

COMMENT

UNIVERSITY PHYSICIAN-RESEARCHER CONFLICTS OF INTEREST: THE INADEQUACY OF CURRENT CONTROLS AND PROPOSED REFORM

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I. INTRODUCTION

The rapidly advancing biotechnology industry continues to generate many critical legal and ethical issues.¹ One unresolved issue is the troubling increase in conflicts of interest,² conflicts of commitment,³ and scientific misconduct⁴ in university research. Conflicts of interest exist when "financial or other personal considerations may compromise, or have the appearance of compromising, an investigator's professional judgment in conducting or reporting research."⁵ Universities and policy makers have become particularly concerned about conflicts of interest arising when a researcher, "any of his Family, or any Associated Entity

1. See generally OFFICE OF TECHNOLOGY ASSESSMENT, U.S. CONGRESS, SPECIAL REPORT OTA-BA-360, NEW DEVELOPMENTS IN BIOTECHNOLOGY: U.S. INVESTMENT IN BIOTECHNOLOGY (1988) [hereinafter INVESTMENT IN BIOTECHNOLOGY].

2. See *infra* note 5 and accompanying text (defining conflicts of interest).

3. Conflicts of commitment are "situations in which [faculty] members' external activities, often valuable in themselves, interfere or appear to interfere with their paramount obligations to students, colleagues, and the school." Harvard Univ. Faculty of Pub. Health, Policies on Conflict of Interest and Commitment 1-3 (Jan. 9, 1991) (on file with author). This Comment focuses on conflicts of interest, although it will discuss problems associated with conflicts of commitment and scientific misconduct where examples help illustrate the risks arising from industry-sponsored research.

4. Scientific fraud or misconduct involves the deliberate misrepresentation of research findings. For example, a researcher may falsify results to present more positive findings than she obtained. Similarly, a researcher may suppress negative findings or plagiarize research papers, methodologies, and results. Researchers may deliberately misrepresent experimental methodologies, thereby preventing replication or disproof of the findings by others. Authors may report fictional "results," having never performed the experiments at all. HOUSE COMM. ON GOV'T OPERATIONS, ARE SCIENTIFIC MISCONDUCT AND CONFLICTS OF INTEREST HAZARDOUS TO OUR HEALTH?, H.R. DOC. NO. 688, 101st Cong., 2d Sess. 4 (1990) [hereinafter COMMITTEE ON CONFLICTS OF INTEREST].

Although the prevalence of scientific misconduct is unknown, many scientists believe such incidents are fairly common. One study found that of 245 university scientists polled, 32% had suspected a colleague of falsifying data and 32% had suspected a colleague of plagiarism. More than half of these suspecting scientists chose not to investigate the veracity of their suspicions, however. COMMITTEE ON CONFLICTS OF INTEREST, *supra*, at 5 (discussing *Scientific Fraud and Misconduct and the Federal Response: Hearing Before the House Comm. on Gov't Operations, 100th Cong., 2d Sess. 101-02 (1988)* (testimony of Dr. June Price Tangney)).

5. ASSOCIATION OF AM. MEDICAL COLLEGES, GUIDELINES FOR DEALING WITH FACULTY CONFLICTS OF COMMITMENT AND CONFLICTS OF INTEREST IN RESEARCH 6 (1990) [hereinafter AAMC GUIDELINES]. A conflict of interest may exist "when an individual involved in conducting evaluative tests of new products (e.g. clinical trials) also holds an interest in a company that stands to gain from the results of the study." PRESIDENT'S COUNCIL ON COMPETITIVENESS, REPORT ON NATIONAL BIOTECHNOLOGY POLICY 7 (1991) [hereinafter COUNCIL ON COMPETITIVENESS].

possesses a Financial Interest in any activity which involves his responsibilities as a member" of a university faculty.⁶

University researchers' increased dependence on private industry funding has contributed to part of the rise in conflicts of interest. As the demand for biotechnology research funding has skyrocketed, the federal portion of total funds available for research grants has diminished. Industry has eagerly stepped in to fill the funding gap.⁷

In its search for profitable technologies, private industry continues to forge innovative funding arrangements with university research departments and individual researchers. University research departments and biotechnology companies are establishing major joint research institutes in unprecedented numbers.⁸ In today's world of "corporate science," industry frequently graces individual researchers

6. Harvard Univ. Faculty of Medicine, Policy on Conflicts of Interest and Commitment 2 (Mar. 22, 1990) (on file with author); see also *infra* note 19 (discussing the Pajaro Dunes Conference).

7. According to National Institutes of Health (NIH) data, total funding for United States health research and development increased dramatically from \$7.94 billion in 1980 to \$20.57 billion in 1989. In that same period, NIH's proportion of total funding dropped from 40% to 33%, while industry's contribution rose from 31% to 45%. Other public funding sources dropped from 25.6% in 1980 to 18% in 1989. Likewise, NIH's awards for new grants decreased from a record high of 6446 in 1987 to only 4600 in 1990. Many of the 1987 NIH new grant awards spanned longer terms than had been customary. As a result, NIH has had less funding available for new grants in recent years. John Carey, 'NIH Is Not the Institution It Was,' NEWSWEEK, Nov. 5, 1990, at 145, 148. The Office of Science and Technology Policy estimates that total federal investment in biotechnology in fiscal year 1990 was \$3.5 billion, of which 80% came from NIH. Industry sources provided approximately \$2 billion for biotechnology research and development, most of which was allocated for specific product development. See COUNCIL ON COMPETITIVENESS, *supra* note 5, at 6.

8. For example, Harvard University's Massachusetts General Hospital received \$70 million from Hoechst A.G., a West German-based chemical company, in 1980. In return, Hoechst received an exclusive option to market any potentially profitable technologies developed by the famous researcher Howard M. Goodman during the ten-year research contract. As early as 1983, E.I. du Pont de Nemours & Company gave Harvard Medical School \$6 million earmarked for the department of genetics; the Celanese Corporation gave Yale \$1.1 million for enzyme studies; the Bristol-Myers Company gave Yale \$3 million for the production of anti-cancer drugs; W.R. Grace & Company gave MIT up to \$8.5 million for commercial applications of microbiology research; and Monsanto gave \$23.5 million to Washington University for research in medical uses of proteins and peptides and \$4 million to Rockefeller University for research in photosynthesis. Katherine Bouton, *Academic Research and Big Business: A Delicate Balance*, N.Y. TIMES, Sept. 11, 1983, § 6 (Magazine), at 62.

In a recent report, the President's Committee on Competitiveness reported that the number of cooperative research and development agreements (CRADAs) under the 1980 Technology Transfer Act increased fourfold during the Bush Administration, rising from approximately 110 in 1988 to more than 400 currently. See COUNCIL ON COMPETITIVENESS, *supra* note 5, at 6; see also Technology Transfer Act, 15 U.S.C. §§ 3701-3714 (1988 & Supp. II 1990) (legislation that fostered joint research and development projects between industry and federally supported universities and laboratories).

with valuable stock options, consulting agreements, or other financial rewards in exchange for agreements to perform valuable research or provide consulting services.⁹ To obtain and retain these financially rewarding arrangements, however, researchers must satisfy their industry sponsors.

Of concern is that industry's commercial objectives are often at odds with patient or scientific interests.¹⁰ For example, when granting a lucrative research arrangement, a company may require a researcher to agree that potentially profitable research findings will remain confidential, unpublished, or significantly delayed in publication.¹¹ As a result, the scientific community may be deprived of valuable findings that suggest treatment options for patients. In efforts to accommodate

9. A *New York Times Magazine* article in 1983 reported, "So many academics have been hired as part time consultants that, a year or two ago, an investment company looking for an unaffiliated molecular biologist reportedly approached 20 researchers before it found one without a commercial tie. Today, scientists agree, it would be difficult to find even that one among top researchers, so rapid and comprehensive has the entanglement with industry been." Bouton, *supra* note 8; *see infra* notes 63-64, 72-144 and accompanying text.

10. *See infra* notes 22-65 and accompanying text.

11. However, some universities, such as the University of California, will not "accept funding that imposes unreasonable restrictions on the publication and dissemination of research results." Richard P. Seligman, *Implementing California's Regulations on Conflict of Interest in Research*, RES. MGMT. REV., Fall 1989, at 27, 33. The Yale University Faculty Handbook states that

[t]he University does not sponsor secret or classified research projects. This policy rests on two closely related judgments: that one part of the University's essential purpose, to impart knowledge, is clearly restricted when free discussion and open publication are prohibited; that the other part of the University's purpose, to enlarge humanity's store of knowledge, also depends on free discussion and criticism of results by a scholar's peers and would be inhibited along with the professional growth and standing of the individual if free dissemination were prohibited.

YALE UNIV., FACULTY HANDBOOK 96 (1986) (on file with author).

In 1985, Yale added to its faculty handbook a provision to clarify the university's policy on several issues related to sponsored research including publication of research results. The handbook states that "[t]he University's mission, openly and freely to disseminate knowledge, implies a presumption against any restriction of the right of the faculty to publish or against any requirement of approval prior to publication." *Id.* at 97. In a memo to the Yale faculty, the Committee on Cooperative Research, Patents, and Licensing warned faculty members considering consulting agreements:

You should at all times remain completely aware that confidentiality is antithetical to the basic values of free and open dissemination of information that are at the core of academic life. To the extent possible, you should attempt to restrict the confidentiality requirements of your outside work to a minimum.

Memorandum from the Committee on Cooperative Research, Patents, and Licensing, to the Faculty of Yale University (May 1986) (on file with author) [hereinafter Yale Consulting Memorandum].

industry, researchers may compromise scientific goals in favor of industry's objectives.¹²

Generally, university-industry collaboration is mutually beneficial. Collaboration allows for rapid technology transfer, thereby facilitating the development of new products.¹³ Many of these new products are of great benefit to the public.¹⁴ Industry draws from "the collective intellectual and creative talents of university faculty, and academia benefit[s] from additional sources of research and other funds."¹⁵ Fortunately for universities, as competition for federal funds has intensified, industry has supplemented research funds.¹⁶ But collaborative relationships have created a culture ripe for abuse by enterprising researchers.

The exposure of numerous incidents of inappropriate faculty behavior involving industry sponsors¹⁷ has prompted examination of university policies governing faculty-industry research relationships.¹⁸ The scientific community has only recently begun asking whether certain types of university-industry commingling are advisable.¹⁹ Consequently,

12. Another related concern is that university scientists may be unprepared to represent university and even personal interests in negotiations with sophisticated industry funding sources, particularly since such lucrative funding arrangements were largely unknown to past generations of scientists. See YALE UNIV., *supra* note 11; Yale Consulting Memorandum, *supra* note 11.

13. "[T]he translation of new [scientific] ideas into the marketplace is a laudable national goal. . . . [S]ociety can often benefit from the commercial application of scientific knowledge." COUNCIL ON COMPETITIVENESS, *supra* note 5, at 6. The Council also recommended that agencies should vigorously implement the provisions of the Technology Transfer Act and "[j]oint efforts among the public, university and private sectors to promote the transfer of scientific knowledge should be encouraged wherever possible." *Id.*

14. For example, biotechnological researchers have developed drugs and drug delivery methods to improve treatment of a wide range of diseases. The Food and Drug Administration has approved preventative agents or treatments for hepatitis B, anemia, diabetes mellitus, acute myocardial infarction, human growth hormone deficiency, AIDS-related Kaposi's sarcoma, hairy cell leukemia, venereal warts, and kidney transplant rejection. Development of many other treatment products and methods is currently underway. Gene therapy, in which researchers insert genetic materials into human cells, is among the most recent experimental treatment modalities. Gene therapies could be used to treat myriad diseases such as cancer, immune system disorders, hemophilia, and sickle cell anemia. *Id.* at 2.

15. AAMC GUIDELINES, *supra* note 5, at 1.

16. See *supra* note 7 and accompanying text; see also National Insts. of Health & Alcohol, Drug Abuse & Mental Health Admin., *Request for Comment on Proposed Guidelines for Policies on Conflict of Interest*, NIH GUIDE FOR GRANTS & CONT., Sept. 15, 1989, at 1 [hereinafter *NIH Proposed Guidelines*].

