.com/newlancet/reg/author/uniform1.html> [hereinafter *Uniform Requirements*]. Even when disclosure is required by journals, though, authors may not comply. *See* Ralph T. King, Jr., *Medical Journals Rarely Disclose Researchers' Ties*, WALL ST. J., Feb. 2, 1999, at B1.

103. For example, the *New England Journal of Medicine* asks authors of research articles to submit information regarding "any financial arrangement they may have with a company whose product figures prominently in the submitted manuscript or with a company making a competing product." *NEJM, Information for Authors*, *supra* note 98. The *Journal of the American Medical Association* requires authors to disclose "affiliations with or financial involvement (e[.]g[.], employment, consultancies, honoraria, stock ownership or options, expert testimony, grants or patents received or pending, royalties) with any organization or entity with a financial interest in the subject matter or materials discussed in the manuscript." *JAMA, Authorship Criteria and Responsibility, Financial Disclosure, Copyright Transfer and Acknowledgement* (visited Oct. 6, 1998) <http://www.ama-assn.org/public/journals/jama/jautform.htm> [hereinafter *JAMA, Authorship Criteria*].

104. *JAMA, Authorship Criteria*, *supra* note 103.

105. *See Writing for* The Lancet, *supra* note 99; *NEJM, Information for Authors*, *supra* note 98.

the disclosure of a conflict would cause them to disqualify an author, which would be analogous to holding an expert's testimony inadmissible. On the contrary, many of the journals that require authors to disclose conflicts to their editors do not even disclose the conflict to their readers.[106] If one were to follow the Supreme Court's formulation in *Daubert* and apply the approach of these journals to evidence, one might forbid inquiry into conflicts even on cross-examination. The policy of the journals, that is, appears equivalent to a requirement that experts disclose conflicts to the lawyers who hired them and to judges, but not necessarily to jurors.

Initially, one might find this rather cavalier approach to conflicts unsurprising. After all, the scientific journals may believe that, because their readership consists not of lay jurors, but of practicing scientists who will judge the published articles on their scientific merit, disclosure of conflicts would be unnecessary. The policies of one journal, however, suggest that the relevant distinction is not that between laypersons and scientists but between different kinds of scientific writing. A typical scientific article purports only to set out facts, rather than, as with expert testimony, opinion on some ultimate issue. The *New England Journal of Medicine* (*NEJM*) distinguishes its standard articles from expressions of opinion on exactly this ground:

> Scientific reports are self-contained. They present original data, and readers can judge for themselves whether the authors' interpretations are supported by the data. Editorials and review articles are different. They are not self-contained, and there are no primary data. Instead, editorialists and authors of review articles evaluate an issue on the basis of what they select from the literature as relevant. . . . It is expected

106. *See Writing for* The Lancet, *supra* note 99 (stating only that the editors "will discuss with [the authors] whether or not disclosure in the journal is necessary"); *see also* King, *supra* note 102, at B1 (revealing that only 0.5% of over 62,000 articles published in 1997 included information regarding authors' conflicts of interest); *NEJM, Information for Authors*, *supra* note 98 (stating that the editors only discuss with an author whether or how to communicate such a disclosure to the reader). The Uniform Requirements for Manuscripts Submitted to Biomedical Journals, however, provides that "the information should be made available so that others can judge their effects for themselves." *Uniform Requirements*, *supra* note 102.

> that they will provide an unbiased and authoritative opinion about the matter. That is why we insist that editorialists have no financial ties to products that figure prominently in their work.[107]

NEJM's stated policy provides that editorialists should not have "any financial interest in a company (or its competitor) that makes a product discussed in the article."[108] The "standard letter" that it sends to prospective editorialists states that the journal "ask[s] that authors not have ongoing financial associations (including equity interest, regular consultancies, or major research support)."[109]

If one were to adopt *NEJM*'s approach, then, one might not allow testimony by any experts that had ongoing relationships with parties to litigation or attorneys in the litigation. Of course, cross-examination is not available for the editorials and review articles in *NEJM*.[110] This may force the journal to be more careful than otherwise necessary, opting for disqualification of the author rather than simple disclosure of the conflict. In other circumstances in which cross-examination is permitted, it might be sufficient to disclose any conflicts of interest and allow the cross-examiner to pursue the issue.

A practice somewhat similar to cross-examination is used in the reviews of research conducted by the scientific review

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107. Angell & Kassirer, *supra* note 47, at 1055. *See also The National Research Council Process* (visited Oct. 6, 1998) <http://www.nas.edu/about/faq4.html> ("The [Council's] process is particularly aggressive in differentiating committee opinions and judgments from findings of fact well-grounded in science"). Ironically, despite the firm position of the *NEJM* on this issue, its editor Marcia Angell has expressed her own, strongly critical opinion of the operation of the trial system in the ongoing silicone-breast-implant litigation, *see* ANGELL, *supra* note 63, without revealing her own interest in that litigation. *See Medical Editor/Civil Justice Critic Doubles as Expert Witness in Breast Implant Cases* (Opinion), CIV. JUST. DIG. (Roscoe Pound Found.), Fall 1996, at 2.

108. *NEJM, Information for Authors*, *supra* note 98.

109. Angell & Kassirer, *supra* note 47, at 1056. Although this was the language that the journal used in 1996, it is not clear whether it currently uses the same language.

110. Letters to the editors may serve to accomplish some of the purpose of cross-examination, but they are obviously an imperfect substitute.

groups, or "study sections," of the National Institutes of Health (NIH). An application for an NIH grant is evaluated by a study section "composed generally of 18 to 20 individuals, nominated by the [Scientific Review Administrator of the study section] from among the active and productive researchers in the biomedical community."[111] The members of a study section debate the merits of a proposal, so an individual member's comments can be challenged by other members, much as cross-examination challenges the statements made in testimony.[112] Although a study section evaluates the quality of a research proposal, whereas an expert witness evaluates the results of research, the two tasks involve many similar issues.[113] The conflict policies of the study sections are therefore at least potentially relevant to the evaluation of expert testimony.

The NIH conflict of interest policy requires that "[a] member must leave the room when an application submitted by his/her own organization is being discussed or when the member, his/her immediate family, or close professional associate(s) has a financial or vested interest even if no significant involvement is apparent in the proposal being considered."[114] As with the *NEJM*

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111. *A Straightforward Description of What Happens to Your Research Project Grant Application (R01/R21) After It Is Received for Peer Review* (visited Oct. 6, 1998) <http://www.csr.nih.gov/review/peerrev.htm>. When the study section does not have the expertise needed to evaluate a particular application, "the study section's membership is frequently supplemented by temporary members and written outside opinions." *Id.*

112. *See id.*

113. *See id.*

114. *Review Procedures for Initial Review Group Meetings* (last modified Aug. 13, 1998) <http://www.csr.nih.gov/guidelines/proc.htm>. The policy states that "[t]he term 'own organization' includes the entire system in which the member is an employee, consultant, officer, director, or trustee or has a financial interest; or with which the member is negotiating or has any arrangement concerning prospective employment." *Id.* The policy also states that: "[I]f the member is available at the principal investigator's institution for discussions; is a provider of services, cell lines, reagents, or other materials, or writer of a letter of reference, the member must be absent from the room during the review." *Id.*

Under the policy, "[m]embers are also urged to avoid any actions that might give the *appearance* that a conflict of interest exists, even though he or she believes there may not be an actual conflict of interest." *Id.* The policy provides several examples:

policy, it is unclear whether the NIH would view freelance expert witnesses as having conflicts of interest, but employees certainly would have them. The policy therefore seems to suggest that the NIH bans input from study section members who have conflicts, much as *NEJM* bans editorials by similarly situated individuals.

The approach of *Daubert II* to conflicts is thus flawed in two important ways. First, expert opinions about scientific facts are not necessarily unreliable simply because they are derived from research conducted in connection with litigation. Second, unlike *Daubert II*, science recognizes that there are a number of circumstances other than litigation that present conflicts for scientists. In many of these circumstances, scientific institutions have adopted strict rules forbidding participation by interested scientists. Because this ban on participation is roughly equivalent to the admissibility decision addressed by the Supreme Court in *Daubert*, it may counsel an approach to expert testimony different from the one currently used by the courts.

C. Conflicts in the Conduct of the Research About Which the Expert Testifies

Even if a litigant's selection of an expert was unbiased and the expert himself had no conflict, the expert's testimony might still be biased. This is possible because the scientific knowledge about which the expert testifies may itself be biased. This can occur in at least three ways. The least difficult of these distortions to detect, perhaps, is the distortion of research results through control over the reporting of those results. Somewhat more difficult to detect is a distortion of the record caused by selective funding. Finally, the most difficult problem is a distortion of research results by researchers themselves.

> Thus, for example, a member should not participate in the deliberations and actions on any application from a recent student, a recent teacher, or a close personal friend. . . . Another example might be an application from a scientist with whom the member has had longstanding differences which could reasonably be viewed as affecting the member's objectivity. Another example which might be considered is the review of a project which closely duplicates work ongoing in the member's laboratory.

Id.

1. Research Reports Distorted by an Interested Party

Not surprisingly, much of the research that is relevant in litigation is conducted or funded by parties to the litigation, or by sponsors with interests similar to those of parties to the litigation.[115] One problem, discussed below,[116] that arises in this context is that the researcher's desire to please her sponsor may taint the research. The issue considered here is the control that the sponsor may have over whether the research results—even assuming that they are unbiased—are made public. A recent article describes the problem:

> Many different types of relationships may exist between sponsors of research studies and independent investigators. A sponsored research agreement allows the author to retain control over the publication of study results. A consulting agreement may not give explicit publication rights to the investigator or author. Consulting agreements can also be designed to require the author to submit the manuscript for publication only after the sponsor reviews the manuscript and provides written permission for publication. Generally, sponsored-research agreements are designed to protect the academic integrity of the study. While the research produced under these agreements may not appear different to the journal or to the reader, the sponsorship agreement may serve to limit the publication of findings that are "negative" from the sponsor's perspective.[117]

This problem is illustrated by the recent, well-publicized contract that gave a research sponsor the power to veto publication by a researcher at the University of California at San Francisco (UCSF).[118] A maker of synthetic thyroid hormones had funded

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115. *See, e.g.*, Geyelin, *Tobacco Papers*, *supra* note 1 (discussing research sponsored by tobacco companies).

116. *See infra* notes 155-74 and accompanying text.

117. Kevin Schulman et al., *Ethics, Economics, and the Publication Policies of Major Medical Journals*, 272 JAMA 154, 154 (1994).

118. *See* Lawrence K. Altman, *Drug Firm, Relenting, Allows Unflattering Study to Appear*, N.Y. TIMES, Apr. 16, 1997, at A1; 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; *Knoll Agrees to Permit Publication of Drug Study*, WALL ST. J., Dec. 9, 1996, at 11F.

Dr. Betty Dong of UCSF to perform a study comparing its brand-name thyroid hormone to several other versions of the same drug.[119] The study found that generic forms of the drug worked just as well as the brand-name form.[120] Dr. Dong had signed an agreement that gave the drug company control over publication of her results, however, and Boots Pharmaceuticals, Inc., which by then had acquired the business of the original sponsor, refused to give her permission to publish, as did Knoll Pharmaceutical Company, which later acquired Boots.[121] Dr. Dong nevertheless sought to publish the study, and it was accepted by the *Journal of the American Medical Association*, but the university, concerned about financial liability, indicated that it would not defend her if the company sued.[122] A public outcry ensued—brought on in part by a *Wall Street Journal* article regarding the incident—and ultimately Knoll allowed the article to be published two years after its publication was originally scheduled.[123] As will be discussed below, Knoll attempted to discredit Dr. Dong's study both prior to and after the article's publication.[124]

The outrage in scientific circles over this incident suggests that such agreements might be considered "unscientific." Indeed, the authors of the passage quoted above believe that "[d]isclosure of these agreements is . . . critical to the development of objective data to aid clinical and health policy decision making."[125] They contend that the lack of reporting requirements suggests "an opportunity for potential manipulation of research findings by sponsors."[126] Courts that heed the instruction of

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119. *See* King, *supra* note 118, at A1.
120. *See id.*
121. *See id.*
122. *See id.*
123. *See Knoll Agrees to Permit Publication of Drug Study*, *supra* note 118, at 11F.
124. *See infra* text accompanying notes 277-80.
125. Schulman et al., *supra* note 117, at 156.
126. *Id.* Furthermore, the authors of this study suggest problems analogous to those described above for the adversary system. They claim that "[i]nvestigators who abide by the principles of requiring academic freedom in sponsorship agreements may find that they are unable to compete with investigators who do not comply with these restrictive investigation rules." *Id.* They further argue that "[s]ince the journals do not inquire about such arrangements, sponsors and investigators will not

Daubert to follow scientific standards therefore might consider disallowing testimony regarding research performed under a contract that imposes limits on publication.

The same authors note, however, that a survey of leading medical journals found that although nine of twelve requested disclosure of the financial arrangements between the authors of papers and the sponsors of their research, only four inquired about the author's publication rights, and only one knew whether the sponsor had the right to prevent or delay publication.[127] This might suggest that scientists in fact do not view this as an important issue.[128]

Journal publication is quite different from expert testimony, though. In publishing an individual study, a journal is concerned only with the accuracy of that study and not with the accuracy of the entire scientific record. A journal therefore would not necessarily be concerned that a study would not have been submitted for publication at all if its results had been different.

In contrast, to the extent that parties to litigation will offer only expert testimony about research the results of which are favorable to the sponsor that funds it, this will distort the factual record at trial.[129] Research funded by the tobacco industry may be an example of this practice. Some anecdotal evidence exists that the tobacco industry has, at least in the past, sought to influence the publication of research results it funded.[130] Al-

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encounter any publication pressure to comply with these standards to maintain the objectivity of research findings." *Id.*

127. *See id.* at 155.