17. See *infra* part II.B.

18. See *infra* notes 19-20.

19. In 1982 the presidents of five universities met with leading scientists and industry executives to discuss the conflict-of-interest and other issues presented by university-industry ties. David Perlman, *Business Boom Sparks Big 'Bio-Ethics' Meeting*, S.F. CHRON., Mar. 19, 1982, at 30. See generally *Pajaro Dunes Conference Draft Statement*, 9 J.C. & U.L. 533

clear policy and guidance for participants in biotechnological research are in their infancy.²⁰

The widely publicized *Moore*²¹ case exemplifies the type of exploitation of conflicts of interest occurring within the biotechnology research arena, largely at the expense of an unwitting patient. In the context of *Moore* and several other disturbing case examples, this Comment discusses the growing prevalence of conflicts of interest in biogenetic research and problems arising out of such conflicts. The particular focus of this Comment is the often overlooked issue of physician-researcher conflict of interest. Part II investigates the impact of increased private industry involvement in biogenetic research and demonstrates that conflict between industry and university research norms fosters physician-researchers' temptation to behave unethically and, consequently, decreases patient protection. Part III discusses the lack of effective university and government regulation of conflicts of interest. It also discusses the failure of the available legal remedies of informed consent requirements and physician's fiduciary duty to fully protect patients. Finally, Part IV proposes reform mechanisms aimed at minimizing incentives to violate ethical standards.

This Comment concludes that in addition to policing physician-researcher conflicts of interest by providing legal remedies to patients, universities and federal research funding sources must develop and enforce their own guidelines regarding industry involvement in scientific research. This Comment proposes that universities require full disclosure of any activities that could present conflicts of interest and demand thorough, multi-tiered review of research proposals. Moreover, universities must minimize physician-researchers' incentives to engage in unethical or illegal activities, promptly investigate allegations of inappropriate behavior, and discipline faculty members who fail to adhere to institutional policies.

This Comment also proposes that funding organizations formulate policies that provide incentives for university researchers to minimize

(1982-83). In 1990, the Human Resources and Intergovernmental Relations Subcommittee reported an oversight investigation of scientific misconduct and conflicts of interest. The investigation included hearings in which over 30 members of the scientific community testified. The views described in the report indicate that many scientific organizations are currently evaluating the conflict of interest issue. COMMITTEE ON CONFLICTS OF INTEREST, *supra* note 4.

20. In a recent study, the Human Resources Subcommittee of the Committee on Governmental Operations found that most universities do not limit the amount of money faculty may accept for research, travel, consulting fees, or gifts from drug companies or from other private sources. COMMITTEE ON CONFLICTS OF INTEREST, *supra* note 4, at 6.

21. *Moore v. Regents of the Univ. of Cal.*, 793 P.2d 479 (Cal. 1990).

conflicts of interest and uphold high ethical standards. Requiring those institutions managing and funding scientific research to take responsibility for problems resulting from conflicts of interest will increase the likelihood that patients' interests will be protected prior to involvement in research. Such additional preventive measures are preferable to merely compensating injured patients after harm has occurred.

II. THE IMPACT OF INCREASED INDUSTRY INVOLVEMENT IN UNIVERSITY RESEARCH

A. Academic Research Norms²²

In the past, private industry funded little university research.²³ The federal government provided the majority of research funds through grants used for "basic"²⁴ scientific research.²⁵ Individual researchers were unconcerned about the availability of funding, whether federal or private, because fundraising occurred at the institutional level.²⁶ As a result, academic researchers' norms, values, and rules of conduct evolved relatively untouched by financial concerns.²⁷

22. One noted sociologist describes several standards that historically have guided academic scientists' behavior. ROBERT MERTON, *The Puritan Spur to Science*, in *THE SOCIOLOGY OF SCIENCE* 228, 228-53 (1973), discussed in Rebecca S. Eisenberg, *Proprietary Rights and the Norms of Science in Biotechnology Research*, 97 *YALE L.J.* 177, 183 (1987). The norm of "universalism" embodies the notion that valid research findings are valid regardless of the particular scientist or institution performing the research. In other words, that which is true is universally true for the entire scientific community. "Communism" expresses the value that because all scientific inquiry relies on prior scientists' efforts to some degree, scientific advancements should be added to the pool of communal knowledge. "Disinterestedness" conveys the idea that scientists should seek truth objectively, without considering their individual interests. Lastly, "organized skepticism" captures the value that before findings are deemed valid, the scientific community at large should examine their veracity. *Id.*

23. Helen Lescovac, *Ties That Bind: Conflicts of Interest in University-Industry Links*, 17 *U.C. DAVIS L. REV.* 895, 897-98 (1984).

24. See *infra* note 34 (defining basic research).

25. See *supra* note 7, *infra* note 45.

26. Rebecca S. Eisenberg, *Academic Freedom and Academic Values in Sponsored Research*, 66 *TEX. L. REV.* 1363, 1364, 1372 (1988).

27. University researchers' norms and values evolved in response to university faculties' assertions of academic freedom. As early as 1915, the American Association of University Professors (AAUP) formulated its definition of academic freedom. Eisenberg, *supra* note 26, at 1364 (discussing American Ass'n of Univ. Professors, Declaration of Principles (1915), reprinted in *ACADEMIC FREEDOM AND TENURE* app. A at 157-76 (Louis Joughin ed., 1969)). It stated that faculty members must possess the freedom to research and publish, to teach, and to speak or write as citizens outside the university. *Id.* at 1366. This and other early definitions of academic freedom reflect a universal concern that

In today's environment, however, individual faculty members pursue federal grants and industry sponsors for research funds on their own, often with minimal involvement by university administrations.²⁸ Once a faculty member attracts a funding source, the university enters the negotiations to finalize the agreement.²⁹ At the same time that faculty members are assuming greater responsibility for soliciting funding, reductions in federal and increases in industry funding³⁰ have changed the motivations and rewards for scientists. These changes are, to a degree, incompatible with traditional research norms and values.³¹ Some observers caution that the scientific community, and ultimately the public, will suffer as a result of these new forces.³²

As beneficiaries of substantial public funds, research universities have historically viewed themselves as quasi-public servants, conducting research for the public benefit and working to maintain the public trust.³³ The pursuit of "basic"³⁴ scientific research was seen as a public good.

faculty members' controversial or unpopular statements might be suppressed by the lay administrators who employ them. University faculty members feared that university administrators might easily be co-opted by the interests of those funding the university.

Eisenberg explains that

academic freedom protects faculty members from trustees and university administrators so that professional scholars will say what they think. In the absence of academic freedom, students and the public at large could not be certain that the views presented by scholars were in fact candid opinions of those experts, undistorted by the less informed views of laypersons on whom the scholars depend for their livelihood.

Id. Eisenberg notes, however, that the AAUP was not "argu[ing] for unqualified professional autonomy for individual faculty members or for an unregulated academic profession. Quite the contrary, they warn that the only way to preserve freedom from lay interference is through a system of accountability to professional peers." *Id.* at 1366-67. Thus, the shared norms and values among university researchers constitute a mechanism for self-regulation. These collective norms function as an honor code to which all members are expected to comply.

28. *Id.* at 1372; see also Yale Consulting Memorandum, *supra* note 11.

29. Eisenberg, *supra* note 26, at 1373.

30. See *supra* note 7, *infra* note 45.

31. See *infra* notes 33-65 and accompanying text.

32. See COMMITTEE ON CONFLICTS OF INTEREST, *supra* note 4; Eisenberg, *supra* note 26; Eisenberg, *supra* note 22.

33. See *infra* text accompanying note 35; see also Eisenberg, *supra* note 26, at 1371.

34. "Basic" research refers to "pure" research conducted for the sole purpose of expanding scientific knowledge. Conversely, "applied research" is conducted for the purpose of solving practical problems. Eisenberg, *supra* note 22, at 178 n.1. Eisenberg suggests that while this distinction is frequently made, it is no longer useful in the context of biotechnology where basic and applied research have become intermingled. Answers to many basic research questions have immediate commercially profitable applications.

For example, cells contain more genetic information than they actually use. Learning what causes cells to "express" certain genes and not others would not only answer major questions in biology, but might suggest ways of

According to one scholar, "[t]he role of the states as funder of basic (non-commodity-oriented) research fostered a powerful ideology—one of scientists working for the public good to improve the health status of Americans."³⁵ Unlike today, when industry avidly pursues marketable biotechnological advances, industry was largely uninvolved in basic scientific research.³⁶ As a result, industry goals and desires were of little concern to university scientists.

Historically, the academic community freely and openly shared information, techniques, and samples to ensure that subsequent researchers could replicate results.³⁷ "It was thought contrary to scientific norms to claim exclusive rights in research discoveries. These norms derive in part from the notion that making new observations available to the scientific community for evaluation and extension in further research facilitates the progress of science."³⁸ Consequently, researchers rarely sought patent protection for their discoveries.³⁹

facilitating the manufacture of desired proteins or suppressing the expression of disease-causing genes. This knowledge would therefore be valuable to both scientists and industry.

Id. at 195 n.96.

35. Eisenberg, *supra* note 22, at 179 n.6 (quoting MARTIN KENNEY, *BIOTECHNOLOGY: THE UNIVERSITY-INDUSTRIAL COMPLEX* 32 (1986)).

36. *See supra* note 7.

37. Eisenberg, *supra* note 22, at 197. In order to validate other researchers' findings or to build on their own work, researchers often obtain the actual materials used by the original researcher. These might include bacterial strains or other self-replicating tissues such as cell-lines. Mere publication of findings may not be sufficient to satisfy the research norm of replicability.

38. *Id.* at 182 (discussing *Commercialization of Academic Biomedical Research: Hearings Before the Subcomm. on Investigations and Oversight and the Subcomm. on Science, Research and Technology of the House Comm. on Science and Technology*, 97th Cong., 1st Sess. (1981); KENNEY, *supra* note 35; MERTON, *supra* note 22).

39. *See generally id.* at 185-90, 196-97 (discussing recent court decisions involving patentability of biological materials and impediments to patentability of basic research findings). Eisenberg explains that traditional patent law protected only applied technology inventions. Consequently, basic research findings that could not be readily applied to practical use were not patentable. *Id.* at 186. Moreover, prior to the Patent and Trademark Act Amendments of 1980, which allowed universities and other institutions of higher education to retain title to patentable inventions derived from government sponsored research, universities assigned most patentable inventions to the government. *Id.* at 196 (discussing Patent and Trademark Act Amendments of 1980, Pub. L. No. 96-517, 94 Stat. 3019 (codified at 35 U.S.C. §§ 200-212 (1988))). The 1980 Amendments promote universities' retention of patent rights by allowing the sponsoring government agency to retain title if the university does not exercise its rights within a reasonable time. Since the 1980 Amendments force universities to share patent royalties with the inventors, the Amendments motivate faculty researchers, as well as universities, to seek patents for their research. *Id.*

Instead, researchers published findings promptly and sought recognition by colleagues as their reward.⁴⁰ Offering recognition and esteem to those who contribute to the shared body of scientific knowledge "insures that scientists' self-interest will coincide with the public good."⁴¹ Most researchers complied with this "professional canon,"⁴² since deviation was unusual and generally frowned upon.⁴³ Thus, even particularly self-interested researchers, unconcerned about contributing to the public domain of scientific knowledge or facilitating future researchers' efforts, were highly motivated to disclose their findings. For without publication, researchers received few rewards.⁴⁴

As private industry funding increases for biomedical research have outpaced those from public sources,⁴⁵ however, new relationships

40. One measure of a scientist's prestige is the frequency of citation of her work. JEROME R. RAVETZ, *SCIENTIFIC KNOWLEDGE AND ITS SOCIAL PROBLEMS* 247, 255 (1971).

41. Eisenberg, *supra* note 22, at 184 (discussing ROBERT MERTON, *The Normative Structure of Science*, in *THE SOCIOLOGY OF SCIENCE* 275 (1973)). Some scholars believe that allowing proprietary rights in research findings conflicts with the norm of sharing information freely with other researchers. However, others point out that because patent law requires complete disclosure and dedication to the public, proprietary rights may actually further norms of sharing research information.