128. *See* Lawrence K. Altman, *Experts See Bias In Drug Data*, N.Y. TIMES, Apr. 29, 1997, at C1 ("[E]xperts said there was little information and few methods to determine how often information was not reported because of restrictive clauses in contracts. Some said they suspected that other cases similar to Dr. Dong's escape attention because academic scientists do not seek publication in the first place."). Presumably this means that scientists do not seek publication when they are subject to contractual restrictions.

129. *Cf.* HUBER, *supra* note 9, at 208 (discussing a proposal by physicist Richard Feynman that a "scientist approached for his expert opinion must resolve at the outset to publish or at least disclose his conclusion, regardless of whose side it will benefit in the forthcoming trial"). Of using a conclusion only when it favors the sponsor of the work, Feynman claims: "'That's not giving scientific advice.'" *Id.* at 207.

130. *See* Freddy Homburger, Letter to the Editor, *Tobacco Research: One Researcher's*

though this may not be the current policy of the industry,[131] it might suggest that it would be unwise for courts to allow expert testimony regarding research funded by the tobacco industry. In possible support of this view, some scientific institutions, such as the Massachusetts General Hospital, refuse to accept funding from the tobacco industry,[132] and some journals do not publish tobacco-industry-funded research.[133] The reasons these institu-

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Experience, 273 SCIENCE 1322, 1323 (1996). In his letter, Homburger describes an incident in the early 1970s in which the director of research and lawyer for the Council for Tobacco Research [CTR] told Homburger that his group "'would never get another penny from CTR' if we published a paper, submitted for their approval, reporting that inhaling cigarette smoke caused laryngeal cancer in a certain inbred Syrian hamster." *Id.* The group "never received another penny from CTR" after it nevertheless published the paper. *Id.*

The same problem may exist with asbestos research:

> Publication [of asbestos research] may be contingent on the words, conditions, and conclusion of a research study, an unfortunate situation that has apparently persisted in this area of research for over 60 years. In fact, the authors have been made aware of threatened or actual lawsuits concerning various publications that have had a chilling effect on the dissemination of information regarding the possible health effects of asbestos.

2 BARBARA J. PETERS & GEORGE A. PETERS, SOURCEBOOK ON ASBESTOS DISEASES: MEDICAL, LEGAL AND ENGINEERING ASPECTS 2 (1986).

131. The author of the letter cited in the previous note states that CTR's more recent policies may be different, *see* Homburger, *supra* note 130, at 1322, and an article analyzing tobacco industry documents notes that the industry maintains that it does not restrict publication and cites no documents contradicting that claim. *See* Lisa Bero et al., *Lawyer Control of the Tobacco Industry's External Research Program: The Brown and Williamson Documents*, 274 JAMA 241, 244 (1995) (citing, however, a letter indicating that a funded researcher submitted an article to a tobacco company lawyer prior to submitting the article for publication). It is possible that the tobacco industry distorts the scientific record through its initial decisions on which research to fund. *See infra* note 140 and accompanying text.

132. *See* Jon Cohen, *Tobacco Money Lights Up a Debate*, 272 SCIENCE 488, 490 (1996). The hospital's policy statement refers to the tobacco industry's citation of scientists who received industry funding and states that this (presumably misleading) use of the scientists' names presents a conflict of interest for the hospital. Massachusetts Gen. Hosp., *Massachusetts General Hospital Policy on Research Support from the Council for Tobacco Research—U.S.A., Inc. and the Smokeless Tobacco Research Council, Inc.*, Mar. 18, 1994, at 2. The citation of the scientist's names might be seen to have distorted the scientific record in a sense, but the hospital statement claims that the industry did not "interfer[e] directly with the research programs of the sponsored investigators." *Id.*

133. Medical journals published by the American Lung Association (ALA) have refused to publish research funded by the tobacco industry since December 1, 1995.

tions spurn tobacco industry research are somewhat unclear,[134] however, so their implications in the present context also are unclear.

2. *A Research Record Biased by an Interested Party*

A court faces a similar but more difficult problem when a litigant proffers evidence in a situation in which the litigant has had control over what research has been conducted, as distinguished from whether the research done has been reported.[135] In products liability cases, for example, it is often the case that the only party with the incentive to pay for research on the product is the defendant.[136] To the extent that the defendant can choose

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See American Lung Association, *American Lung Association Journals Will Not Publish Research Funded by Tobacco Industry* (press release) (n.d.) (on file with author). The reasons for the ALA policy are somewhat unclear. The press release issued when the policy went into effect cited a statement by a past president of the ALA, Dr. Alfred Munzer, that "the peer review process that screens and evaluates all research that is accepted by [the *American Journal of Respiratory and Critical Care Medicine* and the *American Journal of Respiratory Cell and Molecular Biology*] ensures that the studies that are published are accurate and non-biased." *Id.* at 1-2. Dr. Munzer nevertheless said that members of the ALA's medical section, the American Thoracic Society (ATS), were concerned about "'even an appearance of conflict.'" *Id.* at 2; *see also* Arthur C. Caplan, *The Smoking Lamp Should Not Be Lit in ATS/ALA Publications*, 151 AM. J. RESPIRATORY & CRITICAL CARE MED. 273, 273 (1995) (supporting ATS's then-proposed policy, in part because of the tobacco industry's research policies). It is unclear, however, why readers would think that the ALA's publication of research funded by the tobacco industry indicated a conflict of interest. Given the ALA's opposition to smoking, one might expect exactly the opposite: that its refusal to publish such research was the product of bias. Efforts to obtain more information on the ALA's reasons for its policy resulted in repeated, but unfulfilled, promises to send such information by ATS officials.

134. *See supra* notes 132-33. Similarly unclear is the justification for the following recommendation by the National Cancer Advisory Board: "Withdraw Federal funding from cancer research organizations that accept tobacco industry support." NATIONAL CANCER ADVISORY BOARD, SUBCOMMITTEE TO EVALUATE THE NATIONAL CANCER PROGRAM, CANCER AT A CROSSROADS: A REPORT TO CONGRESS FOR THE NATION 21 (1994).

135. A recent news article quoted Dr. Alan Garber, Associate Professor of Medicine at Stanford University, on this point: "'There are so many ways to influence what works get published,'" he said, "'including how a drug company funds research, the grants they give, whether those writing articles that are favorable to a particular drug or device get on a speakers list, get honoraria, do consulting.'" Gina Kolata, *Safeguards Urged for Researchers: Aim Is to Keep Vested Interests From Suppressing Discoveries*, N.Y. TIMES, Apr. 17, 1997, at D23.

136. *See* SHEILA JASANOFF, SCIENCE AT THE BAR: LAW, SCIENCE, AND TECHNOLOGY

to fund research that focuses only on satisfactory aspects of the product, therefore, it may be able to create a misleading record for the product. This could happen in at least four different ways.

First, the defendant could fund, for example, five studies to examine characteristics of the product for which it expects to find no problems. When those expectations are confirmed, the defendant then could offer an expert to testify that five studies have found the product harmless. These findings would reflect nothing about the likelihood of harm from some other, unstudied aspect of the product, but nevertheless might make the product appear safer to a fact finder. The danger of this approach seems small, though, because if the studies conducted are not relevant to the issue in the case, the trial judge should not admit them.[137]

A more serious variation on this problem arises when scientists who are considering undertaking research that might discover problems are deterred from doing so by interested parties. In a recent article, a scientist reported that after he published research indicating that calcium channel blockers—drugs used to lower blood pressure—were associated with an increased risk of heart attacks, he was harassed by one of the manufacturers of the drugs and by academic consultants to the manufacturers.[138] A commentator observed that "experiences like those . . . 'could hinder an investigator's choice of what to study.'"[139]

A third possibility presents more of a problem. The defendant might fund studies that are relevant to the issue in the case, but that are designed to be unlikely to detect a problem, even if one exists. Some researchers believe that this is a practice in which the tobacco industry engages,[140] and an example of this strategy

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(1995) ("Often research is undertaken only when a lawsuit points to the existence of a previously unsuspected causal connection, such as electromagnetic fields and cancer or silicone gel breast implants and immune system disorders.").

137. *See* FED. R. EVID. 402.

138. *See* Richard A. Deyo et al., *The Messenger Under Attack—Intimidation of Researchers by Special-Interest Groups*, 336 NEW ENG. J. MED. 1176, 1177 (1997).

139. Kolata, *supra* note 135, at D23 (quoting Dr. Suzanne Fletcher, Professor of Ambulatory Care and Prevention at Harvard Medical School).

140. *See* Henriques, *supra* note 1; Homburger, *supra* note 130 ("[S]tudies implicating cigarette smoke as a health hazard have not been getting support from CTR [the industry-funded Council for Tobacco Research] or are limited to projects with

arguably occurred in In re *Orthopedic Bone Screw Products Liability Litigation*.[141] In that case, manufacturers of bone screws, together with orthopedic surgeons and professional societies, conducted a study to evaluate the use of the screws for non-FDA-approved purposes.[142] The screws were being used widely for these alternative purposes, and the manufacturers intended the study to evaluate the safety of such use.[143] The surgeons asked to conduct the study had used the screws, and they were told that the study might lead to FDA approval for the new use.[144] The plaintiffs argued to exclude the study as biased "because the surgeons who participated in [the study] did so as supporters of pedicle screw fixation in response to the announcement that the study was expected to determine that pedicle screw fixation was safe and effective and therefore lead to FDA approval."[145] The court held, however, that this was only a potential source of bias, not a proven one, and it did not "prevent the study from crossing the reliability threshold of Rule 702."[146]

This seems to be an incorrect result. The issue under *Daubert* is one of reliability, and bias can suggest that a study is unreliable without proving that it is invalid. If a litigant had to prove the *effects* of bias, no evidence would ever be excluded on that ground: courts would exclude studies in which bias was proven not because they were biased, but because they were false. In the pedicle-screw litigation, therefore, if the plaintiffs had shown a source of bias in the selection of study participants, the study would have been rendered less reliable, and it at least should have been subject to some form of judicial scrutiny. For example, the court could have required the defendants to show that scientific journals would not have believed that the bias was suffi-

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predictably negative outcome, such as having mice inhale cigarette smoke that kills them because of their sensitivity to nicotine before carcinogenic doses are reached.").

141. MDL Docket No. 1014, 1997 U.S. Dist. LEXIS 6441 (E.D. Pa. May 5, 1997).

142. *See id.* at *1-*2.

143. *See id.* at *2, *5.

144. *See id.* at *3.

145. *Id.* at *14.

146. *Id.* at *22. The plaintiffs also argued that the study was rendered less reliable by "the failure by the doctors to report their financial interests," but the court held that this was a factor bearing on the weight, not the admissibility, of the testimony. *Id.* at *13 n.7.

cient to disqualify the study. Only then, perhaps, should it have been admissible.

Finally, a defendant might influence the research record by funding *no* research. In a recent article, Professor Wendy Wagner pointed out that "[a] manufacturer that conducts no research can generally avoid liability because plaintiffs and government research programs are unlikely to conduct scientific research on their own."[147] She argues that, because research always presents the possibility of discovering evidence of a risk associated with the manufacturer's product, conducting research stands to increase the liability of the manufacturer.[148] Professor Wagner argues that much of the resulting scientific uncertainty is preventable[149] and that public programs, such as the National Toxicology Program, the federal program that tests chemicals for toxicity and carcinogenicity,[150] are not sufficient to prevent it.[151]

To a large extent, of course, this issue is simply one concerning the placement of the burden of proof. As Professor Wagner argues, it might suggest that the burden would be better placed, at least to some extent, on the defendant.[152] Even in the absence of such a shift, though, her point may have implications for evidentiary admissibility in light of *Daubert*'s direction to use scientific standards in the admissibility decision. Although some courts might be willing to admit expert testimony that draws a conclusion of no causation from the absence of sufficient proof of causation, it might not be scientifically legitimate to do so in the absence of any study of the matter.[153] In other words, if, in the

147. Wendy E. Wagner, *Choosing Ignorance in the Manufacture of Toxic Products*, 82 CORNELL L. REV. 773, 775 (1997) (citation omitted). Wagner also notes that "victims are able to challenge the adequacy of a manufacturer's safety and design decisions only in the small percentage of cases where a substantial body of scientific studies exists." *Id.* at 794. *See also* Rebecca S. Dresser et al., *Breast Implants Revisited: Beyond* Science on Trial, 1997 WIS. L. REV. 705 (noting manufacturers' failure to perform product safety research as a means of avoiding liability).

148. *See* Wagner, *supra* note 147, at 794.

149. *See id.* at 780-83.

150. *See National Toxicology Program* (visited Oct. 7, 1998) <http://ntp-server.niehs.nih.gov/main_pages/about_NTP.html>.

151. *See* Wagner, *supra* note 147, at 785-86 & 801 n.99.

152. *See id.* at 833-52; *see also* Dresser et al., *supra* note 147, at 775-76.

153. This issue is, of course, different from the issue of whether one can draw a conclusion of no causation from one or more studies that investigate the issue and

absence of any study, scientists would be unwilling to say any more than that no studies had been conducted, perhaps courts should not allow expert witnesses to say more.[154]

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find no evidence of causation. *See, e.g.*, FOSTER & HUBER, *supra* note 4, at 131-34.

154. Foster and Huber make this point:

> Ignorance is never relevant in a trial, and therefore never admissible—least of all when it is affirmed by an "expert" who is supposed to testify exclusively about "scientific knowledge." Unadorned statements about ignorance are inadmissible because they are irrelevant. They don't tend to prove one side of the case or the other. Legally speaking, they are just superfluous fluff.