42. *Commercialization of Academic Biomedical Research: Hearings Before the Subcomm. on Investigations and Oversight and the Subcomm. on Science, Research and Tech. of the House Comm. on Science and Technology*, 97th Cong., 1st Sess. 62-63 (1981) [hereinafter *Commercialization Hearings*] (statement of Dr. Jonathan King).

43. Regarding violation of the norm of sharing research information, Dr. Jonathan King testified: "I don't mean to say there isn't professional jealousy [sic]. We have ambition and we have fame and recognition, but it is considered a departure from the normal and you are embarrassed when it comes out. It is not what you are supposed to be doing." *Id.* at 63.

44. See RAVETZ, *supra* note 40.

45. By 1950, the federal government funded more than 83% of the research in natural sciences. Predominantly, government funding has financed the development of research departments, equipped laboratories, paid the salaries of support staff, purchased supplies and materials, and provided for the training of researchers. Lescovac, *supra* note 23, at 897 n.11. According to one estimate, federal funding of university research and development declined from 73.5% in 1966 to 65.1% in 1981, while industry sponsorship increased from 2.4% to 3.8% over those years. Donald R. Fowler, *University-Industry Research Relationships: The Research Agreement*, 9 J.C. & U.L. 515 (1982-83).

Between 1980 and 1984, industrial funding for research and development at universities and colleges increased 93%, from \$237,025,000 in 1980 to \$457,227,000 in 1984, while federal funding increased only 31%, from \$4,096,029,000 to \$5,386,578,000. Adjusted for inflation, the total investment in research and development at universities and colleges rose only 4% between 1980 and 1983. This extremely modest rise reflects cutbacks in federal funding, particularly in the health area.

NATIONAL SCIENCE FOUND., *NATIONAL PATTERNS OF SCIENCE AND TECHNOLOGY RESOURCES* 12-13, 65 (1986) (tbl. 51); Eisenberg, *supra* note 22, at 178 n.2. Another study found that private industry may be funding up to one quarter of all university biotechnology research and that nearly one half of all biotechnology companies fund some university

between universities and industry have evolved. Some new practices contrast dramatically with previously accepted research norms and can create conflicts of interest.⁴⁶ A variety of relationships currently exist, including industry sponsorship of university research, university ownership or interest in biotechnology firms, and commercial joint ventures or research consortia between universities and private industry.⁴⁷ Relationships between individual university researchers and private industry are also quite commonplace.⁴⁸ For instance, university researchers may own stock in biotechnology companies or enter into research contracts, grants, or consulting agreements.⁴⁹ Many researchers become company officers or directors or members of scientific advisory boards for industry.⁵⁰

Researchers involved in private industry face pressures from two often-incompatible value systems.⁵¹ For instance, traditional research norms required that researchers remain disinterested⁵² by having no stake in the outcome of their studies,⁵³ whereas industry promotes the pursuit of profits. Entering into collaboration with industry results in conflicts of interest because a researcher's financial tie to a private company may be directly affected by research outcomes. For example, the value of the researcher's company stock may increase if a discovery is favorable to the company's plans.⁵⁴

research. David Blumenthal et al., *Industrial Support of University Research in Biotechnology*, 231 SCIENCE 242, 243-44 (1986).

46. See generally *supra* notes 22-32 and accompanying text.

47. See *supra* note 8; see also Lescovac, *supra* note 23, at 899 nn.16-17 (additional examples of university-industry collaborative arrangements).

48. See *supra* note 9, *infra* notes 63-64 and accompanying text (commentary and examples of relationships between industry and individual researchers).

49. See *infra* note 64.

50. INVESTMENT IN BIOTECHNOLOGY, *supra* note 1, at 111-27; Patricia A. Martin & Martin L. Lagod, *Biotechnology and the Commercial Use of Human Cells: Toward an Organic View of Life and Technology*, 5 SANTA CLARA COMPUTER & HIGH TECH. L.J. 211, 217 (1989); see also *supra* note 48.

51. One observer posits that sponsored research relationships threaten fundamental academic values in several ways. She asserts that sponsored research promotes secrecy of research results, which is in conflict with the norm of disseminating research results. Likewise, she claims that sponsored research relationships may insidiously distort researchers' viewpoints in favor of their sponsors' interests, or may influence research agendas in favor of projects that sponsors will fund. Eisenberg, *supra* note 26, at 1377-78; see also Eisenberg, *supra* note 22.

52. See MERTON, *supra* note 22, at 275. According to Merton, disinterestedness means that scientists should seek truth rather than furthering their own personal interests by making false claims.

53. Eisenberg, *supra* note 22, at 183 (discussing MERTON, *supra* note 22, at 267).

54. See *infra* part II.B.2.

Whereas traditional scientific research ideals conflicted with industry's desire to develop marketable technologies, today the research goals of universities and industry overlap. Under traditional norms, objective scientists pursued "basic"⁵⁵ research purely for the advancement of science,⁵⁶ not because it facilitated the development of the latest widget. In modern biogenetic research, however, the lines between basic and applied research are blurred because many scientific discoveries are directly relevant to commercial applications.⁵⁷ As a means of furthering commercial interests, industry now funds a substantial portion of university research.⁵⁸ The modern researcher therefore serves two masters—private industry and the public.

Industry-allied researchers encounter pressures to tailor research agendas to either fit their sponsoring company's needs or risk losing their private funding.⁵⁹ Because funding from outside sources is badly needed by universities,⁶⁰ researchers are rewarded for their ability to attract industry funding and sponsorship. To the extent that adopting industry norms enables researchers to please industry, these norms are valued in academia. Universities may offer substantial rewards to those who pursue applied research and gain industry support,⁶¹ whereas under traditional norms the scientific community deemed applied research non-intellectual, and therefore less valued. Some fear that, as a result, "true academic freedom will be threatened as will the honest interchange of

55. See *supra* note 34 and accompanying text.

56. See Eisenberg, *supra* note 22, at 182 n.17. Eisenberg explains that departures from traditional research norms such as disinterestedness, information sharing, and the pursuit of scientific research for the public benefit occur frequently as scientists jockey to establish their own professional reputations. That overtly self-interested, competitive behavior elicits disapproval within the scientific community, however, demonstrates that traditional norms remain intact.

57. See *supra* note 34.

58. See *supra* notes 7, 45 and accompanying text.

59. Eisenberg, *supra* note 22; see also COMMITTEE ON CONFLICTS OF INTEREST, *supra* note 4; Lescovac, *supra* note 23, at 900. Other problems include bypassing traditional peer review mechanisms in allocating research funds, with consequent deterioration in the quality of research; altering the research and subsequent employment opportunities available to graduate students; and dividing loyalties of faculty affiliated with industry. See generally KENNEY, *supra* note 35; David Blumenthal et al., *University Industry Research Relationships in Biotechnology: Implications for the University*, 232 SCIENCE 1361 (1986); Gerald E. Markle & Stanley S. Robin, *Biotechnology and the Social Reconstruction of Molecular Biology*, 10 SCI. TECH. & HUM. VALUES 70 (1985); David E. Korn, Note, *Patent and Trade Secret Protection in University-Industry Relationships in Biotechnology*, 24 HARV. J. ON LEGIS. 191 (1987).

60. See *supra* notes 7, 45 and accompanying text.

61. See Eisenberg, *supra* note 26, at 1373. Eisenberg asserts that because academic scientists capable of obtaining funds are highly desirable to universities, those researchers have gained leverage in their dealings with universities. Consequently, universities may be more inclined to accommodate a researcher's demands in order to attract and or retain skilled fundraisers.

new ideas or the latest research findings. Graduate students and faculty members alike will risk having their efforts more tailored to commercial needs than scholarship or the best interests of society as a whole."⁶²

Unlike the objective scientist of the past, many of today's scientists are better described as entrepreneurs,⁶³ seeking to capitalize on their latest research findings before someone else reaps the profits.⁶⁴ These

62. Albert H. Meyerhoff, *Ties that Bind: Conflicts of Interest in University-Industry Links—An Introduction*, 17 U.C. DAVIS L. REV. 891, 894 (1984).

63. Most faculty earn substantial income above their base salaries from consulting relationships and other ties to private industry. One unpublished faculty compensation study found that 70% of faculty earned additional income totaling 21.5% of their base salaries from industry affiliations. Lescovac, *supra* note 23, at 905 (discussing K. Dillon et al., *Faculty Compensation: Total University Earnings at Research Universities 1-3* (1979) (unpublished manuscript on file with author)); *see infra* note 64 (examples of scientist-entrepreneurs who have made fortunes through their research endeavors).

64. The University of California annual summary of disclosure statements filed with the California Fair Political Practices Commission reported 340 "positive" cases of university scientists having financial interests in business entities also sponsoring their university research. The Commission Report provides the following eye-opening examples:

A UCLA scientist proposed a research project with Cetus Corporation, in which he had an investment of between \$10,000 and \$100,000, as well as income of \$1,000 to \$10,000. While the director of the University's Molecular Biology Institute stated that "the contract calls for work . . . at the border of basic research and technology," the project was approved. Cetus received an exclusive, world-wide, royalty-bearing license to any patentable discoveries.

[Another UCLA] scientist was involved with a project with Global Geochemistry, of which he was president, 100% owner, and held an investment of between \$10,000 and \$100,000. He also received in excess of \$10,000 in outside income from Global. Global's contract with the University was eventually not renewed.

Another UC scientist proposed a research contract with Serex International from which he had been promised \$10,000 per year consulting income and a 5000-share stock option as a "signing bonus." Serex was to receive exclusive patent rights.

Meyerhoff, *supra* note 62, at 893 (discussing Staff Memorandum of the Fair Political Practices Commission, at 10-14, 20-22 (1983)).

Forbes magazine noted several prominent academic research scientists who have profited tremendously from their biotechnological advances, including:

David M. Goldenberg: founder, chairman and director of Immunomedics, owns approximately 16 million shares, equivalent to 69% of outstanding stock worth \$112 million; University of Medicine and Dentistry of New Jersey adjunct professor.

Herbert W. Boyer: founder, vice president and director Genentech since April, 1976, owns over 2 million shares of stock worth \$30 million; professor of biochemistry, University of California at San Francisco since 1976.

William J. Rutter: cofounder and chairman of Chiron Corp., owns 930,000 shares or approximately 8% of outstanding stock worth \$14 million; chairman, department of biochemistry and biophysics at UCSF from 1969 to 1982.

new pressures, motivations, and incentives introduced into the academic world by industry involvement in research may be irreconcilable with traditional scientific values. As a result, some scientists have abandoned or deviated from the communal research canons that past generations deemed essential.⁶⁵

Increased physician-researcher conflicts of interest are particularly troubling because of physicians' direct involvement with patients. Conflicts can arise from accepting gratuities or special favors from research sponsors, or undertaking clinical research when the physician or a family member has a financial, managerial, or ownership interest in the sponsoring company or the company developing the technology. In conflict situations, basic science researchers risk compromising university autonomy in choosing research agendas and faculty appointments, or inability to report findings freely. Unlike basic researchers, physicians

Thomas P. Maniatis: member of Genetics Institute's advisory board, owns 637,000 shares of stock worth \$9.5 million; professor of biochemistry and molecular biology at Harvard University since 1981.

Mark S. Ptashne: member of Genetics Institute's scientific advisory board, owns 568,000 shares worth \$8.5 million; professor of biochemistry and molecular biology, Harvard University.

Donald A. Glaser: founder and chairman of board of scientific advisors, Cetus Corp., owns 570,000 shares or 2.14% of stock worth \$6.2 million; professorships in physics, molecular biology and neuroscience at University of California, Berkeley.

Edward E. Penhoet: cofounder and president, Chiron Corp., owns 237,000 shares, or 2.3% of stock worth \$4.1 million; faculty member, University of California, Berkeley for 16 years.

Phillip A. Sharp: chairman of scientific board, Biogen, Inc., owns 322,000 shares worth \$2.6 million; director of the Center for Cancer Research and professor of biology at Massachusetts Institute of Technology.

John D. Baxter: founder, director and chief scientific consultant, California Biotechnology, Inc., since 1982, owns 470,000 shares or 4% of stock worth \$2.7 million; professor of medicine, biochemistry and biophysics at University of California Medical Center in San Francisco.

Kenneth Murray: vice chairman of scientific board of Biogen Inc., owns 295,000 shares of company stock worth \$2.4 million; professor of molecular biology at the University of Edinburgh, Scotland.

Patrick J. Scannon: president and director of science, Xoma Corp., owns 200,000 shares or 1.8% of stock worth \$2.5 million; clinical researcher at Letterman Army Institute of Research (1979 to 1981).

Walter Gilbert: member of scientific board, Biogen, Inc., owns 211,000 shares of stock worth \$1.7 million; Nobel laureate, Carl M. Loeb University Professor, Harvard University.

Gretchen Morgenson, *In Pecunia Veritas?*, FORBES, Nov. 28, 1988, at 208, 208.

65. See *supra* notes 22, 27, 33-64 and accompanying text; see also Eisenberg, *supra* note 26, at 1375-78 (discussing threats to academic freedom resulting from industry sponsored research).

inappropriately influenced by industry involvement risk harming patients who have entrusted them with their care.⁶⁶

A recent congressional committee report found that "[t]he most widely publicized cases of scientific misconduct in recent years have tended to involve physicians conducting biomedical research . . ."⁶⁷ Authors of the report attribute this alarming trend, at least in part, to the fact that physicians are more likely to receive funds from companies.⁶⁸ The subcommittee's conclusions indicate that in order to protect patients from potential harm, ties between industry and physicians must be monitored more carefully than in the past.

Current guidelines governing the appropriate scope and nature of relationships between industry and universities or their faculties are minimal.⁶⁹ This has already resulted in serious problems for physician-researchers, as well as scientific researchers in general.⁷⁰ Such findings may have grave implications for patient welfare. As one expert noted:

Faculty members who are financially dependent on research sponsors may not be counted on to uphold academic values on their own. In such situations, the protection of academic values may require limiting the autonomy of potentially co-opted faculty members. Moreover, the institution of faculty procured research grants has increased the power of outside funding sources and individual faculty members relative to that of universities. These changed circumstances call for a reassessment of traditional mechanisms for preserving academic values in sponsored research.⁷¹

Appropriate policy must be formulated quickly to ensure that ethical standards are not violated, research participants are not exploited, and public support for scientific research is not sacrificed.

66. Human subjects involved in research experiments are protected to some degree by the Human Subjects Law, 45 C.F.R. § 46 (1991). See *infra* note 166. However, the goal of human subjects law is not to protect against researcher conflicts of interest arising out of ties to industry. Like informed consent law, human subjects regulations focus on the subject's autonomy and rights to receive full information about participation in research. See *infra* part II.B (illustrating that physician-researchers involved in conflict of interest situations may risk harm to patients).

67. COMMITTEE ON CONFLICTS OF INTEREST, *supra* note 4, at 6.

68. *Id.* However, the authors noted that "[i]t is not known whether scientific misconduct is more frequent among physicians, or if biomedical research misconduct is more likely to be reported by individuals and the media because of the implications for public health."

69. See *supra* note 20.

70. See *infra* part II.B.

71. See Eisenberg, *supra* note 26, at 1374.

B. Some Illustrations of Conflicts of Interest

1. *MOORE V. REGENTS OF THE UNIVERSITY OF CALIFORNIA*

Moore v. Regents provides a shocking example of the violation of ethical standards that can occur when a physician-researcher becomes influenced by the pursuit of industry profits. The conflict of interest in *Moore* began on October 6, 1976, when John Moore first visited Dr. David W. Golde at the UCLA Medical Center. After examining blood and bodily substances drawn from Moore, Dr. Golde determined that Moore suffered from a rare condition, hairy cell leukemia, and that Moore needed a splenectomy⁷² immediately. Several days later, surgeons at UCLA successfully completed the operation.

Prior to the surgery, Dr. Golde provided written instructions to members of his research staff at UCLA informing them that Moore's blood and bodily substances were unusual and "instructing them to study and characterize the nature of his unique cells."⁷³ When Dr. Golde diagnosed Moore's condition, he found that Moore's cells were likely to be commercially valuable because they "overproduced certain [proteins], thus making the corresponding genetic material easier to identify."⁷⁴ Using Moore's genetic materials, Dr. Golde could try to develop a cell-line⁷⁵ from which bioengineering companies might produce highly

72. A splenectomy is the removal of the spleen. *STEDMAN'S MEDICAL DICTIONARY* (25th ed. 1990).

73. *Moore v. Regents of the Univ. of Cal.*, 249 Cal. Rptr. 494, 499 (Ct. App. 1988), *rev'd*, 793 P.2d 479 (Cal. 1990).

74. *Moore v. Regents of the Univ. of Cal.*, 793 P.2d 479, 482 (Cal. 1990). Lymphokines, produced by T-lymphocytes, are proteins which regulate the immune system. Because some lymphokines are of therapeutic value, researchers are interested in locating the genetic materials responsible for producing certain lymphokines. Through recombinant DNA techniques therapeutic lymphokines can be manufactured from the genetic materials. The genetic code for lymphokines is identical among individuals, but is normally very difficult to locate and identify. Because Moore's cells overproduced certain lymphokines, the desired genetic materials were more easily located. *See generally* OFFICE OF TECHNOLOGY ASSESSMENT, U.S. CONGRESS, *NEW DEVELOPMENTS IN BIOTECHNOLOGY: OWNERSHIP OF HUMAN TISSUES AND CELLS* 31-46 (1987). According to research conducted by Dr. Golde and Quan, Moore's T-lymphocytes had been infected by a virus which has been shown to result in the overproducing characteristic. Irvin S.Y. Chen et al., *Human T-Cell Leukemia Virus Type II Transforms Normal Human Lymphocytes*, 80 *PROC. NAT'L ACAD. SCI. U.S.A.* 7006, 7006 (1983).

75. A cell-line is a culture capable of reproducing indefinitely. Because the cells continue to reproduce, attempts at identification of genetic materials can be repeated until they are successful. However, the process of developing a cell-line is exceedingly difficult. Generally, it is unlikely that any particular tissue sample will result in a successful cell-line. *Moore*, 793 P.2d at 481 n.2 (discussing OFFICE OF TECHNOLOGY ASSESSMENT, U.S. CONGRESS, *supra* note 74, at 31-46).

profitable products. In pursuit of the cell-line, Dr. Golde requested that Moore travel from Seattle to the UCLA Medical Center on numerous occasions under the guise of treatment.⁷⁶ Dr. Golde never told Moore about the cells' possible commercial value, or about the nature of the research that Dr. Golde and his research assistant, Shirley Quan, had undertaken using his cells. In fact, when Moore inquired as to whether there might be commercial value in the research, Dr. Golde and Quan insisted that there was none.⁷⁷

Sometime before August 1979, Dr. Golde and Quan successfully established a cell-line from Moore's cells. In January 1981, the Regents of the University of California applied for a patent to protect the cell-line which they later received.⁷⁸ Subsequently, Dr. Golde negotiated development agreements with two biotechnology companies from which he received a consulting contract, 75,000 shares of common stock, and payments to the Regents and himself totaling \$440,000.⁷⁹ According to Moore's complaint, the potential market for such lymphokines could reach \$3 billion by the year 1990.⁸⁰ Although Dr. Golde may not have initially predicted such enormous profitability, he was unquestionably aware that a cell-line developed from Moore's cells would be highly profitable.⁸¹

76. Moore was required to travel to UCLA from Seattle many times over the course of seven years. "[B]lood, blood serum, skin, bone marrow aspirate, and sperm" were removed on these visits. *Id.* at 481.

77. *Id.* at 485-86.

78. *Id.* at 481-82.

79. Dr. Golde entered into a contract with Genetics Institute. In exchange for exclusive rights to the materials and research performed on the cell line, Genetics agreed to pay Dr. Golde as a consultant, give Dr. Golde rights to 75,000 shares of common stock, and pay Dr. Golde and the Regents \$330,000 over three years including a pro rata share of Dr. Golde's salary and fringe benefits. Sandoz, another biotechnology development company, was added to the contract in June 1982 and agreed to pay Dr. Golde and the Regents an additional \$110,000. *Id.* at 482.

80. Moore v. Regents of the Univ. of Cal., 249 Cal. Rptr. 494, 500 (Ct. App. 1988).

The complaint alleges that products from Moore's cell line included:

"(a) Colony-Stimulating Factor (CSF) . . .

"(b) Erythroid-Potentiating Activity (EPA) . . .

"(c) Immune Interferon (Type II) . . .

"(d) Neutrophil Migration-Inhibitory Factor (NIF-T) . . .

"(e) T-cell Growth Factor (TCFG, Interleukin II) . . .

"(f) Macrophage-Activating Factor (MAF) . . .

"(g) Factor-Stimulating Fibroblast Growth . . .

"(h) Factor-Stimulating Human Pluripoten Hematopoietic Stem Cell . . .

"(i) Factor-Stimulating Human leukemic Cells in vitro . . ."

Id. at 501 n.6.

81. Moore, 793 P.2d at 481.

After Dr. Golde gave Moore a second consent form asking that he relinquish all rights in his cells, Moore became suspicious.⁸² Soon after, he sued Dr. Golde, Quan, the Regents of the University of California, and the biotechnology companies. The complaint stated thirteen causes of action,⁸³ including failure to provide informed consent, breach of fiduciary duty, and conversion.⁸⁴ The superior court considered only the cause of action for conversion and sustained the Regents' demurrer to the entire complaint.⁸⁵ But the California Court of Appeal held that Moore had adequately stated a cause of action for conversion and directed the superior court to give Moore leave to amend the allegations against the biotechnology companies and to decide the remaining causes of action.⁸⁶

In its July 1990 decision, the California Supreme Court rejected the conversion theory, but did not leave Moore without a remedy.⁸⁷ It held that Moore's complaint stated a cause of action for breach of fiduciary duty and failure to obtain adequate consent,⁸⁸ but not for conversion. According to the court, Moore stated a cause of action because Dr. Golde allegedly failed to inform Moore of the extent of the research and of his economic interest in Moore's cells before obtaining Moore's consent to research.⁸⁹ This constituted an invasion of Moore's legally protected interest in determining the use of his body.⁹⁰ The court concluded that:

82. *Moore*, 249 Cal. Rptr. at 501.

83. The 13 causes of action were conversion, lack of informed consent, breach of fiduciary duty, fraud and deceit, unjust enrichment, quasi-contract, bad faith breach of the implied covenant of good faith and fair dealing, intentional infliction of emotional distress, negligent misrepresentation, intentional interference with prospective advantageous economic relationships, slander of title, accounting, and declaratory relief. *Moore*, 793 P.2d at 482.

84. *Id.* at 482 n.4.

85. The superior court reasoned that subsequent causes of action were incorporated in the conversion allegation. Because the first allegation was defective, all further allegations were also defective. In a later proceeding, Genetics Institute's and Sandoz's demurrers were sustained without leave to amend because Moore had not stated a cause of action for conversion and the allegations regarding secondary liability were conclusory. *Id.* at 482-83.

86. *Id.*

87. *Id.*

88. *Id.* at 485. Informed consent is the requirement that medical and behavioral practitioners inform patients and human research subjects of the risks and benefits of procedures and obtain the patients' or subjects' agreement to undergo any risks. See Alexander M. Capron, *Informed Consent in Catastrophic Disease Research Treatment*, 123 U. PA. L. REV. 340 (1974); Richard Delgado & Helen Leskovic, *Informed Consent in Human Experimentation: Bridging the Gap Between Ethical Thought and Current Practice*, 34 UCLA L. REV. 67 (1986); Robert J. Levine, *Informed Consent in Research and Practice*, 143 ARCHIVES INTERNAL MED. 215 (1983).

89. *Moore*, 793 P.2d at 483.