Id. at 220-21.

Some courts have come quite close to admitting this sort of statement. Consider, for example, Christophersen v. Allied-Signal Corp., 902 F.2d 362 (5th Cir. 1990). The plaintiff's decedent died of small-cell carcinoma of the colon, and the plaintiff claimed that the cancer was caused by his exposure, while working for the defendant, to nickel and cadmium fumes. *See id.* at 363-64. The plaintiff's expert proposed to testify that small-cell carcinoma in the lung had been associated with nickel and cadmium exposure and that, "'based on what's known about the biochemical nature of small-cell' carcinoma," it was likely that such carcinomas in other areas of the body also would be associated with such exposures. *Id.* at 366 (quoting expert's deposition testimony). One of the defendant's experts testified that this conclusion was "'without basis in fact and ha[d] no scientific merit,'" apparently relying on the fact that the lung and colon tumors had "'never been shown to have a common causation or share a proven common origin.'" *Id.* (quoting expert's affidavit).

The district court excluded the testimony of the plaintiff's expert, but the court of appeals stated that this created a conflict between the experts, and that the district court inappropriately "chose sides" between them. *Id.* It is not clear, though, that the district court's choosing between the experts was the real problem: if the defendant's expert was testifying on the basis of a lack of studies showing causation, his testimony should not have been admitted at all, because there would have been no factual basis for his testimony. He should only have been able to testify to flaws in the analysis of the plaintiff's expert, or to the existence of studies that did not show causation but that would have done so if there was in fact a causal relationship. On rehearing en banc, the majority of the court of appeals sided with the district court, but on a more acceptable theory—that the testimony of the defendant's expert was that the plaintiff's expert merely had a "hunch" and that he rejected his methodology. *See* Christopherson v. Allied-Signal Corp., 939 F.2d 1106, 1115 & n.16 (5th Cir. 1991) (en banc); *cf.* Peterson v. Sealed Air Corp., Nos. 86-C3498, 88-C9859, 1991 U.S. Dist. LEXIS 5333, at *14-*17 (N.D. Ill. Apr. 23, 1991) (discussing the testimony of three of defendant's experts, one of whom noted the lack of any studies supporting the plaintiff's theory, of causation, but could not testify that no causal relationship existed; a second who testified, based on the lack of evidence supporting the plaintiff's theory, together with some apparently anecdotal evidence, that no causal relationship existed; and another who testified that other studies would have shown the causal relationship had it existed).

Even if one were unwilling to go this far, this source of bias might suggest a need for more tolerance of weaknesses in plaintiffs' evidence when defendants have conducted no studies themselves. A plaintiff in such a situation is left to do the best it can, often with limited control over the experimental conditions under which the defendant's action or product can be tested. In those circumstances, a plaintiff might not be able to produce a study that meets usual scientific standards. In some cases, the court nevertheless should admit plaintiff's work if the defendant could have produced a valid study itself, but chose not to.

3. Research Biased by Researchers

The final possibility is that research will be biased not by its sponsors, but by the researchers themselves. As *Daubert II* suggests, this possibility is perhaps most obvious when the research is conducted in connection with litigation and the researcher presumably knows the result that the client seeks.[155] Researchers also may have incentives to reach particular results in other contexts, though, as when their research is funded by a sponsor from whom the researcher might reasonably expect future support. In response, a variety of scientific institutions have adopted procedures to address researchers' conflicts of interest.

The recently adopted policy of the Food and Drug Administration (FDA) is typical of several similar agency regulations.[156] The FDA regulations "require an applicant whose submission relies in part on clinical data to disclose certain financial arrangements between sponsor(s) of the covered studies and the clinical investigators and certain interests of the clinical investigators in the product under study or in the sponsor of the covered studies."[157] The regulations cover a range of these financial arrangements.[158]

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155. *See* PETERS & PETERS, *supra* note 130, at 2 ("In some cases, the source of research funds may, directly or indirectly, hopefully anticipate a 'favorable' outcome, and if this does not come to pass, the displeasure may result in an absence of funds for future investigations.").

156. *See* Financial Disclosure by Clinical Investigators, 63 Fed. Reg. 5233 (1998) (to be codified in scattered sections of 21 C.F.R.). The policies of the Public Health Service (PHS) and National Science Foundation (NSF) are similar. *See* Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding is Sought, 42 C.F.R. §§ 50.601 to .606 (1997).

157. Financial Disclosure by Clinical Investigators, 21 C.F.R. § 54.1(b) (1998). The

As a preliminary matter, one might ask whether these regulations represent the views of scientists themselves or are simply imposed on scientists by federal agencies. Only in the former case, of course, would they be relevant under *Daubert*. The agencies point out, though, that the regulations are at least in part a response to a perceived need in the scientific community.[159] In addition, the specific recommendations of the agencies are con-

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PHS regulations are similar, requiring institutions that receive research funding from PHS sources like the NIH to "identify conflicting interests," but they also require those institutions to "take such actions as necessary to ensure that such conflicting interests will be managed, reduced, or eliminated." 42 C.F.R. § 50.604(d).

158. The FDA rule requires disclosure of

> (i) Any financial arrangement entered into between the sponsor of the covered study and the clinical investigator involved in the conduct of a covered clinical trial, whereby the value of the compensation to the clinical investigator for conducting the study could be influenced by the outcome of the study;
>
> (ii) Any significant payments of other sorts from the sponsor of the covered study, such as a grant to fund ongoing research, compensation in the form of equipment, retainer for ongoing consultation, or honoraria;
>
> (iii) Any proprietary interest in the tested product held by any clinical investigator involved in a study;
>
> (iv) Any significant equity interest in the sponsor of the covered study held by any clinical investigator involved in any clinical study; and
>
> (v) Any steps taken to minimize the potential for bias resulting from any of the disclosed arrangements, interests, or payments.

21 C.F.R. § 54.4(a)(3). The rule states that

> *[c]ompensation affected by the outcome of clinical studies* means compensation that could be higher for a favorable outcome than for an unfavorable outcome, such as compensation that is explicitly greater for a favorable result or compensation to the investigator in the form of an equity interest in the sponsor of a covered study or in the form of compensation tied to sales of the product, such as a royalty interest.

21 C.F.R. § 54.2(a).

Again, the PHS regulations are similar, focusing on what they call "Significant Financial Interests," which are defined as "anything of monetary value, including but not limited to, salary or other payments for services (e.g., consulting fees or honoraria); equity interests (e.g., stocks, stock options, or other ownership interests); and intellectual property rights (e.g., patents, copyrights, and royalties from such rights)." 42 C.F.R. § 50.603.

159. *See* Financial Disclosure by Clinical Investigators, 59 Fed. Reg. 48,708, 48,708 (1994) (to be codified in scattered parts of 21 C.F.R.) (proposed Sept. 22, 1994) ("There is a growing recognition in the academic and scientific communities that certain financial arrangements between clinical investigators and product sponsors, or the personal financial interests of clinical investigators, can potentially bias the outcome of clinical trials.").

sistent with, though more formal than, those proposed by scientists themselves.[160] For example, the agencies' recommendations are very similar to those proposed by the Association of American Medical Colleges.[161]

Applying these policies to research that is the subject of expert testimony nevertheless is not straightforward. The first question that one would need to ask is whether, as the Public Health Service (PHS) puts it, the source of the research funding "could directly and significantly [have] affect[ed] [its] design, conduct, or reporting."[162] One might argue that this criterion would not apply to employees of interested parties, because their compensation and continued employment is not explicitly contingent on the results of their research, and their employment status therefore is unlikely to "significantly affect" the research. Even though their continued employment may not be explicitly contingent on the results achieved, though, employees are still likely to feel pressure that might skew their research. The FDA has recognized this in its policy. Although the FDA policy generally focuses on financial interests that are more explicitly contingent than those of employees,[163] it does not exclude employees

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160. *See* Objectivity in Research, 59 Fed. Reg. 33,242, 33,246 (1994) (to be codified in 42 C.F.R. pt. 50 and 45 C.F.R. pt. 94) (proposed June 28, 1994) ("Such management methods are common in the sciences . . . ."); Michael D. Witt & Lawrence O. Gostin, *Conflict of Interest Dilemmas in Biomedical Research*, 271 JAMA 547, 550 (1994) ("Investigators who have material interests (including equity, royalty incentives, and ongoing sponsored research activities) in a for-profit corporation licensing a product from their research institute warrant careful scrutiny.").

161. In the conflicts of interest guidelines adopted by the Executive Council of the Association of American Medical Colleges (AAMC) on February 22, 1990, the AAMC lists the following "Situations That May Impart Bias in Research":

> ·Undertaking basic or clinical research when the investigator or the investigator's immediate family has a financial, managerial, or ownership interest in the sponsoring company or in the company producing the drug/device under evaluation
>
> ·Accepting gratuities or special favors from research sponsors
>
> ·Entering into a consultantship arrangement with an organization or individual having an economic interest in related research

AAMC, *Guidelines for Dealing with Faculty Conflicts of Commitment and Conflicts of Interest in Research* (visited Oct. 5, 1998) <http://www.aamc.org/research/dbr/coi.htm#interest> [hereinafter AAMC, *Guidelines for Dealing with Faculty Conflicts*].

162. 42 C.F.R. § 50.605(a)(1997).

163. *See generally* Financial Disclosure by Clinical Investigators, 63 Fed. Reg. 5,233,

from scrutiny. On the contrary, the FDA "treats data from clinical investigators who are the employees of sponsors with maximum scrutiny and will continue to do so because such employees can be assumed to have significant financial interests in the outcome of studies."[164]

Moving beyond employees, it may be more difficult to determine whether a particular researcher has a conflict. Some nonemployment relationships will present straightforward conflicts of interest, of course. The FDA policy cited above lists contingent payment arrangements and proprietary and equity interests among these problematic relationships.[165] The implications of other relationships, such as intermittent consulting arrangements, are less clear. This lack of clarity was exactly the problem in the dispute discussed above involving editorialists in the *New England Journal of Medicine*,[166] and one can easily imagine other, similarly borderline relationships. When such relationships are involved, it is necessary to determine, as the FDA requires, whether they are "significant" enough to create conflicts.

A more fundamental problem is that none of the agency regulations specify what action they will take in case of a conflict. The FDA rule is typical in providing a list of possible actions:

> (1) Initiating agency audits of the data derived from the clinical investigator in question;
>
> (2) Requesting that the applicant submit further analyses of data, e.g., to evaluate the effect of the clinical investigator's data on overall study outcome;
>
> (3) Requesting that the applicant conduct additional independent studies to confirm the results of the questioned study; and
>
> (4) Refusing to treat the covered clinical study as providing data that can be the basis for an agency action.[167]

5,233 (1998) (to be codified in scattered parts of 21 C.F.R.) (requiring disclosure of "financial interests of and arrangements of clinical investigators that could affect reliability of data submitted to FDA in support of product marketing").

164. *Id.* at 5240.

165. *See* Financial Disclosure by Clinical Investigators, 21 C.F.R. § 54.4(a)(3) (1998).

166. *See supra* text accompanying notes 45-51.

167. Financial Disclosure by Clinical Investigators, 21 C.F.R. § 54.5(c). The remedies other agencies provide are similar. For example, the PHS policy states that pos-

Because the rule does not describe in which circumstances the FDA would apply each of these actions—the regulations state only that the agency "may consider both the size and nature of a disclosed financial interest . . . and steps that have been taken to minimize the potential for bias"[168]—it is difficult to draw from them much in the way of guidance for expert testimony.

Importantly, though, each of the actions appears to involve more than the rough scientific equivalent of cross-examination. The fourth option, that of refusing to treat the study as a basis for FDA action, is roughly equivalent to a court holding testimony inadmissible. The second and third options of requiring more confirmatory information are perhaps similar to holding testimony insufficient to overcome a motion for summary judgment. The first option, that of reviewing the original data on which the study is based, is closest to cross-examination, except that the

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sible actions "include, but are not limited to," the following:

(1) Public disclosure of significant financial interests;
(2) Monitoring of research by independent reviewers;
(3) Modification of the research plan;
(4) Disqualification from participation in all or a portion of the research funded by the PHS;
(5) Divestiture of significant financial interests; or
(6) Severance of relationships that create actual or potential conflicts.

42 C.F.R. § 50.605(a) (1997).

The 1990 AAMC conflict of interest guidelines state that:

[p]ossible options include, but are not limited to:
· Public disclosure of all relevant information,
· Reformulation of the research workplan,
· Close monitoring of the research project,
· Divestiture of relevant personal interests,
· Termination or reduction of involvement in the relevant research project,
· Termination of inappropriate student involvement in projects, and
· Severance of outside relationships that pose conflicts.

AAMC, *Guidelines for Dealing with Faculty Conflicts*, *supra* note 161. The NSF cited the AAMC guidelines, along with those of the Association of American Universities, as useful "[g]uidance" in its conflicts policy. Investigator Financial Disclosure Policy, 59 Fed. Reg. 33,308, at 33,311 & n.1 (1994) (citing, e.g., ASSOCIATION OF AMERICAN MEDICAL COLLEGES, GUIDELINES FOR DEALING WITH FACULTY CONFLICTS OF COMMITMENT AND CONFLICTS OF INTEREST IN RESEARCH (1990); ASSOCIATION OF AMERICAN UNIVERSITIES, FRAMEWORK DOCUMENT FOR MANAGING FINANCIAL CONFLICTS OF INTEREST (1993)).

168. 21 C.F.R. § 54.5(a).

original data supporting scientific expert witness testimony is often not available to the opposing party in litigation.