90. *See id.*

1) a physician must disclose personal interests unrelated to the patient's health, whether research or economic, that may affect the physician's professional judgment; and 2) a physician's failure to disclose such interests may give rise to a cause of action for performing medical procedures without informed consent or breach of fiduciary duty.⁹¹

Thus, under the court's ruling, as long as a physician asks the patient for consent to the research and explains anything necessary to the patient's decision, the patient's interests are fully protected.⁹²

2. CHEMICAL DELIVERY SYSTEM

Several other recently reported instances of physician misconduct and conflict of interest demonstrate the profound impact of industry forces within university research communities. For example, the University of Florida's financial interests "conflict[ed] with such important scientific questions as the safe conduct of research, as well as the fair treatment of faculty."⁹³ In the Florida case, a graduate research professor in the University of Florida's College of Pharmacy, Dr. Nicholas Bodor, invented and patented a new drug delivery system, CDS (chemical delivery system). In return for the patent license, a private company slated \$1 million for university funding, and named Dr. Bodor vice president of a start-up company, Pharmatec, created to develop the drugs. Pharmatec hired several other prominent university faculty members and compensated them with Pharmatec stock.⁹⁴

Subsequently, another university researcher, Dr. Kenneth Sloan, uncovered evidence that CDS was similar to a known neurotoxin and could pose serious risks to those working with CDS.⁹⁵ Dr. Sloan's repeated attempts to make his suspicions known were rebuffed by pharmacy department faculty members involved with the Pharmatec project.⁹⁶ After the media publicized Dr. Sloan's accusations, he received a negative review resulting in a salary increase substantially smaller than

91. *Id.*

92. *Id.* at 497.

93. COMMITTEE ON CONFLICTS OF INTEREST, *supra* note 4, at 19.

94. *Id.* at 16-17. In addition to Dr. Bodor, Pharmatec hired three faculty members. Pharmatec compensated them with 1000 shares of stock worth \$5000, plus stock options. Pharmatec also gave the Dean of the College of Pharmacy, as well as several prominent administrators, 1000 shares of stock each. *Id.*

95. *Id.* at 17. Based on several research articles, Dr. Sloan cautioned that CDS may be structurally similar to the neurotoxin MPTP and could cause symptoms similar to those found in Parkinson's disease sufferers. *Id.*

96. *Id.* at 17-18. By the late 1980s, the Associate Dean of Research, Chairman of the Department of Pharmaceutics, and Chairman of the Department of Pharmacodynamics were all associated with Pharmatec as consultants or company officials. *Id.* at 18.

his professional accomplishments warranted.⁹⁷ Throughout the controversy, university officials insisted that CDS was safe and refused to conduct toxicity testing suggested by Dr. Sloan.⁹⁸ Eventually, Dr. Bodor conducted the requested toxicity tests and, perhaps not surprisingly, reported results affirming the university's earlier statements that CDS was non-toxic.⁹⁹

Dr. Bodor's involvement with Pharmatec presented a conflict of interest which may have impaired his ability to evaluate objectively whether CDS is harmful. The University of Florida's refusal to investigate the matter formally and conduct the toxicity testing suggests that the university itself may have been afraid of jeopardizing its Pharmatec ties. Although it is not known whether CDS actually poses any risk, the failure to fully investigate potentially dangerous technologies due to financial interests could result in serious physical harm to physician-researchers and ultimately to patients. Moreover, scandals such as the Pharmatec incident erode the public trust in university research institutions and discourage university scientists from raising concerns about the appropriateness of sponsored research activities.

3. *TIMI TRIALS*

The case of the Number 5 t-PA Multicenter Trial (TIMI Trials)¹⁰⁰ suggests that physician-researchers who own stock in the companies developing products they are evaluating may be unduly influenced by the rise and fall of the stock market. In the mid-1980s, NIH funded research at medical schools and hospitals throughout the country comparing the clotting effectiveness of two thrombolytic agents, t-PA¹⁰¹ and streptokinase (SK),¹⁰² typically used to treat heart attacks. The first findings, published in a 1985 article, pronounced the superiority of t-PA over SK in dissolving blood clots.¹⁰³ At least five of the authors of the

97. *Id.* Reports of retaliation against those who raise concerns about possible conflicts of interest is profoundly disturbing. Researchers may conclude that it is more advisable to join the pack than stand up for ethical principles in biomedical research. *Id.*

98. *Id.* at 17-19.

99. *Id.* at 19.

100. *See id.* at 19-28; *see also* David P. Hamilton, *White Coats, Black Deeds*, WASH. MONTHLY, Apr. 1990, at 23, 23-24.

101. t-PA is a drug developed to dissolve clots associated with acute myocardial infarction, or heart attacks. At the time of the TIMI trials, t-PA had not yet been approved by the FDA. COMMITTEE ON CONFLICTS OF INTEREST, *supra* note 4, at 19.

102. At the time of the TIMI trials SK had been approved by the FDA for intracoronary administration. SK had been approved in 1982. *Id.*

103. *Id.* at 20 (discussing *TIMI Study Group: The Thrombolysis in Myocardial Infarction (TIMI) Trial*, 312 NEW ENG. J. MED. 932 (1985)).

article owned stock in Genentech, the company manufacturing t-PA.¹⁰⁴ Following the article's publication, Genentech stock rose to \$28, from a high of \$18 a few months earlier.¹⁰⁵ Because the article failed to report results unfavorable to t-PA,¹⁰⁶ some critics argued that the NIH researchers were biased toward t-PA due to their later-revealed equity interests in Genentech.¹⁰⁷

As the TIMI trials progressed, the pattern of researcher involvement with Genentech and reporting of favorable results for t-PA continued.¹⁰⁸ According to findings of the Committee on Government Operations, stock ownership "could have created a conflict of interest for individuals who received Federal funds to study whether t-PA was safe and effective."¹⁰⁹ Most alarming is that scientists with stock in Genentech

104. The stock owners included Dr. Harold Dodge, Dr. James Willerson, Dr. James Chesebro, Dr. Carl Apstein, and Dr. Joseph Benotti. Dr. Burton Sobel had also received options for 14,000 shares. COMMITTEE ON CONFLICTS OF INTEREST, *supra* note 4, at 20 n.98.

105. *Id.* at 20. "It is difficult to pinpoint the impact of the article, since information about its findings was available prior to publication. In addition, it would be important to compare the increased value of Genentech stock to a pharmaceutical index during that period." *Id.* at 20 n.99.

106. *Id.* The article did not report evidence that t-PA and SK patients' left ventricle function was equivalent. Generally, left ventricle function is a more important predictor of mortality than is dissolving of blood clots. This finding was later reported by a non-TIMI researcher. *Id.* In addition, the 1985 article left out findings that t-PA and SK could cause bleeding problems. Those findings remained unpublished until other studies reported findings of bleeding problems. *Id.*

107. COMMITTEE ON CONFLICTS OF INTEREST, *supra* note 4, at 20.

108. In 1987, at least 13 researchers involved in the NIH-funded research owned Genentech stock or held options to buy the stock at a discount. None of the researchers publicly reported their financial interests in Genentech. The Subcommittee report concluded that "[t]he research literature on t-PA has repeated examples of more positive evaluations of t-PA by scientists with relationships with Genentech, compared to scientists without such relationships." *Id.* at 25. By contrast, results reported by international groups were generally favorable to both t-PA and SK. During the TIMI trials, several other research teams were studying the effectiveness of t-PA and SK. These included extremely large trials conducted by GISSI (*Gruppo Italiano Per Lo Studio Della Streptochinasi Nell'Infarto Miocardio*), an Italian group, the International Study of Infarct Survival (ISIS-2), an international group based at Oxford and funded by one of the manufacturers of SK, and ASSET (Anglo-Scandinavian Study of Early Thrombolysis), funded by a European distributor of t-PA. These researchers' results showed that both t-PA and SK reduced mortality. *Id.* at 22-24.

109. *Id.* at 21-22. The eventual approval of t-PA caused the value of Genentech stock to increase significantly. Since then, studies comparing the efficacy of t-PA and SK have continued to influence Genentech stock prices and analysts' forecasts for Genentech. The *Los Angeles Times* attributed a drop in Genentech stock to a rumor that forthcoming results of a British study showed no difference between t-PA and SK. Victor F. Zonana, *Investors Rush to Sell Genentech Stock*, L.A. TIMES, May 28, 1988, § 4, at 2.

In response to subsequent reports of researchers' finding that t-PA and SK were equally effective, securities analysts as well as physicians defended t-PA as the superior treatment. Following the release of GISSI-2 results, a major study of 20,000 patients from 13 countries reporting that t-PA and SK were equally effective, a University of Michigan

participated in decisions to significantly increase dosages of t-PA given to patients participating in the study.¹¹⁰ These researchers' decisions, which increased risks associated with t-PA use for the study participants, may have been influenced by their stock ownership. Even if the researchers' recommended increases were medically appropriate, their stock ownership casts doubt upon the motivations underlying their decision to increase dosages.

At the time of the suspect dosage increases, the TIMI Steering Committee and Executive Committee¹¹¹ controlled study procedures, including changes in t-PA dosages. The Steering Committee recommended that NIH researchers substantially increase t-PA dosages twice in four months.¹¹² At one facility, the dosage increases caused severe intracranial bleeding in 5 of 311 patients.¹¹³ As a result, three patients died and 41 suffered major non-cranial bleeding.¹¹⁴ Subsequent dosage reductions to one half the amount indicate that these dosages were grossly inappropriate.¹¹⁵ The magnitude and timing of the increases suggest that NIH researchers tried to rush the research process, since FDA approval could be hastened by reports of successful treatment without complications.

Others have alleged that physician-researchers involved in the clinical trials may have violated the patients' right to informed consent in

cardiologist and paid consultant to Genentech in t-PA testing, Dr. Eric Topol, was quoted in the *Washington Post* as having criticized the research methods, thus casting doubt on the study's findings. Malcolm Gladwell, *Comparison of Heart Drugs Challenged as Misleading*, WASH. POST, Mar. 10, 1990, at A3. At the time, Dr. Topol held options on 6,000 shares of Genentech stock. COMMITTEE ON CONFLICTS OF INTEREST, *supra* note 4, at 24.

110. COMMITTEE ON CONFLICTS OF INTEREST, *supra* note 4, at 26.

111. Initially, NIH charged the Safety and Data Monitoring Committee with responsibility for overseeing the safety of the TIMI trials. After several Safety and Data Monitoring Committee members expressed concern about the safety and effectiveness of t-PA, NIH eliminated that committee and relieved all but one committee member of any responsibility in the trials. Thereafter, the TIMI Steering Committee and Executive Committee made decisions regarding dosage increases and study procedures. *Id.* at 20-21.

112. *Id.* at 21. At least three of these TIMI Steering Committee members owned Genentech stock when the Steering Committee decided to increase dosages. Since NIH lacked a policy restricting stock ownership in a company by researchers evaluating the effectiveness of that company's product, NIH was unaware of stock ownership. Other sources reported stock ownership by Steering Committee members and TIMI trial researchers. *Id.* at 24-25. The Committee on Government Operations concluded that it was not possible to determine whether the researchers dosage decisions had been "clouded" by stock ownership. However, the Committee implied that where patients are concerned, those making treatment decisions should remain free of conflicts of interest. *Id.* at 26.

113. *Id.* at 21; see also Hamilton, *supra* note 100, at 24.

114. COMMITTEE ON CONFLICTS OF INTEREST, *supra* note 4, at 21.

115. *Id.*

their zeal to sign up willing participants.¹¹⁶ The son of one patient who died from cranial bleeding believes that a physician-researcher pressured his mother into participating in the trials without adequately explaining the risks involved.¹¹⁷ Although patients signed informed consent forms, those forms failed to state that t-PA was an experimental treatment not yet approved by the FDA.¹¹⁸ The forms also minimized potential risks associated with t-PA treatment, even after several patients died of complications induced by t-PA.¹¹⁹

In fact, Wall Street, Genentech, and NIH researchers pushed to get early FDA approval for t-PA.¹²⁰ As expected, following approval, the value of Genentech stock increased substantially.¹²¹ Assuming that seriously ill patients trust that their physicians have their best interests in mind, even the suggestion that stock profits may have factored into a physician-researcher's treatment decisions is quite disturbing.

4. TRETINOIN

In yet another incident, a Harvard University researcher violated university research rules while reaping the financial benefits of stock price increases which may have been fueled by his initial positive

116. *Id.* at 26.

117. Jacques Galin, the son of Marion Galin, a woman who died of cerebral hemorrhage suffered after receiving t-PA, testified before a Senate subcommittee about the manner in which a physician-researcher obtained his mother's consent to participate in the TIMI trials. Galin stated that his mother was taking morphine and "could not hold the pen to sign the form." Galin added: "My mother asked the doctor, what would you do. He said I would go with the drug. I thought that was very big of him considering it was his program." *Id.*

118. *Id.* at 26-27.