The FDA rule therefore suggests that scientists[169] find simple disclosure of conflicts of interest an insufficient remedy when some decision turns on the results of research.[170] If the courts were to take seriously the deference to science counseled by *Daubert*, they would take a more strict approach than allowing mere cross-examination regarding conflicts in research about which an expert witness testifies. This is especially so in that jurors often will not have the FDA's expertise in evaluating possible flaws in the research.[171] Indeed, the FDA initially considered simple public disclosure of the information about conflicts that they received, but it met a number of objections, some arguing that "the public would not be in a position to interpret this information properly,"[172] and it decided instead to resolve disclosure issues on a case-by-case basis.[173]

Finally, the source of funding for a study about which a scientific expert witness proposes to testify may not always be clear. If no such information is available, should the testimony nevertheless be permitted? The FDA states in its rule that "[it] may refuse to file any marketing application . . . that does not contain the [conflict of interest] information required . . . or a certif-

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169. As pointed out above, scientists have recognized the need for policies similar to those of the FDA (as well as the PHS and the NSF), and scientific institutions themselves have adopted such policies. *See supra* notes 161 & 167 and accompanying text.

170. This claim is not contrary to the observations above that scientific journals generally are content with authors' disclosure of financial interests and often do not transmit those disclosures to their readers. *See supra* text accompanying note 106. Articles in scientific journals usually are not intended to prompt immediate action; when, as with editorials and review articles, action is expected to turn on the journals' publications, their policies can be more strict. *See supra* text accompanying notes 107-09. With expert testimony, as with FDA submissions, actions turn on the research results.

171. In a similar context, involving patients rather than jurors, two writers have suggested that disclosure may be an inadequate remedy, because "those who receive the information, especially patients, may not know how to evaluate it." Ezekiel J. Emanuel & Daniel Steiner, *Institutional Conflict of Interest*, 332 NEW ENG. J. MED. 262, 265 (1995).

172. Financial Disclosure by Clinical Investigators, 63 Fed. Reg. 5233, 5237 (to be codified in scattered parts of 21 C.F.R.) (1998).

173. *See id.*

ication by the applicant that the applicant has acted with due diligence to obtain the information but was unable to do so and stating the reason."[174] This suggests that, at a minimum, courts should require expert witnesses to disclose conflicts of interest of the scientists who conducted the research about which they testify, or a certification similar to that required by the FDA. Only then will courts be able to assess the significance of the conflicts.

III. LEGAL AND SCIENTIFIC STANDARDS FOR CONFLICTS

Part I of this Article suggested that *Daubert*'s rationale for deferring to science in determining the proper legal treatment of scientific evidence also may apply to conflicts of interest, and Part II showed that the lower courts have not taken this approach. One therefore faces two alternatives. If *Daubert*'s deference to science also should apply to conflicts, one could conclude that the lower courts are wrong, and that they should adhere to scientific standards in handling the conflicts of interest of scientific experts. Part II suggested, in a general way, what this might entail. Alternatively, one could conclude that *Daubert*'s deference to science is inappropriate in the conflicts context and that law should not defer to science, or should defer only partially, in assessing the significance of conflicts of interest. The goals and methods of law may differ sufficiently from those of science to require a different approach to conflicts.

A. The Importance of Context in Addressing Conflicts of Interest

Deference to science in evaluating conflicts of interest in expert testimony does not seem to be the proper approach. Expert testimony is at issue in legal contexts that are, for the most part, quite different from those of science. Law must be concerned with conflicts that will distort an individual decision. Science is less concerned with conflicts that will affect an individual decision than with those that will cause systematic distortions of the scientific record. One therefore would expect science to be most concerned with conflicts that affect the research *process*,

174. 21 C.F.R. § 54.4(c) (1998).

and with those that would persist over a series of research projects.

This analysis is generally borne out by the above discussion. The lack of concern in science about conflicts in individual instances is reflected in the failure of many scientific journals even to ask their authors about financial interests they may have in the articles they submit.[175] The rationale for this approach presumably is that errors caused by these conflicts will not persist in light of efforts to repeat the research. When the potential for systematic distortion of the research record exists, however, as with research funded by the tobacco industry, scientific institutions have acted to prevent that distortion.[176]

There are some instances in which science shows concern regarding possible bias in individual statements. Such concern is exhibited, for example, in the *New England Journal of Medicine*'s ban on editorials and review articles by interested parties,[177] the NIH's efforts to avoid conflicts in its funding decisions,[178] and the FDA's policy regarding drug approval applications.[179] The common feature in all of these instances, however, is the obvious effect that the individual scientific decision will have on financial interests, which takes them out of the realm of pure science.

Moreover, in an important sense these circumstances also could be viewed as not quite "scientific." The NIH and FDA policies both apply in the context of federal government decisionmaking—funding in the former case, regulatory approval in the latter—so they could be said to fall more in the realm of policy than of science. Editorials and, to a lesser extent, review articles generally assess the current state of scientific knowledge when it is somewhat uncertain. Although science often simply postpones decisions in such circumstances, postponing the deci-

175. *See* Kevin Schulman et al., *Ethics, Economics, and the Publication Policies of Major Medical Journals*, 272 JAMA 154, 155 (1994); *cf. supra* text accompanying notes 106-07 (discussing journals' failures to disclose conflicts to their readers).

176. *See* Alan Blum & Howard Wolinsky, *AMA Rewrites Tobacco History*, 346 LANCET 261, 261 (1995); *supra* notes 130-34 and accompanying text.

177. *See* Angell & Kassirer, *supra* note 47, at 1055.

178. *See supra* text accompanying notes 111-14.

179. *See* Financial Disclosure by Clinical Investigators, 63 Fed. Reg. 5233, 5238 (to be codified in scattered parts of 21 C.F.R.) (1998).

sion is not an option when, for example, doctors must make medical treatment decisions. In these cases, then, the medical needs of patients, rather than the scientific search for knowledge, drive the need for a decision. Thus, when financial, legal, or medical issues are at stake, science adopts a more careful approach to conflicts than it does in other, more purely scientific circumstances. Because analogous financial and legal issues are at stake in litigation, one would expect science to adopt a similarly careful approach to conflicts in that context.

Even the more careful approach that science sometimes takes to conflicts may not be especially applicable to litigation, though. Conflicts policies may need to be more specifically tailored to particular contexts, even in these conflict-conscious areas. This can be seen in the FDA's response to comments stating that it should conform its conflict of interest policy to the policy of the Public Health Service (PHS). The FDA pointed out that it was concerned with "ensur[ing] data integrity for the purposes of product review," whereas the PHS was concerned with grant making and "the credibility of the scientific enterprise."[180] If the objectives of the FDA and the PHS differ sufficiently to require distinct conflict of interest rules, the objectives of litigation certainly require different rules from either, and different rules from other scientific contexts.

B. How Do Conflicts in Litigation Differ from Conflicts in Science?

To decide how the treatment of conflicts of interest in litigation should differ from their treatment in science, one must examine how the two contexts differ. The previous section discussed the most fundamental difference: law is concerned with reaching correct individual decisions, whereas science, or at least the scientific journal, is concerned with the overall scientific record. This difference, though real, is of little value in determining how to deal with particular conflicts because it describes the respective goals of law and science, not their fact finding approaches. One can, however, find guidance as to the proper ap-

180. *Id.*

proach to conflicts in each discipline in their approaches to fact finding.

Broadly speaking, two types of differences exist in the fact finding of law and science. First, there are important differences in the methods the two disciplines use in fact finding. The basic difference is that between the examination and cross-examination of the legal adversarial system, and scientific peer review. Cross-examination can be very effective at uncovering more or less obvious flaws in testimony, whereas peer review for journal publication can let even very significant errors slip through.[181] This suggests that the law could be more tolerant of bias in *testimony* than in the underlying research. Because testimonial bias is more likely to be detected and neutralized, it is less likely to be a serious problem.

On the issue of bias in the underlying research that is the subject of the testimony, however, the situation is reversed. The scientific process of attempted replication is certain in the end to detect any flaws in previous research. In a particular case, though, the law does not have the benefit of this process. Moreover, cross-examination often will be an ineffective means of exposing these sorts of flaws, both because such flaws may be reflected in subtle choices the implications of which are difficult to expose on cross-examination and because trial judges may be unwilling to allow attorneys to delve deeply into the content of research, particularly if the witness is not the one who conducted the research.

Therefore, in focusing its admissibility decision on the conflicts of witnesses, rather than on the conflicts of researchers, *Daubert II* may have it backward. As described above, the approach of *Daubert II* reflects skepticism regarding the testimony of witnesses who have not themselves performed the relevant research—that is, reflects skepticism regarding witnesses *qua* witnesses—but makes no effort to address conflicts in the underlying research, which in fact may be a greater problem. Cross-examination is likely to be a more effective means of addressing conflicts of witnesses than conflicts of researchers. Even if those

181. *See* FOSTER & HUBER, *supra* note 4, at 171-75, 180.

researchers are themselves on the stand, therefore, *Daubert II*'s approach seems inappropriate.

The second important difference in the fact finding of law and science is that, as described in the previous section, law often must reach a final conclusion in cases in which information is lacking, whereas science usually need not make decisions before information is complete.[182] It is somewhat unclear how uncertainty in legal fact finding should affect the treatment of conflicts. Here, the emphasis of *Daubert II* on witness conflicts rather than researcher conflicts may be more appropriate. The selection of the expert to testify is particularly important when little actual research is available to constrain the expert's statements. When there is much research available, an expert is constrained by that research, and the expert's pre-existing biases are less important. But this effect may be countered by another: witnesses who have performed some of the (little) research available—that is, those witnesses that *Daubert II* would favor—may be biased. In fact, witnesses who have done the only research available might present special problems, combining the normal difficulty that all researchers, indeed all people, have in seeing flaws in their own work with the absence of other work with which to compare it.[183]

This is not to say, of course, that newcomers to the relevant issues present no problems. The problems, however, are less likely to be scientific than purely venal. As discussed above,

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182. *See* JASANOFF, *supra* note 136, at 9; *see also* J.M. ZIMAN, PUBLIC KNOWLEDGE: AN ESSAY CONCERNING THE SOCIAL DIMENSION OF SCIENCE 14-15 (1968). Ziman makes exactly this point:

> [Of] course, in Science, when the evidence is conflicting, we withhold our assent or dissent, and do the experiment again. This cannot be done in legal disputes, which must be terminated yea or nay. . . .
>
> The Law is thus unscientific because it *must* decide upon matters which are not at all amenable to a consensus of opinion.

Id.

183. In other words, *Daubert II*'s point that "there is usually a limited number of scientists actively conducting research on the very subject that is germane to a particular case," Daubert v. Merrell Dow Pharms., Inc., 43 F.3d 1311, 1317 (9th Cir. 1995), is a two-edged sword. It is true that, as the court in *Daubert II* wrote, this "provides a natural constraint on parties' ability to shop for experts who will come to the desired conclusion," *id.*, but it also is true that many or all of the (few) scientists working on a particular question may share the same biases.

many "experts" seem to do no scientific work at all,[184] relying instead on their work as witnesses for their livelihood. Consequently, the better question to ask may be not whether their scientific work is biased, or whether their legal work is scientific, but whether they are acting as scientists at all.

IV. AN APPROACH TO INCORPORATING SCIENTIFIC STANDARDS IN ADMISSIBILITY DECISIONS

The preceding sections suggest an approach to conflicts that differs both from the current approach of lower courts, as represented in decisions such as *Daubert II*, and from the deference to science underlying *Daubert*, yet draws from each. *Daubert II* emphasizes the conflicts of interest that can be present when science is performed or used in connection with litigation. The approach proposed here follows *Daubert II* in focusing on conflicts but recognizes the broader set of circumstances that can bias the research record. The approach proposed here also follows *Daubert* in looking to the methods of science, but it recognizes that conflicts of interest present special problems in litigation, both in themselves and as they affect the *Daubert* admissibility factors.

A. Separating the Witness from the Researcher

Although the Ninth Circuit in *Daubert II* seemed to assume that the testimony of a scientific expert witness always concerns the witness's own research, that is not the case. An expert often testifies regarding research performed by others. This sometimes happens directly, as when an expert presents another researcher's work, but it also can happen indirectly, as when an expert presents her own analysis drawing on other work. In either situation, the witness's testimony can be skewed either by her own conflicts of interest or by those of the researchers whose work forms part of her testimony. It is therefore appropriate, where possible, to separate the analyses of the conflicts of witnesses and researchers. This section will consider how these separate analyses should be performed; the next section will consider how

184. *See supra* text accompanying notes 59-61.

to analyze the implications of conflicts of interest for one who is both witness and researcher.

1. The Expert Witness Testifying About the Research of Others

The Party Witness. As described earlier, conflicts in testimony are less troubling than conflicts in the research underlying testimony because testimonial conflicts are easier for fact finders to appreciate and to incorporate in the decisionmaking process.[185] This suggests that when a witness is testifying about the research of others, the fact finder should consider the conflicts of the witness *qua* witness in determining the weight to give his testimony and that the judge generally should not exclude testimony on the basis of those conflicts. This is especially so in that, when the witness presenting the research has not herself performed it, the opposing party is at no disadvantage in analyzing and presenting an opposing view of that research. There are certain circumstances, however, in which bias might appropriately factor into an admissibility decision.[186]

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185. *See supra* text accompanying note 181.