119. The forms failed to warn patients that t-PA could cause a stroke or death and instead stated that the drug rarely caused bleeding into the brain that could result in permanent damage. *Id.*

120. Prominent research physicians, as well as Wall Street analysts, criticized the May 1987 FDA refusal to approve t-PA for intravenous use. The *Wall Street Journal* denounced the FDA refusal. *Human Sacrifices*, WALL ST. J., June 2, 1987, § 1, at 30 (editorial). Following the refusal, Genentech stock dropped from a high in March of \$64.50 to \$36.35. The FDA finally gave approval to t-PA for intravenous use the following November, holding a special press conference to announce the approval. By contrast, the approval of SK, which had occurred just days before, was not publicized at all. See COMMITTEE ON CONFLICTS OF INTEREST, *supra* note 4, at 22-23.

121. COMMITTEE ON CONFLICTS OF INTEREST, *supra* note 4, at 23. In addition, reports of research results and rumors of research findings continue to influence Genentech stock prices. For example, following rumors that a British study found no difference between t-PA and SK, the stock fell sharply. See *supra* note 109. Researchers can easily predict how their results will influence a stock's value. Through selective release of findings, researchers who own stock can prevent personal losses or increase personal gains. This use of researchers' specialized information for personal gain in the stock market could be likened to insider trading.

research findings.¹²² Scheffer C.G. Tseng, a former Harvard researcher now at University of Miami, was conducting research on a condition known as dry eye.¹²³ Tseng and his clinical supervisor, Kenneth Kenyon, were treating patients with Tretinoin, a vitamin A ointment made by Spectra Pharmaceutical Services, a company formed by Tseng and his colleagues.¹²⁴

During the clinical trials, Tseng was a consultant to Spectra.¹²⁵ Tseng owned 530,000 shares of Spectra stock and Kenyon also owned stock.¹²⁶ When Spectra went public in 1985, the stock was worth just \$2.00 per share. A few months later, after Tseng reported favorable research results for 22 patients, the stock rose to \$8.25.¹²⁷ Soon after, Tseng began clinical Tretinoin testing on over 200 patients without university authorization and cashed in 200,000 of his Spectra shares.¹²⁸ Tseng and his relatives made over \$1 million from Spectra stock sales.¹²⁹ Tseng has maintained that he merely followed Kenyon's orders.¹³⁰

After Tseng left Harvard in 1986, Harvard began investigating Tseng's research.¹³¹ At the same time, Spectra announced that earlier claims of Tretinoin's effectiveness had been premature; the stock fell from a 1987 high of \$6.25 to \$0.375 per share.¹³² Although Tseng's misbehavior did not result in harm to any of his patients,¹³³ Tseng's stock interest presented a serious conflict of interest that created the appearance of having motivated his unauthorized research activities.

5. RETIN-A

Scientists studying the drug Retin-A have been criticized in a House Report for failing to disclose their financial ties to companies whose product they were evaluating.¹³⁴ Contrary to the *Journal of American Medical Association's* (JAMA) policy mandating disclosure, authors of a

122. See Peter G. Gosselin, *Flawed Study Helps Doctors Profit on Drug*, BOSTON GLOBE (city ed.), Oct. 19, 1988, at 1; Hamilton, *supra* note 100, at 24; Morgenson, *supra* note 64, at 210.

123. Gosselin, *supra* note 122, at 1, 16; Morgenson, *supra* note 64, at 210.

124. Gosselin, *supra* note 122, at 1.

125. Morgenson, *supra* note 64, at 210.

126. *Id.*; see Hamilton, *supra* note 100, at 24.

127. Morgenson, *supra* note 64, at 210.

128. *Id.*

129. Gosselin, *supra* note 122, at 1.

130. Hamilton, *supra* note 100, at 24.

131. Morgenson, *supra* note 64, at 210.

132. *Id.*

133. See Hamilton, *supra* note 100, at 24; Morgenson, *supra* note 64, at 210.

134. COMMITTEE ON CONFLICTS OF INTEREST, *supra* note 4, at 43-44.

1988 *JAMA* article¹³⁵ and editorial¹³⁶ about Retin-A failed to disclose their financial ties to Johnson & Johnson, the manufacturer of Retin-A.¹³⁷ The article and editorial described Retin-A as a wonder drug that could reverse wrinkles and other damage caused by photo aging.¹³⁸ After widespread media coverage announced highly promising results, sales of Retin-A jumped from 217,000 to 1,162,000 tubes in just one year.¹³⁹ A subsequent *Money* magazine article exposed the authors' extensive financial ties to Johnson & Johnson and evidence indicating that photographic techniques had been used to exaggerate Retin-A's effectiveness.¹⁴⁰ However, because the initial articles received extensive positive media coverage, many consumers and physicians may be unaware of the conflicts of interest and allegedly exaggerated results.

In addition, subsequent contradictory findings indicate that under industry pressure, the authors of the *JAMA* article and editorial released their positive findings prematurely. At a recent National Institutes of Health (NIH)¹⁴¹ conference, participants acknowledged that Retin-A's effectiveness had not been established and that Retin-A's effect on the development of ultraviolet-induced carcinomas is in dispute.¹⁴² Unfortunately, because of the initial favorable results, consumers may be applying Retin-A to lessen wrinkles when they may in fact be irreversibly damaging their skin.

The cases discussed above, as well as many others,¹⁴³ indicate the desperate need for guidance within the research community regarding

135. Jonathan S. Weiss et al., *Topical Trentinoin Improves Photoaged Skin: A Double-Blind Vehicle-Controlled Study*, 259 *JAMA* 527 (1988).

136. Barbara A. Gilcrest, *At Last! A Medical Treatment for Skin Aging*, 259 *JAMA* 569 (1988).

137. Leslie N. Vreeland, *The Selling of Retin-A*, *MONEY*, Apr. 1989, at 74.

138. Gilcrest, *supra* note 136, at 569-70; Weiss et al., *supra* note 135, at 531.

139. Johnson & Johnson held a press conference that coincided with the release of the *JAMA* article. All three network newscasts featured the Retin-A results that night. In addition, the article and editorial authors appeared on talk shows and morning news programs to further hype the product's effectiveness in combating wrinkles. COMMITTEE ON CONFLICTS OF INTEREST, *supra* note 4, at 43 (citing Vreeland, *supra* note 137).

140. Vreeland, *supra* note 137.

141. *See infra* note 167.

142. COMMITTEE ON CONFLICTS OF INTEREST, *supra* note 4, at 44 (discussing NIH Consensus Conference 1990 (documents available in the Human Resources and Intergovernmental Relations Subcommittee files)).

143. For example, Dr. Herbert Boyer, University of California at San Francisco professor and founder of Genentech, became a millionaire overnight when Genentech stock was first sold on the stock market. The stock rose from its initial \$35 per share to \$89 per share by mid-afternoon. Lescovac, *supra* note 23, at 900. According to *Forbes* magazine, as of November 1988, Boyer owned \$30 million worth of Genentech stock. Morgenson, *supra* note 64, at 209.

In another case, University of California at Davis (UC Davis) Professor Ray Valentine secured a \$2.5 million research grant from Allied Chemical Co. to investigate nitrogen

university-industry relationships. In particular, faculties must determine which types of arrangements with industry are compatible with their roles as university researchers and educators and which are not. Critics have challenged the university community to "clean its own house" and put forth policy resolving these critical issues.¹⁴⁴

III. THE INADEQUACY OF CURRENT REGULATION AND LEGAL REMEDIES AIMED AT PROTECTING AGAINST CONFLICTS OF INTEREST

A. University Policy Governing Conflicts of Interest

Although universities have become increasingly involved with private industry,¹⁴⁵ not all universities have developed policies governing industry-sponsored research.¹⁴⁶ Even those universities that have

fixation in plants. Shortly thereafter, Allied Chemical Co. purchased 20% of the stock in Valentine's start-up company Calgene. After UC Davis identified this conflict of interest, it presented Professor Valentine with an ultimatum. UC Davis insisted that Valentine either terminate his affiliation with Calgene, remove himself from other agricultural research projects at Davis, or resign from the Allied project. Valentine chose to withdraw from the Allied project. However, Valentine has maintained both his financial ties to Calgene and his university position. Because no one else at Davis was qualified to perform the research, the University lost \$1 million of the Allied research grant. Lescovac, *supra* note 23, at 907 n.53 (discussing an interview with Dr. Charles E. Hess, Dean of the College of Agricultural and Environmental Sciences, UC Davis (Mar. 3, 1982)); *see also supra* note 64 (for additional examples of researcher-entrepreneurs).

144. Albert H. Meyerhoff, Staff Attorney for the Natural Resources Defense Council, has suggested that universities set policy regarding whether:

- 1) exclusive patent licenses should be provided to corporate or private sponsors of research when public funds and resources are expended;
- 2) "faculty entrepreneurs" should be permitted to engage in business ventures that parallel their university functions and make use of "intellectual property" created at the public expense;
- 3) private funds should be provided to university scientists "earmarked" for specific research, thereby potentially leveraging greater amounts of public money for commercial purposes;
- 4) scientists should be disqualified from participating in research when they have a direct financial interest in its private sponsor; and
- 5) public disclosure should be required by university scientists of financial interests in business firms or other sources of income that foreseeably may benefit from publicly financed research and development efforts.

Meyerhoff, *supra* note 62, at 894.

145. *See supra* notes 7-9, 45-50 and accompanying text.

146. COMMITTEE ON CONFLICTS OF INTEREST, *supra* note 4, at 6. *But cf.* April Burke, *University Policies on Conflict of Interest and Delay of Publication: Report of the Clearinghouse on University-Industry Relations, Association of American Universities, February, 1985, 12 J.C. &*

implemented policies face several ongoing dilemmas. First, industry continues to propose unique and innovative relationships with universities and individual researchers that may not have been contemplated by an existing policy.¹⁴⁷ Second, the university research community has yet to voice collective normative standards outlining the kinds of relationships that are ethically acceptable and those that are not.¹⁴⁸ Likewise, federal funding sources have not presented fully developed guidelines regarding industry sponsorship of projects that also receive federal funding.¹⁴⁹

Without common wisdom to guide them, university administrators have used their own instinct and intuition to develop ad hoc policies to meet present needs. The wide range of policies among universities demonstrates that norms outlining the proper way to handle industry ties are still evolving. For example, some universities' policies include mandatory intensive monitoring of industry ties while others have no formal policy at all.¹⁵⁰ Collective discussion of industry sponsored research began only recently, as universities and researchers alike acknowledged that financial inducements and other types of industry arrangements may present significant conflicts of interest.¹⁵¹ Some members of the scientific community have found the lack of institutional leadership in the area of conflict of interest disturbing.¹⁵² According to

U.L. 175, 181 (1985) (finding that 46 out of 51 university survey respondents in 1984 had established written policies governing potential conflicts of interest arising from privately sponsored research).

147. For example, when receipt of stock options by top researchers was a rarity, universities probably did not think of placing limitations on the equity interest a faculty member could hold in industry. As those arrangements became more common, and resultant conflicts more problematic, some universities saw a need for limitations. See *infra* note 150.

148. The academic research community has begun to discuss conflicts of interest and various means of handling them. See *supra* note 19; *infra* note 150. But these discussions have not yet produced consensus among the experts.

149. See *infra* notes 169-74 and accompanying text.

150. For example, the Association of American Universities' survey found that of those respondents who had policies in place, 19 required faculty-initiated disclosure where a faculty member herself determines whether her industry relationship may present a conflict, while 26 required university-initiated disclosure, an annual report from each faculty member engaged in industry-sponsored research, or university approval of industry consulting or funding arrangements. Similarly, only 21 universities had policies governing faculty equity interest and managerial involvement in industry, requiring disclosure and university approval. None of the universities prohibited faculty members from holding equity interests in industry ventures. Some did, however, limit the amount of equity interest a faculty member could hold. See Burke, *supra* note 146, at 182-83.