186. The witness-oriented approach proposed here is somewhat similar to, though differently directed than, Professor Margaret Berger's *Evidentiary Framework*, published in the Federal Judicial Center's *Reference Manual on Scientific Evidence*. *See* Berger, *supra* note 21. Professor Berger recommends a two-pronged approach to evaluating an expert's education and qualifications under Rule 702, the first prong focusing on the expert's basic qualifications and the second on whether "the expert's particular expertise, however acquired, enables the expert to give an opinion that is capable of assisting the trier of fact." *Id.* at 55. Although her focus is primarily on whether the expert's particular field of expertise is appropriate for the relevant question at trial, she also discusses concerns about the "professional witness" that are related to the issues here.

Even if research is properly "scientific," it might not be appropriately introduced in court. As Judge Barbara Crabb has noted, the Supreme Court in *Daubert* "did not suggest that [scientifically accepted] methods would be the sole means of challenging a theory or a study." Barbara B. Crabb, *Judicially Compelled Disclosure of Researchers' Data: A Judge's View*, LAW & CONTEMP PROBS., Summer 1996, at 9, 14. The Supreme Court in *Daubert* addressed not only the Rule 702 requirement that a scientific expert witness testify to "scientific knowledge" but also the requirement that the testimony "assist the trier of fact." *See* Daubert v. Merrell Dow Pharms., Inc., 509 U.S. 579, 591 (1993). This latter requirement, the Court said, "goes primarily to relevance," i.e., to whether the proffered scientific evidence "properly can be applied to the facts in issue." *Id.* at 591, 593. Although commentators generally have read the word "primarily" out of the Court's statements, one could interpret *Daubert* to require, or at least to permit trial courts to require, more than mere

As pointed out above, a witness's bias can be very important, perhaps even outcome-determinative, in cases in which the scientific evidence is scant.[187] Courts cannot, of course, adopt a special rule for such cases—there is only one Rule 702—but the nature of the witnesses that often appear in these cases suggests an alternative approach. Specifically, in cases in which science is inconclusive, the witnesses often are individuals who spend little time conducting research in a scientific context and a great deal of time doing "science" in a litigation context.[188] Yet it is precisely when the science is inconclusive that a witness's familiarity with and conformity to the practices of science are most important.

Therefore, disqualification of a witness might be appropriate when (1) the case is one in which there is little relevant research available, and (2) the witness is one who spends little time doing research outside the litigation context.[189] As a commentator recently put it, an "expert's strength as a witness depends on her experience."[190] This commentator pointed out that the role of experience is critical in cases in which the data is inconclusive:

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relevance; specifically, it could require that proffered testimony, even if formally scientific, be sufficiently objective to be suited to a legal fact finding role (as distinguished from a scientific role).

187. *See supra* text accompanying notes 182-83.

188. *See* JASANOFF, *supra* note 136, at 131-34 (discussing testimony of clinical ecologists and the lack of scientific evidence for their testimony).

189. That is, the witness would be excluded under Federal Rule of Evidence 702 as not "qualified as an expert by knowledge, skill, experience, training, or education." *See supra* note 18. Such disqualification would not entirely avoid the problem of applying Rule 702 differently in different cases, but the different application can be justified on the view that what (or who) "will assist the trier of fact" in one case may not do so in another.

190. Christopher P. Murphy, Note, *Experts, Liars, and Guns for Hire: A Different Perspective on the Qualifications of Technical Expert Witnesses*, 69 IND. L.J. 637, 651 (1994). Mr. Murphy was writing about engineer experts, but the same principles apply to scientific experts. A somewhat similar, but more general, point was made by Professor Gross in his article on experts:

> Unfortunately, this screening process turns almost entirely on credentials, which are an imperfect proxy for knowledge. The graduate student who knows more about the effects of a particular virus than anybody might not qualify as an expert witness on the topic, and therefore would probably never be called as a witness. The chairman of the graduate student's department, on the other hand, will qualify easily, no matter what she knows.

Gross, *supra* note 25, at 1160-61.

> When the underlying empirical data is incomplete or questionable assumptions supplement the data, an educational background [or, I would add, instinctive talent] cannot fill the gaps. Under those conditions when the connection between the underlying empirical data and the expert's opinion is tenuous, the jury receives unreliable testimony. Judges should exclude such testimony.[191]

In a sense, such a rule would be conflict-based, though the conflict would not be so much a financial one as one between the legal and scientific cultures. It would be based on the intuition that the techniques of a person who spends no time in actual scientific practice, even when that person once did so, will inevitably diverge from those accepted in science. Eventually, the person's work techniques will move closer and closer to what is effective in trial or deposition practice, and at some point it does not make sense to treat that person as a scientific expert at all.[192]

One might be concerned that it would be difficult to find experts who are both qualified and disinterested, but that is unlikely to be the case. Indeed, an approach like this seems to have succeeded in the ongoing breast implant litigation.[193] The recent court-appointed expert panel in the consolidated state and federal breast implant cases in Oregon was composed of experts in four scientific areas, none of whom had previously done research on the risks of silicone.[194]

It nevertheless might be the case that sometimes the only available experts would be individuals who, from a scientific perspective, were considered to have conflicts.[195] In such a case,

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191. Murphy, *supra* note 190, at 651 (citation omitted).

192. Peter Huber argues that the process of expert selection almost inevitably results in expert testimony of poor quality. As he describes it, the system forces the lawyers on each side to select experts that exaggerate the certainty of their position and downplay any uncertainty. *See* HUBER, *supra* note 9, at 17-20 (1991). One of the court-appointed experts in *Hall v. Baxter Healthcare Corp.*, 947 F. Supp. 1387 (D. Or. 1996), made the same point. *See id.* at 1448.

193. *See Hall*, 947 F. Supp. at 1393.

194. *See id.*

195. *See, e.g.*, MICHAEL D. GREEN, BENDECTIN AND BIRTH DEFECTS: THE CHALLENGES OF MASS TOXIC SUBSTANCES LITIGATION 196-97 (1996). Professor Green reports

perhaps experts who otherwise would be disqualified because of bias should be allowed to testify. As one court has noted:

> In determining whether an expert is sufficiently knowledgeable to be admitted to testify, one of the factors that the district court ought to consider is whether other experts exist who are more specifically qualified and who are nonetheless not in the employ of the company or industry whose practices are being challenged. If the only experts permitted to testify inevitably represent the same side of a civil case, those who possess these experts can, for all practical purposes, set their own standards.[196]

The Court-Appointed Witness. Some courts hearing cases of contentious scientific evidence have appointed their own experts. This would seem to overcome the problem of bias, though it has been suggested that no expert is truly unbiased, so that any biases of a court-appointed expert—who necessarily comes with the imprimatur of the court—will perhaps be more insidious.[197]

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that when the judge in the multidistrict Bendectin litigation proposed using court-appointed experts, the plaintiffs "argue[d] that virtually all experts were tainted by some connection to Merrell [Dow Pharmaceuticals, the defendant]." *Id.* at 196. Green notes that "[t]here was some basis to [the plaintiffs'] claim: Merrell had funded a number of the researchers who had studied Bendectin and had contacted and hired others to serve as expert witnesses on its behalf." *Id.* at 196-97. Green indicates that the judge did not find the plaintiffs' claim credible, yet he did not appoint any experts in the case. *See id.* at 197.

196. Stagl v. Delta Air Lines, Inc., 117 F.3d 76, 81 (2d Cir. 1997); *see also* Berger, *supra* note 21, at 56 (noting that "[w]hen the experts in a field are all arrayed on one side of the case . . . a court may have to allow some leeway" in admitting the other side's expert testimony).

There also might be circumstances in which a litigant who already has a biased expert could not afford to retain another, disinterested expert. In such circumstances, the court might appoint its own expert. *Cf.* Joe S. Cecil & Thomas E. Willging, *Accepting* Daubert's *Invitation: Defining a Role for Court-Appointed Experts in Assessing Scientific Validity*, 43 EMORY L.J. 995, 1052 (1994) (describing a court's appointment of an expert in a case in which an indigent family claimed damages as a result of exposure to toxic chemicals, but were limited by their finances in presenting expert testimony, and "[t]he judge doubted the integrity of the defendants' expert testimony").

197. *See* Cecil & Willging, *supra* note 196, at 1022 (discussing survey of federal district court judges regarding their use of court-appointed experts, and noting that "[s]everal judges doubted that such testimony would be truly neutral"); E. Donald Elliott, *Toward Incentive-Based Procedure: Three Approaches for Regulating Scientific Evidence*, 69 B.U. L. REV. 487, 509 (1989) ("Many people object to appointing a sin-

At the very least, cross-examination of court-appointed experts should be permitted; at present, sometimes it is not.[198] Alternatively, perhaps the law should impose an obligation on court-appointed experts to be even-handed in their testimony, as some professional organizations require of their members;[199] or, as Professor Elliott has recommended, the use of court-appointed experts could be limited to narrowly defined circumstances in an effort to lessen this problem.[200]

With these protections, the relative independence of court-appointed experts at least has the potential of reducing concerns about bias in the courtroom. This potential, however, is not always realized. Consider, for example, *Hall v. Baxter Healthcare*

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gle expert to testify as a witness for the court because all experts have their own views which, if presented with the court's implicit imprimatur, may be given undue weight by a jury."); *The Fifteenth Annual Judicial Conference of the United States Court of Appeals for the Federal Circuit*, 180 F.R.D. 467, 505 (1998) (quoting District Judge Marvin J. Garbus's observation that a "genuine" fear exists that "if a court-appointed expert appears before a jury, it is, for all practical purposes, outcome determinative" and his conclusion that "that has to be avoided").

198. Indeed, courts sometimes intentionally avoid cross-examination of their experts. This was the case in *Hall v. Baxter Healthcare Corp.*, 947 F. Supp. 1387 (D. Or. 1996), a silicone-breast-implant case, in which the district court judge appointed "independent advisors," noting: "To keep the advisors independent of any ongoing proceedings, I appointed them under FRE 104, not FRE 706, which requires court-appointed experts, in effect, to act as additional witnesses subject to depositions and testifying at trial. Although certain plaintiffs . . . moved to invoke Rule 706 procedures . . . I denied those motions." *Id.* at 1392 n.8; *cf.* Cecil & Willging, *supra* note 196, at 1002-04 (stating that courts' "inherent power" to appoint technical advisors is "virtually undisputed," but that such appointments should be rare).

199. The National Society of Professional Engineers, for example, states that "[e]ngineers shall be objective and truthful in professional reports, statements or testimony. They shall include all relevant and pertinent information in such reports, statements or testimony . . . ." NATIONAL SOC'Y OF PROF'L ENG'RS, *supra* note 72, § II.3.a. Not all organizations impose such an obligation, though. For example, the AMA says that "[t]he attorney for the party who calls the physician as a witness should be informed of all favorable and unfavorable information developed by the physician's evaluation of the case," AMA, CODE OF MEDICAL ETHICS, *supra* note 70, § 9.07, but it does not require a similar disclosure to the court. In cases of bias, perhaps greater obligations should be imposed.

200. Elliott would attempt to ameliorate the problem of biased court-appointed experts by (1) using them only in cases in which "substantial doubt" exists as to the scientific validity of the testimony offered by one of the parties, so that there is a pre-existing risk of misleading the fact finder, and (2) having them testify not to their own opinions, but to the views of the scientific community. *See* Elliott, *supra* note 197, at 509-10.

Corp.,[201] a silicone breast implant case. In *Hall*, Judge Robert Jones appointed four "technical advisors"[202] whom he described as "totally unbiased and uncommitted experts in the necessary fields," which were epidemiology, immunology/toxicology, rheumatology, and chemistry.[203] The epidemiology advisor, Dr. Merwyn Greenlick, evaluated the proposed testimony of the epidemiology experts employed by both the plaintiffs and defendants, and he observed that "both [the defendants' expert's] and [the plaintiffs' expert's] opinions are based on scientifically valid data" and that they had both used valid scientific methodologies.[204] Referring to a particular study of the effects of breast implants, Dr. Greenlick said that "it is even possible for reasonable epidemiologists to arrive at diametrically opposed conclusions, as do [the defendants' and plaintiffs' experts], with regard to the . . . study."[205]

Judge Jones nevertheless excluded the testimony of the plaintiffs' expert, which primarily related to a rather ill-defined phenomenon labeled atypical connective tissue disease (ACTD).[206] Judge Jones rejected the testimony because he had decided to reject all testimony regarding ACTD.[207] He wrote that "[b]ecause ACTD is at best an untested hypothesis, there is no scientific basis for any expert testimony as to its causes and presence in plaintiffs."[208] In adopting this view, Judge Jones apparently accepted the defendants' argument that "the plaintiff's expert's position is 'merely a hypothesis—not proven—not science.'"[209] However, the judge's expert, Dr. Greenlick, specifically rejected [the plaintiffs' expert's] argument: "That represents a serious misunder-standing of what is intended by this statement. In fact, [this] statement is at the heart of science."[210]

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201. 947 F. Supp. 1387 (D. Or. 1996).
202. As discussed above, these "technical advisors" were not experts appointed under Federal Rule of Evidence 706. *See supra* note 198.
203. *Hall*, 947 F. Supp. at 1393.
204. *Id.* at 1448.
205. *Id.* at 1450.
206. *See id.* at 1404 & nn.37-38.
207. *See id.* at 1402.
208. *Id.*
209. *Id.* at 1448 (quoting defendants' closing argument).
210. *Id.*

Why, then, did the judge disregard the advice of his own court-appointed expert? His decision seemed to rest, at least in part, on a belief that when a scientific expert witness begins theorizing with little information to back up his theories, the expert is motivated by bias. The plaintiffs' witness in *Hall*, Dr. David Goldsmith, was initially unwilling to testify that it was more likely than not that silicone leaking from breast implants could cause disease in women.[211] When the abstract of a new study reporting a higher risk from silicone appeared,[212] however, Dr. Goldsmith was willing to testify that causation was more likely than not.[213] Judge Jones disallowed Dr. Goldsmith's testimony, indicating his belief—contrary to the advice of his own expert—that it would be unreliable.[214] The judge, however, went further, stating that he found Dr. Goldsmith's "change in so-called 'scientific opinion' not only suspect, but shocking."[215] This suggests that the judge might have been influenced in his opinion of the expert's testimony by what he evidently believed was some sort of bias. Although Judge Jones's skepticism seems to have been a result of the change in Dr. Goldsmith's opinion, that seems odd: one would think that an expert who was initially unwilling to provide testimony that would favor his client demonstrated at least some freedom from bias.