151. See *supra* note 143.

152. As part of the Human Resources Subcommittee study, numerous researchers testified regarding concern about conflicts of interest. Hearings were held in April and

some university leaders, conflicts presented by certain types of industry ties are irreconcilable with a researcher's role in the scientific community.¹⁵³ In response to this increased concern, several universities and scientific organizations have begun promoting reform.¹⁵⁴

Following amendments to the state of California's conflict of interest regulations in 1982, the University of California took a leading role in developing conflict of interest policy.¹⁵⁵ The amendments mandated that the University of California, as a state agency, require faculty to disclose financial interests in private, non-government sponsors of their research to the university administration when they apply for or renew projects.¹⁵⁶

September 1988 and June 1989. Over 25 research experts testified at these combined hearings. COMMITTEE ON CONFLICTS OF INTEREST, *supra* note 4, at 2-3. The Committee on Government Operations report contained several examples of incidents involving conflict of interest. Undoubtedly some of these were revealed by those who testified. In addition, some of those testifying expressed concern over the lack of sufficient guidelines. For example, in a 1989 article, Dr. Arthur Caplan, Director for the Center for Biomedical Ethics at the University of Minnesota, argued that disclosure of financial interests was not enough and advocated complete divestment of researchers' financial interests. Dr. Caplan testified at the hearings. *Id.* at 57 (citing Arthur Caplan, *A Question of Ethics: Divest Your Stock and Do Your Duty*, ST. PAUL PIONEER PRESS DISPATCH, Oct. 9, 1989 (syndicated nationally by Knight-Ridder Newspapers)).

153. *Id.* at 54-55 (noting "considerable support" for PHS restrictions on financial relationships between researcher and sponsor where the researcher is undertaking clinical trials). *Id.* at 57 (quoting Caplan, *supra* note 152).

154. See COMMITTEE ON CONFLICTS OF INTEREST, *supra* note 4, at 59; *supra* note 19. Harvard University's Faculty of Medicine, for example, instituted a new policy on conflicts of interest in 1990 that "takes a broader view of conflict and contains far more stringent guidelines than did the earlier Faculty of Medicine policy of 1983," thereby suggesting an increased awareness and concern about the potential dangers accompanying conflicts of interest at Harvard. Harvard Univ. Faculty of Medicine, *supra* note 6, at 7. Likewise, the Office of Cooperative Research at Yale University is currently debating revisions in its policy on conflict of interest and conflict of commitment. Telephone interview with Henry S. Lowendorf, Office of Cooperative Research, Yale University (Apr. 1991).

155. See Lescovac, *supra* note 23, at 908. The California Political Reform Act of 1974 established the Fair Political Practices Committee (FPPC) as an agency of state government to administer and implement conflict of interest provisions of the Act. CAL. GOV'T CODE §§ 83100, 83111 (West 1976). In 1982, the FPPC amended conflict of interest guidelines to include some university researchers. The amendment, which applies only to the University of California and California State Universities and Colleges, states:

(b) Disclosure shall be required under Government Code Section 87301 or any Conflict of Interest Code in connection with a decision made by a person or persons at an institution of higher education with principal responsibility for a research project to undertake such research, if it is to be funded or supported, in whole or in part, by a contract or grant (or other funds earmarked by the donor for a specific research project or for a specific researcher) from a nongovernmental entity

CAL. CODE REGS. tit. 2, § 18705 (amendment filed June 4, 1982).

156. *Id.*

The amendments do not require researchers to disclose financial interests in private entities that benefit from research ties to other private entities or government-supported research, however.¹⁵⁷ For example, suppose company *A* benefits from company *B*'s success. Further suppose a researcher, Joe, is collaborating with company *B* and owns stock in *A*. Joe would not be required to report financial ties to company *A* even though his work with company *B* may dramatically affect his financial interest in *A*. Similarly, if Joe's government-supported research affected company *A*, he would not be required to report financial ties to *A*. Consequently, in 1982, California's disclosure requirement affected only ten percent of funds supporting research at the University of California.¹⁵⁸ Despite its limited impact, the disclosure requirements imposed on the University of California provide an example of the type of conflict of interest policy a major state university might adopt.

The University of California procedure for review of research proposals and renewals attempts to eliminate conflicts of interest. At each University of California campus, independent substantive review committees (ISRCs)¹⁵⁹ examine research applications to evaluate whether projects are within regulatory guidelines.¹⁶⁰ The ISRC submits its recommendations to the university chancellors who make the final decision regarding project approval. Generally, if a principal researcher has a conflict on a project, the chancellor asks her to eliminate the conflict or replaces her with another principal researcher.¹⁶¹ In some cases, researchers are allowed to go forward despite the conflict if the ISRC gives its approval.¹⁶²

157. Lescovac, *supra* note 23, at 911.

158. *Id.*

159. For example at the University of California, Los Angeles (UCLA), the chancellor appoints five faculty members to serve on each ISRC, with the advice and consent of the Academic Senate. Seligman, *supra* note 11, at 31. The ISRC must consider six separate criteria in determining whether to recommend approval of a proposal. To satisfy the review criteria: 1) traditional conflict of interest situations should be avoided; 2) the proposed research must be appropriate for the university; 3) the teaching and research environment must be open; 4) there must be no restriction on the freedom to publish and disseminate research results; 5) licensing agreements must be appropriate; 6) university facilities and resources must be used appropriately. *Id.* at 32-33. According to Richard P. Seligman of the Office of Contract and Grant Administration at UCLA, "the confirmation of the absence of these problems—as well as those identified earlier as 'traditional conflicts'—permits the ISRC to determine that a proposed arrangement would not constitute a conflict of interest." *Id.* at 34.

160. The FPPC regulations also precluded the university from accepting grants, gifts, or contracts in which a principal investigator had a financial interest in the research sponsor unless the arrangement gained approval from an "independent substantive review committee" comprised of faculty members. *Id.* at 28.

161. Lescovac, *supra* note 23, at 912.

162. *Id.*

The chancellor files reports documenting the ISRC's findings with the Fair Political Practices Committee (FPPC), the state agency charged with responsibility for implementing conflicts of interest regulations.¹⁶³ Filing with the FPPC provides a permanent record of the review committee process and ensures that campuses implement the policy uniformly. Documentation of review proceedings adds credibility to the process and assures researchers that decisions are not arbitrary or capricious. Consequently, faculty are more likely to support university monitoring of research endeavors and outside relationships.

Although the University of California policy provides some protection against conflicts of interest, increasing university-industry collaboration, with the resulting increase in potential conflicts of interest, warrants more comprehensive and stringent policies. For example, the University of California policy should require disclosure of researchers' interests in companies *affected* by outcomes of research, including government-supported research.¹⁶⁴ Without more complete disclosure, many conflicts of interest will remain undiscovered and therefore, unmonitored.

Similarly, faculty members may resist implementing policies requiring divestment of private interests or severing of certain outside relationships.¹⁶⁵ Because the University of California policy is subject to review and acceptance by faculty committees, the university may be unable to implement policies that effectively minimize conflicts of interest. To achieve more objective monitoring of university-industry relationships, government funding sources, as well as universities, must develop and impose stringent guidelines.

163. *Id.*

164. *See supra* text accompanying notes 155-58.

165. *See Lescovac, supra* note 23, at 908 (stating that Berkeley Senate refused to adopt disclosure policies, finding no need to reform the university's policies regarding consulting); Anne C. Roarl, *UCLA Conflict Rules Will Be Investigated: Panel Orders Full Probe After Disclosure That Data on 23 Professors Was Withheld*, L.A. TIMES, Aug. 3, 1983, at A3 (discussing UCLA faculty's resistance to disclosure policies, on grounds that review committee deliberations would violate professors' academic freedom).

B. Federal Government Regulation

Current federal government regulation of university research in the area of conflict of interest is extremely limited.¹⁶⁶ Although the NIH¹⁶⁷ provides the majority of federal funds for university research,¹⁶⁸ it has not yet presented its views regarding conflict of interest management.

The Public Health Service (PHS),¹⁶⁹ which includes NIH and several other agencies, requires that institutions receiving PHS funds implement policies regarding conflicts of interest.¹⁷⁰ Since institutions that have no conflict of interest guidelines may lose PHS funding, the PHS

166. The Interstate Commerce Clause provides the basis for federal regulation of research. See U.S. CONST. art. I, § 8. For example, human subjects research is regulated by the federal government. Lescovac, *supra* note 23, at 916 n.94; see *infra* text accompanying notes 169-77 (discussing current federal funding sources' regulation of conflicts of interest).

167. NIH is comprised of 13 institutes involved in biomedical research investigating the cause, prevention, and cure of disease. These include the National Cancer Institute; the National Heart, Lung and Blood Institute; the National Eye Institute; the National Institute of Allergy and Infectious Diseases; the National Institute of Arthritis and Musculoskeletal and Skin Diseases; the National Institute of Child Health and Human Development; the National Institute on Aging; the National Institute of Dental Research; the National Institute of Environmental Health Sciences; the National Institute of General Medical Sciences; the National Institute of Neurological and Communicative Disorders and Stroke. In addition, NIH includes the National Center for Nursing Research, the Clinical Center, and the Fogarty International Center. COMMITTEE ON CONFLICTS OF INTEREST, *supra* note 4, at 2.

168. See *supra* note 7.

169. The Public Health Service is the principal health agency of the Federal Government and is one of five principal operating divisions of the Department of Health and Human Services. PHS, which is under the direction of the Assistant Secretary for Health, is comprised of the Office of the Assistant Secretary for Health (OASH) and eight major agencies: The Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA); the Centers for Disease Control (CDC); the Food and Drug Administration (FDA); the Health Resources and Services Administration (HRSA); the Indian Health Service (IHS); the National Institutes of Health (NIH); the Agency for Toxic Substances and Disease Registry (ATSDR); and the Agency for Health Care Policy and Research (AHCPR).

U.S. DEP'T OF HEALTH & HUMAN SERVS., PHS GRANTS POLICY STATEMENT, DHHS PUB. NO. (OASH) 90-50,000, at i (rev. 1991) [hereinafter PHS GRANTS POLICY].

170. PHS requires that

[r]ecipient organizations . . . establish safeguards to prevent employees, consultants, or members of governing bodies from using their positions for purposes that are, or give the appearance of being motivated by a desire for financial gain for themselves or others such as those with whom they have family, business, or other ties. Therefore, each institution receiving financial support must have written policy guidelines on conflict of interest and the avoidance thereof. These guidelines should reflect State and local laws and must cover financial interest, gifts, gratuities and favors, nepotism, and other areas such as political participation and bribery.

Id. at 8-17.

requirement provides a significant incentive for universities to implement some kind of policy governing conflicts of interest. PHS further requires that university guidelines provide safeguards against even the appearance of financial motivation on the part of researchers.¹⁷¹ Yet, despite their mandatory nature, the PHS requirements merely express general disapproval of activities that potentially may be financially motivated, without offering any specific standards.¹⁷² For example, current PHS requirements do not disallow any specific industry relationships nor do they place limitations on the dollar amounts researchers may receive as industry consultants.¹⁷³ Instead, PHS allows individual universities to develop guidelines, within general parameters, as they see fit.¹⁷⁴

Through the grant process, federal government funding sources have enormous power to dictate policy to which university researchers must conform.¹⁷⁵ For example, NIH could mandate that receipt of NIH funds be contingent on divestment of private financial interests related to the proposed research project. Presently, however, NIH has chosen not to use its position to mandate specific kinds of conflict of interest policies.¹⁷⁶ Although guidelines for policies on conflict of interest are being formulated,¹⁷⁷ government funding sources have yet to make their views regarding conflict of interest explicit.

In September 1989, NIH and the Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA)¹⁷⁸ released preliminary proposed research guidelines that caused such controversy that then Secretary of Health and Human Services Louis Sullivan revoked them.¹⁷⁹ The

171. *Id.*

172. *Id.*

173. *Id.*

174. *Id.*

175. *See id.*

176. *See infra* note 177.

177. COMMITTEE ON CONFLICTS OF INTEREST, *supra* note 4, at 52-53 (discussing NIH's preliminary proposed guidelines on conflict of interest). The proposed guidelines met such disapproval that Secretary Sullivan withdrew them in December 1989, announcing that NIH would establish revised guidelines. No revised guidelines have been issued to date. *See infra* notes 178-89 and accompanying text.