Regardless of whether the party witness was biased, though, one would think that when the judge's court-appointed witness vouched for the scientific validity of his testimony, the issue of bias would have been removed from the case. Providing objectivity is, after all, the reason the court appoints its own expert. That is not to say that Judge Jones might not have had other reasons to exclude the testimony of the plaintiffs' expert,[216] but

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211. *See id.* at 1405.
212. *See id.*
213. *See id.*
214. *See id.* at 1405-06.
215. *Id.* at 1405 n.39.
216. One unsatisfactory reason was offered by Judge Jones in his ruling that the epidemiological studies about which the expert would have testified "cannot support expert testimony that silicone 'more likely than not' causes disease or signs and symptoms of disease in women." *Id.* at 1405. Judge Jones explained that none of the studies showed a relative risk of greater than 2.0, which would be the risk necessary to make the cause of disease more likely due to the silicone implants than to

in light of his comments one is led to wonder whether his perception of bias might have played a role that the testimony of the court's expert should have eliminated. If a trial judge uses court-appointed experts, and those experts accept the scientific validity of the testimony of party witnesses, the judge should admit the party witnesses' testimony, at least in the absence of any showing that the court-appointed experts are themselves biased.[217]

2. Testimony About Research When the Researcher Is Not Present

When a scientific expert witness testifies regarding the research of others, elimination of the bias of the witness does not

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some other, presumably pre-existing cause. *See id.* Exclusion on this basis, however, was directly contrary to the report of the court's own expert. Dr. Greenlick wrote that "[f]rom a scientific point of view it is not appropriate to disregard relative risks of less than 2.0." *Id.* at 1450. He noted that the epidemiological studies about which the expert would have testified did not test specifically for the conditions for which the plaintiffs were claiming damages. *See id.* at 1451. The strongest of the studies tested for various specific connective tissue diseases, rather than ACTD. *See id.* at 1404 nn.37-38. Dr. Greenlick therefore claimed that the proper approach was to use the studies in association with other evidence, such as the evidence suggesting the biological plausibility of a causal link. *See id.* He said that "the only way one can ultimately assess the significance of the epidemiological data in this case is through relatively complex integration of that information with the scientific testimony from other fields," and that, depending on the nature of that other evidence, the epidemiological studies might "provide evidence for the causal link to atypical disease at a relative risk even greater than that for typical disease." *Id.* at 1451.

A more valid reason for excluding the testimony might have been that, as Judge Richard Posner noted in another case, "the courtroom is not the place for scientific guesswork, even of the inspired sort." Rosen v. Ciba-Geigy Corp., 78 F.3d 316, 319 (7th Cir. 1996). Judge Posner seemed to concede in this statement that certain testimony was *scientific*, even if guesswork. Posner's comments suggest an avenue for excluding the testimony in *Hall* as unscientific, despite the contrary view of the court-appointed scientific expert, who presumably knew better. That is, Judge Jones might reasonably have excluded the testimony not because it was scientific guesswork, but because he concluded that it was, as a legal matter, guesswork. In taking this approach, though, he should acknowledge that he is making a legal decision, not a scientific one.

217. In *Hall*, as noted above, Judge Jones said that the court's experts were "totally unbiased and uncommitted." *Hall*, 947 F. Supp. at 1393. The judge permitted no cross-examination of his witnesses, so the parties were apparently unable to test that statement. *See supra* note 198.

exhaust the conflict of interest problems. As described above, research may be subject to conflicts of interest that can distort the design and reporting of research projects.[218] In this area, where the conflicts affect the research itself, rather than its presentation in court, it seems reasonable to look to science's approach to handling conflicts. This approach, of course, is in accord with *Daubert*'s direction that the courts look to scientific standards. Moreover, it is quite feasible because both federal regulators of science and scientific institutions have established rules to address these conflicts.

At a minimum, scientific institutions require disclosure of potential conflicts,[219] and a similar requirement would be reasonable in litigation. This means that when witnesses testify about research done by others, courts should require them to disclose any conflicts of the scientists who performed the research. Of course, instances may exist in which witnesses will not have access to information about the conflicts of those about whose research they testify. In such cases, presumably the best a court could do is require, as the FDA does in analogous circumstances, that the litigant provide a certification that it has "acted with due diligence to obtain the information but was unable to do so and stating the reason."[220]

A more difficult question is how to handle conflicts that *are* disclosed. As described above, science generally goes further than the rough equivalent of cross-examination,[221] which is the usual approach in litigation. Cross-examination in this context is not likely to be entirely effective because lay fact finders are likely to find it difficult to assess the significance of conflicts in research. It will be even more ineffective when the witness did not conduct the research and therefore may not be able to respond to questions about it. Scientists generally require at least the disclosure of the data underlying the final research report in

218. *See supra* notes 115-74 and accompanying text.
219. *See id.*
220. Financial Disclosure by Clinical Investigators, 21 C.F.R. § 54.4(c) (1998); *see also supra* text accompanying note 174.
221. *See supra* notes 107-10, 114, 169-71, and accompanying text.

these circumstances,[222] and courts also could impose such a requirement in litigation. This would give the opposing party a better opportunity to expose any problems in the research. As with information regarding the existence of conflicts, it might not always be possible for litigants to obtain research data, but, again, a requirement that the litigant show due diligence could be substituted.[223]

Beyond the conflicts of researchers, and even more troubling, are conflicts that affect the selection of research to be funded and reported.[224] The issues here do not fit well within the framework set out by *Daubert* because that framework focuses on how to determine whether a particular item of proffered research is scientific, and these sorts of conflicts alter the items that are in fact proffered. Probably the most universally condemned of the limitations on scientific research are those that restrict what researchers may disclose about work that they have performed. The effect of these limitations in skewing the scientific record is obvious. An appropriate solution, it seems, would require litigants to disclose all publication limitations that were imposed on the research they present. This requirement should apply not only to proffered testimony, but to all research funded by the sponsors of proffered research, because only then could a court determine whether some scientific evidence was being withheld only because a sponsor had suppressed it.

In some cases, as with research performed in-house by a litigant, explicit contracts governing what research may be published are unlikely. In these cases, there would seem to be two possible solutions. The solution most likely to produce full infor-

222. *See supra* note 167 and accompanying text.

223. It is important to note that this approach should lessen the problems of court-ordered disclosure of research data. For a discussion of such problems, see Symposium, *supra* note 36. Because the burden would be on the proponent of the evidence to disclose the underlying data or to show diligence in attempting to do so, court-ordered disclosure would be necessary only when due diligence was insufficient to produce the data. Further, because disclosure would be necessary only in case of conflicts, *see infra* note 228, when a relationship between the proponent of the evidence and the research sponsor is likely to exist, diligence would usually produce the data.

224. *See supra* text accompanying notes 115-54.

mation would be to require that the sources of the in-house research disclose all of the research that they perform. Courts could implement this rule through discovery when the sources of research are themselves parties to the litigation. For example, in the case of In re *Silicone Gel Breast Implant Products Liability Litigation*,[225] District Judge Sam C. Pointer, Jr. required the parties quarterly to "provide each other . . . all unredacted documents concerning ongoing research."[226] The judge specified that the research to which his order was applicable included research

> that the producing party (a) is conducting or has conducted with its own employees, facilities, or consultants; (b) is directly funding or has directly funded in whole or in part but is being performed or was performed through outside investigators; (c) is receiving or has received reports or data about from any other party or non-party.[227]

If a party to litigation were to offer research sponsored by others—e.g., others in the same industry—some other approach would be necessary, because discovery would not necessarily reach non-parties. One might think that this is an area in which the *Daubert II* distinction between research conducted independent of litigation and that conducted in connection with litigation—though not the implications that *Daubert II* drew from the distinction—might be valid. It seems plausible that when research is conducted in connection with litigation, the sponsor of that litigation is more likely than in other circumstances to seek to suppress unfavorable results.[228]

As the discussion above shows, however, suppression of scientific results occurs in circumstances both connected and un-

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225. Master File No. 92-P-10000-S (N.D. Ala. filed Nov. 27, 1996). To access the pleadings in this case, see *Index of /BREIMLIT/* (visited Oct. 3, 1998) <http://www.fjc.gov/BREIMLIT>.

226. Order 36 (Production and Exchange of Information Regarding Ongoing Studies), *Breast Implant Litigation* (No. 92-P-10000-S).

227. *Id.*

228. *See* Francis E. McGovern, Comment, *Implementing a Taint Test to Address the Problems Raised by Compelled Disclosure*, LAW & CONTEMP. PROBS., Summer 1996, at 185, 190 (suggesting that "[i]f . . . preliminary discovery reveals that a party either supported or influenced the research it seeks to introduce at trial, then mindful deconstruction [i.e., pretrial discovery of research results] would be allowed").

connected with litigation. Courts therefore should address the suppression problem even when the sponsor of proffered research is not a party to the litigation in which it is presented. Requiring disclosure of all research results, as suggested above for parties, however, might be thought too intrusive. Alternatively, a court might require, when a party offers research funded by an entity that reasonably could be viewed as interested in the results of that research, that the party also make a reasonable attempt to obtain information from the funding entity regarding its publication policies.

B. When the Witness Is the Researcher

As one would expect, conflict of interest problems are more difficult when an expert is both witness and researcher. Although it might be possible to distinguish the two sources of potential bias when the expert testifies to research that she did prior to, and unconnected with, litigation, the two sources are inextricably linked when she performs research specifically for litigation. As a result, the claim made earlier—that the biases of a witness generally are manageable for legal fact finders—is no longer applicable in these circumstances. The bias of the witness may be reflected not only in her testimony, but also in the design of her research, in which case it will be more difficult for a layperson to understand.

This, of course, was exactly the concern of *Daubert II*. That case, however, failed to draw distinctions that can be used to determine the seriousness of the problems that a conflict of interest presents. Most importantly, as described above, it failed to recognize that "pure" research can present conflicts as serious as those in litigation.[229] Conversely, it also failed to realize that it is possible to make distinctions among different instances of research conducted in connection with litigation. Not all such research presents the same problems.

As described above, it may be reasonable to exclude testimony by witnesses who do no research in a purely scientific setting—

229. *See supra* text accompanying notes 33-34.

that is, witnesses who are not truly scientific experts.[230] This rule is as applicable when a party is presenting research performed in connection with litigation as when the research was unconnected with litigation. In general, there seems no reason why a party could not hire one expert to perform research for it and hire another, who is a practicing scientist, to testify regarding that research. To be sure, a compelling reason might exist for some litigants: it might be too expensive to hire two experts. In that case, though, the litigant should at least be required to make a showing that the additional expense is significant in relation to the overall costs of the litigation.[231]

One might ask why, if the party can find a practicing scientist to testify to the research, it could not find a practicing scientist to perform it as well. The reason, however, has been acknowledged by the courts. In considering the argument that "most of the [expert's] work since 1976 has been for the plaintiffs in litigation," the Third Circuit in a recent case noted that "[f]or litigants to have access to experts, it may be necessary for some experts to concentrate on litigation."[232] This seems a valid concern, at least when the litigant's need is for an expert to perform research, which can be very time-consuming.

One might also object that a litigant could find it as difficult to hire a scientist to take the time to testify to research as it would to hire one to perform that research. That seems unlikely, though: testimony is generally less time-consuming than research. Moreover, if legitimate scientists are unwilling to testify to particular research, a court reasonably might be concerned that their unwillingness is a result of the quality of the research rather than of the time their testimony would consume. As a result, although a court in certain circumstances might permit an expert who is not a practicing scientist to present research,

230. *See supra* text accompanying notes 185-92.

231. When the litigant is pursuing the case on a contingency-fee basis, the required showing should take into account the lawyer's position and the relationship of the case to others that the lawyer is pursuing.

232. Brown v. Southeastern Pa. Transp. Auth. (*In re* Paoli R.R. Yard PCB Litig.), 35 F.3d 717, 753-54 (3d Cir. 1994).

the court also should require the litigant to disclose why its efforts to hire practicing scientists to present the research were unsuccessful.

The implications of these suggestions can be illustrated by two examples. Consider first the testimony of Dr. Alan Done, a prominent witness in the Bendectin litigation and in other toxic-tort litigation.[233] Dr. Done was the plaintiff's primary witness in *Oxendine v. Merrell Dow Pharmaceuticals, Inc.*[234] The plaintiff won at trial in *Oxendine*, the trial judge granted the defendant judgment notwithstanding the verdict, and the court of appeals reversed, reinstating the trial verdict.[235] Merrell Dow subsequently sought to reopen the case, alleging perjury by Dr. Done in describing his academic position.[236]

The perjury proceedings are described in Professor Michael Green's book on the Bendectin litigation, *Bendectin and Birth Defects: The Challenges of Mass Toxic Substances Litigation.*[237] As Professor Green describes it, the basis of the perjury claim was that Dr. Done had testified, after he had resigned from his position, that he was on the faculty of Wayne State University.[238] Professor Green notes that this sort of issue generally would be unlikely to lead to overturning a jury verdict, but the trial judge did in fact overturn the judgment and order a new trial.[239] The judge found "'that [Dr. Done's] testimony [regarding his position at Wayne State] was so deliberately false that *all* his testimony on behalf of plaintiff is suspect.'"[240] The court of appeals reversed again.[241]

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233. *See* GREEN, *supra* note 195, at 277 (relating Done's experience in another pharmaceutical case, *Mekdeci*, and "a number of drug cases").

234. 563 A.2d 330 (D.C. 1989).

235. *See id.* at 334-37. The trial judge also had granted a new trial as an alternative to the judgment notwithstanding the verdict, and that grant also was reversed by the court of appeals. *See id.*

236. *See* GREEN, *supra* note 195, at 280.

237. *See id.* at 280-81.

238. *See id.*

239. *See Oxendine*, 563 A.2d at 331.

240. GREEN, *supra* note 195, at 281 (quoting Oxendine v. Merrell Dow Pharms., Inc., Civ. No. 1245-82 (D.C. Super. Ct. Feb. 11, 1988) (Memorandum Order)).

241. *See id.*

Professor Green's interpretation of this sequence of events is that the trial judge initially granted judgment notwithstanding the verdict because he did not believe Dr. Done's testimony and that, though the judge was reversed by the court of appeals, he used the perjury claim as a second opportunity to reject Dr. Done's testimony.[242] That interpretation seems correct in light of the judge's statement quoted above, but consider another possibility. In the perjury litigation, the dean of Wayne State's medical school testified "that he had requested Done's resignation because he had been derelict in fulfilling his academic duties at Wayne State and that he was devoting a 'large percentage' of his time to testifying as an expert in lawsuits."[243] The trial judge referred to this circumstance, noting that Dr. Done's "'professional witness status led him to shirk his duties at the Wayne State Medical School.'"[244]

A judge might reasonably have been concerned that, in light of Dr. Done's shift from scientific to legal activities, he was no longer qualified as a scientific expert witness. Dr. Done had impressive academic qualifications,[245] but, as his dean testified, he had moved away from his scientific activities to his legal ones. It would not be unreasonable to think that he had also moved away from scientific skepticism and rigor to a more credulous adversary posture.[246] In a sense, he would fit the analogy of a lawyer who had once tried many cases but had left active trial work to work as an actor in dramatic productions of trials. Inevitably, a transition like this will cause one to deviate from the practices of one's original profession to those of one's new profession. Just as the lawyer might abandon those techniques that work in real trials in favor of those that work in dramatic representations of trials, Dr. Done might have abandoned scientific techniques for those that work in the courtroom.

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242. *See id.*

243. *Id.* at 280.

244. *Id.* at 281 (quoting *Oxendine*).

245. *See id.* at 278-79.

246. Lawyers who have engaged in litigation, and even those who have not, should be able to sympathize. When making particular arguments day after day, it is difficult to retain one's objectivity regarding those arguments.

The approach proposed here would require—because Dr. Done was no longer a practicing scientist—that his epidemiological analyses be presented by some other, practicing scientist. Thus, without excluding his testimony entirely, it would supply an additional check on it through requiring the plaintiff to find a practicing scientist who would vouch for it.[247] The plaintiff, Mary Oxendine, could avoid this requirement only by showing either (1) that requiring her (or her lawyer) to hire an additional expert would be too financially burdensome, or (2) that she was unable to find a practicing scientist to present the evidence, in which case she would also have to explain why she was unable to do so.

In contrast, when the plaintiff offers the testimony of a practicing scientist about research that scientist has performed, there should be less concern about bias. Such a scientist is less likely to adopt unscientific methods, both because he uses scientific methods in his non-legal scientific work and because he has a scientific—not just a legal—reputation to protect. That is not to say that such a scientist would never skew the design of his research; he still should be required to disclose the underlying data from which his testimony derives. But the danger of bias should be less than in the case of the "professional witness."

These distinctions are not always recognized. For example, in *Braun v. Lorillard, Inc.*,[248] the plaintiff offered the testimony of Dr. David Schwartz, an expert who had tested Braun's lung tissue for asbestos, which he found. Dr. Schwartz was a professor of biochemistry and was experienced in testing building materials for asbestos using a technique called high-temperature ashing.[249] He used the same technique to test Braun's tissue, though different techniques were standard for testing body tissue for asbestos.[250] The Seventh Circuit affirmed the decision of the trial court to exclude his testimony.

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247. This approach is similar to one proposed by Judge Posner in *Braun v. Lorillard Inc.*, 84 F.3d 230 (7th Cir. 1996), which is discussed below. *See infra* text accompanying notes 251-54.

248. 84 F.3d 230 (7th Cir. 1996).

249. *See id.* at 233-34.

250. *See id.*

The court's reason for excluding the testimony was purportedly that the testimony was not scientific. It pointed out that Dr. Schwartz did not investigate whether his technique could validly be extended from the testing of building materials to the testing of body tissue and said that "[t]he scientific witness who decides to depart from the canonical methods must have grounds for doing so that are consistent with the methods and usages of his scientific community."[251] It is difficult to know, though, in what way Dr. Schwartz's methods were unscientific. The extension of a test from one domain to another is certainly something done in science.[252] It is true that Dr. Schwartz did not test his procedure, and it might have been reasonable to exclude his testimony on that ground,[253] but the lack of testing was not the focus of the opinion in *Braun*. In fact, the court wrote that "[t]he plaintiffs' lawyers could have called one of the recognized experts in the testing of human tissues to validate Dr. Schwartz's novel methodology—the ones they had hired, for example—but they did not,"[254] which suggests that the objection was to Dr. Schwartz, not to his testimony.

At another point, the court indicated that it was not Dr. Schwartz himself, but his expertise, that was the problem: "An expert in the detection of asbestos in building materials cannot be assumed to be an expert in the detection of asbestos in human tissues."[255] This reasoning, and the willingness of the court to turn to the tissue-testing experts, is questionable. It is not clear why the relevant area of expertise was that of testing human tissue rather than that of using high-temperature ashing, the technique used by Dr. Schwartz. One might well replace the Seventh Circuit's statement that "[a]n expert in the detection of asbestos in building materials cannot be assumed to be an expert in the detection of asbestos in human tissues"[256] with the

251. *Id.* at 234.

252. Testing biological materials for asbestos using the same method that is used to test building materials might be a valid technique, but it might not. More testing would be required to know, but at no point during the testing process would the theory suddenly become "scientific."

253. *See infra* notes 261-65 and accompanying text.

254. *Braun*, 84 F.3d at 235.

255. *Id.*

256. *Id.*

statement that "an expert in the use of bleach digestion and low-temperature plasma ashing cannot be assumed to be an expert in the use of high-temperature ashing,"[257] and thus could not validate Dr. Schwartz's testimony.[258]

The court's real concern is perhaps suggested by the statements that followed the above quotation:

> The fact that the plaintiffs' lawyer turned to this nonexpert, having already consulted experts without obtaining any useful evidence, is suggestive of the abuse, or one of the abuses, at which *Daubert* and its sequelae are aimed. That abuse is the hiring of reputable scientists, impressively credentialed, to testify for a fee to propositions that they have not arrived at through the methods that they use when they are doing their regular professional work rather than being paid to give an opinion helpful to one side in a lawsuit.[259]

The concern here is not with Dr. Schwartz's scientific validity, but with his objectivity, a concern also reflected elsewhere in the opinion.[260]

There are several problems with this focus. First, it is not at all clear that Dr. Schwartz really did have a conflict. He appears to have had a successful business testing building materials. It is possible, of course that he was anticipating a new sideline in testing human tissue, but if the mere possibility of future employment as a witness were enough to infer bias, *every* expert

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257. Bleach digestion and low-temperature plasma ashing are the techniques generally used in tissue testing. *See id.* at 233-34.

258. As an analogy, imagine the early use of DNA matching, when the process had been established but had not been applied to the identification of human beings. Imagine, further, that an expert in DNA matching offered to give testimony using the technique to identify a criminal defendant. Such identification might never have been attempted before, and therefore might have been questionable testimony if its accuracy were not tested. To that extent, the Seventh Circuit is correct. If the testimony were questionable, however, it could not be "validated" by experts who used other kinds of identification techniques, like fingerprinting, the analogy to the court's suggestion that experts in human tissue testing could have validated Dr. Schwartz's testimony. On the contrary, one would expect the experts in DNA matching to be the ones most likely able to assess its performance in identification.

259. *Braun*, 84 F.3d at 235.

260. *See id.* (stating that a witness who departs from the usual testing methods must "ground his departure in demonstrable and scrupulous adherence to the scientist's creed of meticulous and objective inquiry").

would be biased. In any event, the court did not discuss any evidence suggesting that he was expecting such future employment. Unlike Dr. Done, Dr. Schwartz appears to have been a practicing scientist, and when such a scientist is offered as a witness, a court should not assume bias without some specific evidence.

Perhaps the court, despite its reference to the fact that Dr. Schwartz was "testify[ing] for a fee,"[261] was not so much concerned with his bias as a witness as with his bias as a researcher. The court did observe that Dr. Schwartz's work was insufficiently "meticulous."[262] This might have been a reasonable concern, and entirely in accord with *Daubert*, if the problem was that insufficient support for the research's scientific validity had been introduced. The court's concern, however, was apparently not the amount of support for the validity of the research but the source of that support. As noted above, the court would have accepted validation of the work by the plaintiff's other experts; it just would not accept it from Dr. Schwartz.[263] In the end, the court's reasoning appears to have been circular: the court's own perception of the insufficient meticulousness of Dr. Schwartz's research, combined with the fact—referred to by the court in the same sentence—that Dr. Schwartz was being paid, led to an inference that Dr. Schwartz was biased, which led back to a refusal to accept his validation of the quality of the research.[264]

The approach of the *Braun* court in requiring validation of Dr. Schwartz's work by other scientists may seem similar to the pro-

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261. *Braun*, 84 F.3d at 235.

262. *See id.*

263. *See supra* text accompanying note 254.

264. The willingness of a scientist to express opinions on the basis of inconclusive data is not necessarily evidence that the scientist is merely responding to the legal exigencies faced by her client. For example, one of the court-appointed experts in *Hall* noted of a controversial issue that "work in the area has progressed to the point that [the plaintiffs' expert's] confidence in the notion of an association has moved far enough away from zero that he and others have begun to make a serious investment in studying the problem." Hall v. Baxter Healthcare Corp., 947 F. Supp. 1387, 1449 (D. Or. 1995). The fact that scientists are making such an "investment" in their own work makes it scientific. Courts still could exclude evidence of such a nature as too uncertain, but they should do so on a legal basis, not a putatively scientific one.

posal above that Dr. Done's work be presented by practicing scientists. The difference, though, is that the justification for requiring another scientist to validate Dr. Done's work was that Dr. Done was not himself a practicing scientist. For Dr. Schwartz, that justification apparently did not apply, and indeed it was not applied by the court. The key point here is separating the biases of witnesses from those of researchers. Courts can appropriately handle the bias of a witness by excluding the witness, but because witness bias is readily appreciated by legal fact finders, exclusion is appropriate only in extreme cases.

The bias of a researcher is *not* appropriately handled by excluding the research. Instead, a court should require the researcher to disclose his conflict of interest and the data underlying his research results. The court then should determine, under *Daubert*, whether the research is scientifically valid. This approach will determine whether the bias had any concrete effects. In contrast, the trial (or appellate) judge's vague sense that the researcher was biased has no place here, because in yielding to that sense the judge would be assessing the researcher's credibility—a task that the jury can perform equally well.[265] If the Seventh Circuit in *Braun* let a perception that Dr. Schwartz was biased affect its assessment of the validity of his research, it usurped the role of the jury.

C. Peer Review, General Acceptance, and Conflicts of Interest

As the previous sections have argued, courts should keep separate the issues of witness bias and the scientific validity of research, taking researcher bias into account only to determine the level of scrutiny to be applied to research. Even when courts honor this separation, though, the inquiry into scientific validity can be affected by conflicts of interest. The two most significant of the Supreme Court's admissibility criteria in *Daubert*, peer review and general acceptance in the scientific community, can themselves be tainted by conflicts.

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265. *Cf. supra* text accompanying notes 77-78 (describing the AMA's similarly substantive approach).

1. Peer Review[266]

To the extent that one can read the Supreme Court's comments in *Daubert* to support either a view that scientific peer review is a standard that is too strict for legal admissibility or too lenient, the court viewed peer review as too strict.[267] The Court observed that "[s]ome propositions . . . are too particular, too new, or of too limited interest to be published."[268] Moreover, this is the view shared by at least some commentators, who have argued that peer review tends to suppress new scientific ideas.[269] One reason for this is that because peer reviewers are generally researchers established in the field, they have an interest in the current structure of research in the area.[270] In other words, they have conflicts of interest. If this is correct, requiring that testimony be peer-reviewed might exclude new scientific theories that could offer plausible, yet untested, theories concerning the cause of a particular harm.

On the other hand, some commentators believe that peer review is too lenient a standard for legal purposes:

> Even if [peer] reviewers had the time and inclination to check every paper very critically, and in exhaustive detail, there are good reasons why they should not. Scientists try to advance knowledge, to raise new and interesting ideas, and to suggest new possibilities—goals that would not be furthered by excessively skeptical peer review. The rigorous quality-control mechanisms that govern some scientific research (such as Good Laboratory Practices) were imposed on

266. "Peer review" means here, as it presumably did in *Daubert*, *see* Daubert v. Merrell Dow Pharms., Inc., 509 U.S. 579, 593-94 (1993), the review by scientists of articles submitted for publication in scientific journals. Commentators also have used the term to refer to the larger process of the review of scientific findings by other scientists. *See, e.g.*, Effie J. Chan, Note, *The "Brave New World" of* Daubert: *True Peer Review, Editorial Peer Review, and Scientific Validity*, 70 N.Y.U. L. REV. 100, 100 & n.1 (1995). For a discussion of the strengths and weaknesses of peer review, see DARYL E. CHUBIN & EDWARD J. HACKETT, PEERLESS SCIENCE: PEER REVIEW AND U.S. SCIENCE POLICY (1990).

267. *See Daubert*, 509 U.S. at 593.

268. *Id.*

269. *See* David F. Horrobin, *The Philosophical Basis of Peer Review and the Suppression of Innovation*, 263 JAMA 1438, 1438 (1990).

270. *See id.* at 1441.

> science by outside forces (the regulatory system, in the case of GLP). Such standards are unpopular among scientists, because they greatly increase the cost and difficulty of doing research. Unlike regulators, editors often accept a paper describing an obviously preliminary or even obviously flawed study if the work promises to be important or usefully provocative and controversial. Thus, the goals of science make it undesirable to strive for too high a level of reliability in published papers, and encourage a little creative noise in the system.[271]

This again suggests a conflict between the goals of law and science. In this case, it suggests that peer review might not be sufficient to ensure reliability of scientific evidence, a conclusion which puts in doubt the reliance of decisions like *Daubert II* on peer review.

This is not the place, however, to discuss the more general failings of a peer review screen.[272] For present purposes, it is important only to note the common features of the two criticisms: they both involve circumstances in which the scientific topic of interest is new or controversial. These are exactly the circumstances, of course, in which scientific issues come before courts. This suggests that even if peer review works well in the majority of cases in science, it may not do so in court. Sheila Jasanoff has pointed out that scientists do not hesitate to use peer-reviewed journals to advance views that will provide them with legal advantages,[273] and that, indeed, peer review standards

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271. FOSTER & HUBER, *supra* note 4, at 180.

272. Some of the more general failings of the process, however, may affect tort litigation. "In recent years, many medical leaders have expressed concern that the reluctance of scientists and journal editors to publish studies that did not show any benefits from a drug or therapy significantly skews the information available to doctors and the public." Altman, *supra* note 128, at C1. The problem here is not necessarily that actual dangers from drugs will not be reported; in the absence of control by a commercial sponsor of a study, a journal would be likely to publish a study reporting dangers. To the extent that juries weigh costs and benefits, however, evidence that suggests more benefit than might in fact exist also will distort the jury's deliberations. *See id.* ("[A] top Food and Drug Administration official said that the end result is that scientific journals present a much more positive picture of new drugs than the information the agency receives.").

273. *See* JASANOFF, *supra* note 136, at 51-52, 55-57.

themselves may differ when the subject of the review is a matter of legal contention.[274]

At the very least, a court should know more about how the peer review process works in cases of controversy before it accepts it as a criterion for evidentiary admissibility. Three recent incidents, detailed below, illustrate the sorts of problems that can arise.[275] None of these incidents show clear bias in the basic journal peer review process.[276] Each does, however, provide an example of a peer evaluation being used as a tool to promote a particular point of view, rather than to provide an objective assessment of research quality. Because the sorts of peer evaluation involved in these incidents are among those accepted by courts as "peer review," the incidents suggest the potential for distortion by conflicts of interest of the review process.

The first incident involved the thyroid research of Dr. Betty Dong.[277] In addition to exercising its contractual rights to prevent publication of Dr. Dong's research, Boots Pharmaceuticals, Inc., later bought by Knoll Pharmaceutical Co., sought to discredit the research by other means.[278] A scientist employed by Knoll wrote to the *Journal of the American Medical Association (JAMA)*, which had accepted Dr. Dong's article for publication, criticizing her study and stating that the journal "should 'be con-

274. *See id.* at 51; *see also* SHEILA JASANOFF, THE FIFTH BRANCH: SCIENCE ADVISERS AS POLICYMAKERS 68 (1990) ("Although its primary purpose is to provide quality assurance, peer review is also used more or less consciously by both editors and granting agencies to further social objectives, from upholding a funding program's legislative mission to providing support for litigation.").

275. Another example arose in Peter Duesberg's advocacy of the view that the HIV virus is not the cause of AIDS. *See* EPSTEIN, *supra* note 83, at 127-29. Duesberg sought to publish an article on his views in the *Proceedings of the National Academy of Sciences (PNAS)*, in which, as a member of the academy, he generally was entitled to publish without submitting his work to peer review. Because his work was controversial, though, the editor of *PNAS* sent his work out to three reviewers. *See id.* at 128. All three objected to the article, but *PNAS* published it nevertheless, with the editor apparently washing his hands of what he still considered an unscientific article. *See id.*

276. An incident in which journal peer review was distorted by the existence of a legal controversy, however, is described by Sheila Jasanoff. *See* JASANOFF, *supra* note 274, at 68.

277. *See supra* notes 118-24 and accompanying text.

278. *See* Altman, *supra* note 118, at A16 (referring to the "energetic campaign" waged by Knoll to discredit Dr. Dong).

cerned about publishing the paper.'"[279] The same scientist then published the company's own interpretation of Dr. Dong's work in the *American Journal of Therapeutics*, reaching the opposite result.[280] The company thus sought both to circumvent the normal peer review process of *JAMA* and to use another peer-reviewed journal to discredit Dr. Dong's work.

A second instance arose from the recent issuance by the Environmental Protection Agency of new standards for airborne particulate matter. Industry representatives have severely criticized these standards as based on inadequate science, and a think tank called the Annapolis Center organized an effort to assess the science supporting the standards.[281] Several scientists noticed, however, that some of the scientists invited to participate in the assessment were associated with industry, and it was discovered that the Annapolis Center received eighty percent of its funding from the National Association of Manufacturers (NAM) and that its president was a vice president of NAM.[282] Because NAM's members generally are opposed to strict environmental regulation,[283] this suggests that the assessment was a matter of advocacy, not objective evaluation.

In a final example, a scientist who conducted a reanalysis of a form of spine surgery and found little evidence of benefit from the surgery was attacked by a spine surgeon society and by a patient advocacy group formed by a spine surgeon.[284] The critics said that "they were simply applying the standards of science to the research findings,"[285] but the scientist argued that the criticism was harassment intended to protect the financial interests of the society's surgeons in the questioned procedure.[286] The process of reanalysis that was at issue in this incident is often used, and criticized, in litigation, so this incident suggests that criti-

279. *Id.* (quoting letter).
280. *See id.*
281. *See* John J. Fialka, *Panel Judging EPA's Proposed Air Regulations Receives Most of Its Funding From the Regulated*, WALL ST. J., Jan. 16, 1997, at A20.
282. *See id.*
283. *See id.*
284. *See* Deyo et al., *supra* note 138, at 1176; Kolata, *supra* note 135, at D23.
285. Kolata, *supra* note 135, at D23.
286. *See* Deyo et al., *supra* note 138, at 1176.

cism that purports to be based on scientific grounds may be motivated by other concerns.

In the end, these incidents suggest that when contentious matters are at issue—as they always are in litigation—courts should approach peer review carefully. Whenever litigants attempt to bolster scientific evidence by showing that it has been peer-reviewed, or to discredit evidence by showing that peers believe it is inadequate, courts should investigate the circumstances of the peer review. If an interested party funds the review, as in the EPA particulate matter and spine surgery examples above,[287] courts should approach it skeptically; moreover, the proponent of a peer review should be required to disclose the source of its funding. If, as in the Knoll example above,[288] an objective body conducted the review, but the reviewed research appears intended to counter other scientific results, the court might look past the satisfactory peer review of the proffered research and assess the quality of the review. If other reviewers rejected the research before its acceptance, or if it was accepted only at a second- or third-tier journal, the court might give the review little weight in determining admissibility.

2. *General Acceptance*

Daubert also retained the *Frye* requirement of general acceptance in the scientific community as a factor to be considered in determining the admissibility of scientific evidence. The Court wrote in *Daubert* that "'a known technique which has been able to attract only minimal support within the community,' may properly be viewed with skepticism."[289] The implications of this statement are somewhat unclear; particularly unclear are the means that are acceptable for determining which techniques have attracted support in the scientific community. One approach that the courts have taken, however, is to look to the statements of professional medical and scientific organizations.[290]

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287. *See supra* text accompanying notes 281-86.

288. *See supra* text accompanying notes 277-80.

289. Daubert v. Merrell Dow Pharms., Inc., 509 U.S. 579, 594 (1993) (quoting United States v. Downing, 753 F.2d 1224, 1238 (3d Cir. 1985)).

290. *See* FOSTER & HUBER, *supra* note 4, at 244-45. Foster and Huber advocate

Sheila Jasanoff notes that various medical societies have issued statements criticizing clinical ecology's claim to scientific status.[291] She points out that at least one of these societies, the California Medical Association, engaged in an extensive inquiry before reaching its conclusions, and that at least one court has relied upon the statements of the societies.[292] She nevertheless says that "the court made no attempt to look behind the consensus generated by [the societies] to question whether these organizations possessed any hidden biases or whether their consensus-building efforts afforded sufficient protection against bias."[293]

Given organized medicine's history of opposing "fringe" groups,[294] a history that other courts have found unjustified by objective data,[295] this failure by the court seems unwise. In a number of antitrust cases, physicians and others have challenged the rules of medical societies as intended to advance their members' financial interests and not science.[296] For example, until 1980, the American Medical Association (AMA) called chiropractic treatment "unscientific."[297] Putting aside the truth *vel non* of this claim, courts found that in opposing chiropractors the AMA was motivated in part by the goal of eliminating com-

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reliance on these reports:

> Such reports often include minority statements or other indications of the range of informed opinion. Any individual witness who holds views sharply at variance with statements like these should bear a heavy burden of explaining why the individual is right and the community, speaking through its committees, academies, or institutes, is wrong.

Id.

291. *See* JASANOFF, *supra* note 136, at 133-34. One such statement was issued by the American Academy of Allergy, Asthma & Immunology. *See* American Academy of Allergy, Asthma & Immunology, *Position Statement #14: Clinical Ecology* (visited Oct. 6, 1998) <http://www.aadmc.org/currentliterature/position/ps14.html>. That statement described clinical ecology as "an approach to medicine that ascribes a wide range of symptoms in the environment." *Id.* (footnote omitted).

292. *See id.* (citing Sterling v. Velsicol Chem. Corp., 855 F.2d 1188, 1208 (6th Cir. 1988)).

293. *Id.* at 134.

294. *See, e.g.*, JASANOFF, *supra* note 274, at 61-62; Mark R. Patterson, *Antitrust Liability for Collective Speech: Medical Society Practice Standards*, 27 IND. L. REV. 51, 63-65 (1993).

295. *See* Patterson, *supra* note 294, at 70.

296. *See, e.g., id.* at 53, 58-59, 63-70.

297. *See* Wilk v. American Med. Ass'n, 719 F.2d 207, 232 (7th Cir. 1983).

petition, and that the AMA was unable to show that its purported concern for the scientific validity of chiropractic treatment was "objectively reasonable."[298] Other cases have demonstrated similar absences of objectivity.[299]

An example of how "general acceptance" can be manipulated arose from the spine surgery research previously discussed.[300] The federal Agency for Health Care Policy and Research funded that research.[301] When data suggesting that the surgery provided little benefit appeared, spine surgeons wrote letters to Congress seeking to abolish the agency; subsequently the agency's budget was cut, and it discontinued the sort of work on treatment guidelines that had produced the spine surgery study.[302] This incident suggests that entities intended to provide consensus views to which courts might look to assess "general acceptance" can be subject to influence from financial interests. Presumably, the influence could come from either side of a litigation issue, but in many cases it may be that only the defendants will have the money and organization sufficient to exercise this sort of influence successfully.

With respect to these organizational evaluations of scientific issues, then, the problem is that interested parties may influence science itself, or at least the most scientific expert bodies. This problem, or potential problem, counsels caution in relying on general acceptance in the relevant scientific community. As with peer review, and as Sheila Jasanoff recommends, courts should look behind expressions of scientific opinion to determine whether they are truly expressions of objective scientific consensus.[303]

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298. *Id.* at 362-63.

299. *See generally* Patterson, *supra* note 294 (discussing a number of cases in which motives other than science influenced the disparagement of certain medical practices or procedures).

300. *See supra* text accompanying notes 284-86.

301. *See* Kolata, *supra* note 135, at D23.

302. *See id.*

303. *See* JASANOFF, *supra* note 274, at 54-55.

CONCLUSION

Conflicts of interest have significant implications for the reliability of scientific expert testimony. However, the courts' treatment of conflicts is not always in accord either with the treatment of conflicts in scientific practice or with the particular problems that scientists' conflicts present in court. In response, this Article proposes two basic changes in the treatment of scientific expert testimony. First, courts should strive to separate issues of bias from issues of scientific validity—the two sets of issues are now conflated at times. Second, courts should pay more attention to biases of scientists who perform the research underlying expert testimony, whereas now the focus is almost exclusively on the biases of the witnesses who testify.

More generally, this Article casts doubt on the wisdom of *Daubert*'s deference to scientific standards for determining evidentiary admissibility. The scientific questions that come before courts are generally both contentious and uncertain. When such questions are at issue, conflicts of interests often alter not only normal scientific research practices, but also the two most frequently used criteria of scientific validity relied upon by *Daubert*: peer review and general acceptance in the scientific community. Although the *Daubert* criteria may be valid in most scientific contexts, they are likely to function least well for exactly those scientific issues that come before the courts.