178. ADAMHA is the Public Health Service agency dedicated to improving mental health and addressing substance abuse problems. The ADAMHA includes the National Institute of Mental Health, the National Institute on Alcohol Abuse and Alcoholism, and the National Institute on Drug Abuse. In fiscal year 1990 ADAMHA was expected to spend \$763.7 million on scientific research. COMMITTEE ON CONFLICTS OF INTEREST, *supra* note 4, at 2.

179. Michael Unger, *Funding Rules Dropped After Scientists Protest*, NEWSDAY, Jan. 23, 1990, Business section, at 37 (stating that scientists' protests were a major factor in shelving the federal guidelines); Joyce Price, *NIH Drops Guidelines on Conflict of Interest*, WASH. TIMES, Jan. 1, 1990, at A8 (reporting that HHS will require NIH to develop new guidelines

guidelines included relatively stringent measures such as requiring that NIH participating investigators have no financial interests in organizations or entities that produce drugs, devices, or other interventions studied in a PHS-sponsored controlled clinical trial¹⁸⁰ and that "[r]esearch activities supported by NIH or ADAMHA must be conducted in an objective manner, free from any potential for undue influence arising from the private financial interests of those responsible for the conduct of the research."¹⁸¹ Moreover, among the guidelines suggested was that universities disallow investigators and their dependents from having "personal equity holdings or options in any company affected by the outcome of the research or that produces a product being evaluated in the research."¹⁸²

Because the relationships that the proposed guidelines restricted or disallowed are commonplace, NIH received many complaints.¹⁸³ University administrators complained that disclosure requirements including dependents would be too burdensome.¹⁸⁴ Likewise, venture capitalists claimed that restrictions on private source relations would restrict technology transfer.¹⁸⁵ While these complaints may have some merit, guidelines lacking some additional procedures and some restrictions on current relationships would simply ratify the status quo. Since PHS currently requires universities to file detailed descriptions of research projects and to disclose outside funding sources,¹⁸⁶ requiring

that impose fewer restrictions on the research process); Kenneth H. Bacon, *NIH Is Interrupted in its Effort to Draft Conflict of Interest Curbs for Scientists*, WALL ST. J., Jan. 2, 1990, § 2, at 2 (noting Secretary Sullivan's concern that regulation could hurt U.S. scientific innovation).

180. *NIH Proposed Guidelines*, *supra* note 16, at 4.

181. *Id.* at 2.

182. *Id.* at 4.

183. COMMITTEE ON CONFLICTS OF INTEREST, *supra* note 4, at 54.

184. *Id.*

185. *Id.*

186. PHS requires that "[t]he source and amount of costs and/or the value of third party in-kind contributions proposed by the applicant or recipient to meet a matching requirement must be identified in the application." PHS GRANTS POLICY, *supra* note 169, at 6-1. Non-federal sources include "cash or in-kind contributions contributed or donated to the project by either the grantee or by third parties." *Id.*

PHS also requires a detailed cost analysis of every grant application, which includes "the process of obtaining cost breakdowns, verifying cost data, evaluating specific elements of cost, and examining data to determine necessity, reasonableness, and allowability of the cost reflected in the grant budget." Grants Management Officers may require applicants to submit:

1. Grantee administrative directives, organization charts, manuals, etc.
2. Corporate charters and bylaws, financial statements, IRS Tax Exemption Certification, etc.

disclosure of researchers' and their dependents' financial ties would add a minimal burden. Likewise, without monitoring private source relations, PHS cannot ensure that technology development is carried out in an ethical manner.

NIH did, however, find "considerable support for *restrictions* on financial relationships with companies making products that scientists were evaluating, particularly in clinical trials."¹⁸⁷ Support for restrictions related to product evaluations suggests that the scientific community fears that scientific integrity may be placed in jeopardy by conflicts of a direct nature. By contrast, commentators opposed restrictions on financial relationships for scientists whose basic research might eventually have product applications in the future.¹⁸⁸ Such objections indicate that universities value autonomy and research freedom highly. Unless researchers' activities present a direct conflict, universities may resist government intervention. Although NIH is in the process of developing revised guidelines,¹⁸⁹ universities that have not yet implemented policies must not wait to begin formulating their own conflict of interest policies.

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3. Grantee accounting manuals, charts of accounts, procedures, etc.
 4. Grantee personnel policies and directives.
 5. Grantee travel policies.
 6. Grantee procurement procedures and property management instructions.
 7. Overall institutional audit reports affecting an individual grant or a number of grants.
 8. Information on indirect cost rates, items included in indirect cost pools, etc.
 9. Copies of, or references to, awards with special conditions (including awards from other agencies), terminations, and any other useful background information.

PHS GRANTS POLICY, *supra* note 169, at 4-14 to 4-15.

Since PHS already requires applicants to submit detailed information regarding program operation and financing, complaints that submitting information about a researcher's and dependents' ties to non-federal funding sources would add *significantly* to the already burdensome process may be overstated. See COMMITTEE ON CONFLICTS OF INTEREST, *supra* note 4, at 6 (noting that "NIH grant applications require grantees to list all sources of funding for research projects").

187. COMMITTEE ON CONFLICTS OF INTEREST, *supra* note 4, at 54.

188. *Id.*

189. See *supra* note 177 and accompanying text.

C. Legal Remedies for Patients Harmed by Conflicts of Interest—Informed Consent and Breach of Fiduciary Duty Theories

Two remedies provided under current legal doctrine, informed consent and breach of fiduciary duty, inadequately protect patients and fail to minimize physician conflict of interest. In *Moore*, the California Supreme Court concluded that the best means to protect future patients was to require researchers to obtain fully informed consent, thereby fulfilling their fiduciary obligations to patients.¹⁹⁰ In reaching its conclusion, the *Moore* Court discussed three basic principles of informed consent theory: 1) a patient's right to self-determination, 2) the requirement that consent be informed, and 3) a physician's fiduciary obligation to disclose all information material to a patient's decision when soliciting consent.¹⁹¹

The right of self-determination constitutes the basis for the informed consent requirement.¹⁹² As applied in the medical treatment context, self-determination means that "a person of adult years and in sound mind has the right, in the exercise of control over his own body, to determine whether or not to submit to lawful medical treatment."¹⁹³ Over time, courts have determined that in order to give meaning to the right of self-determination, patients' consent must be fully informed.¹⁹⁴ According to one circuit court, physicians must provide patients with information that patients would consider material in deciding whether or not to undergo medical treatment, rather than allowing the physician to determine what is material from her perspective.¹⁹⁵

190. *Moore v. Regents of the Univ. of Cal.*, 793 P.2d 479, 485-86, 496-97 (Cal. 1990); see *infra* notes 196-99 and accompanying text.

191. *Moore*, 793 P.2d at 483.

192. JAY KATZ & ALEXANDER M. CAPRON, *CATASTROPHIC DISEASES: WHO DECIDES WHAT?* 80 (1975).

193. *Cobbs v. Grant*, 502 P.2d 1, 9 (Cal. 1972); see also *Schloendorff v. Society of N.Y. Hosp.*, 105 N.E. 92, 93 (N.Y. 1914), *overruled on other grounds by Bing v. Thunig*, 143 N.E.2d 3 (N.Y. 1957).

194. *Cobbs*, 502 P.2d at 9-10; see also *infra* note 195. See generally Alan Meisel, *A "Dignitary Tort" as a Bridge Between the Idea of Informed Consent and the Law of Informed Consent*, 16 LAW MED. & HEALTH CARE 210, 214 (1988) (requiring physician to inform patient about the risks associated with treatment, the nature and purpose of treatment, potential benefits of treatment and alternative treatments, including no treatment).

195. *Canterbury v. Spence*, 464 F.2d 772 (D.C. Cir.), *cert. denied*, 409 U.S. 1064 (1972). "The scope of the physician's communications to the patient, then, must be measured by the patient's need, and that need is whatever information is material to the decision." *Cobbs*, 502 P.2d at 11.

Similarly, a physician-researcher's fiduciary duty to her patients militates that she act in the patient's best interest, not in her own.¹⁹⁶ In general, fiduciaries¹⁹⁷ possess particular skills or specialized knowledge of value to those who have placed their trust in the fiduciary.¹⁹⁸ To protect these parties against exploitation by fiduciaries, fiduciaries are held to high standards of moral behavior¹⁹⁹ which include minimizing conflicts of interest.

In addition to conflicts created by investment or other commercial interests, physician-researchers routinely face a variety of other conflicts of interest. For example, "[t]he physician's interest in pursuing a medical breakthrough and thereby enhancing both his or her own reputation and that of the department and university may lead the physician to seek less than informed consent."²⁰⁰ The scientific community tolerates some level of conflict because motivating researchers to achieve status via new scientific discoveries is also in the interest of science.²⁰¹ To balance these potentially conflicting interests, some experts have suggested that physician-researchers should be held to a "strict standard of disclosure," thereby lessening their ability to influence subjects or patients inappropriately.²⁰² As seen in *Moore*, the California Supreme Court deemed this traditional wisdom adequate to protect patients from the conflicts of interest that accompany increasingly prevalent²⁰³ and lucrative²⁰⁴ researcher collaboration with industry.²⁰⁵

The *Moore* court placed too much faith in traditional concepts of informed consent and fiduciary duty, which cannot adequately protect patients against conflicts of interest arising from university-industry collaboration.

196. See, e.g., *Canterbury*, 464 F.2d at 782-83 (informed consent is an aspect of a doctor's fiduciary duty of disclosure); *Hammonds v. Aetna Casualty & Sur. Co.*, 237 F. Supp. 96, 102 (N.D. Ohio 1965); *Cobbs*, 502 P.2d at 9-11; *Lockett v. Goodil*, 430 P.2d 589, 591 (Wash. 1962); see also *Delgado & Lescovac*, *supra* note 88, at 108.

197. See, e.g., BLACK'S LAW DICTIONARY 626 (6th ed. 1990) (describing the fiduciary relationship as "one founded on trust or confidence reposed by one person in the integrity and fidelity of another").

198. See *Delgado & Lescovac*, *supra* note 88, at 108.

199. See *id.* See generally *id.* at 107 n.173.

200. *Id.* at 91-92 (suggesting that less than informed consent may result from experimenters misrepresenting risks of an experimental treatment, misrepresenting the extent to which a new treatment has been accepted by the medical community, or withholding information about treatment alternatives).

201. AAMC GUIDELINES, *supra* note 5, at 6.

202. *Delgado & Lescovac*, *supra* note 88, at 92.

203. See *supra* notes 7-12.

204. See *supra* note 8 and accompanying text.

205. See *supra* note 190 and accompanying text.

1. THE INADEQUACY OF INFORMED CONSENT

A non-disclosure action cannot protect the interests of patient-research participants, such as Moore, because under current law, patients are unlikely to recover damages for non-disclosure. Informed consent has been termed "illusory"²⁰⁶ as a remedy, a mere "medical Miranda-warning," and has frequently been trivialized by the courts.²⁰⁷ It is no news to wronged patients that "[a] serious and fundamental failing of the law of informed consent is its continued lack of recognition that inadequate disclosure of information to patients by doctors is itself a wrong meriting legal protection."²⁰⁸ In general, courts have denied recovery for lack of proper consent if the patient suffers no resultant *physical* harm.²⁰⁹ Much to the dismay of uninformed patients, courts have yet to grant legal recompense solely for the violation of a patient's right to choose.²¹⁰

Second, because plaintiffs must prove that had they been provided all relevant information, they would have declined treatment, most plaintiffs' actions will fail.²¹¹ A desperate patient suffering from a serious illness, such as Moore, would seldom decline proper medical treatment on account of a physician-researcher's research interests. As a result, few patients can successfully bring a non-disclosure action. Moore himself never faced this dilemma since Dr. Golde did not ask him to relinquish any commercial interests in his cells until *after* Dr. Golde had removed his spleen. Moore did, however, allege that if he had known of Dr. Golde's commercial research plans, he would have declined treatment.²¹²

Not only must a plaintiff prove that he or she would have declined treatment, the plaintiff must also prove that "no reasonably prudent person would have consented to the proposed treatment if the doctor had disclosed" fully.²¹³ This requirement presented Moore with a nearly insurmountable burden, since few juries would conclude that a reasonably prudent person, dying of leukemia, would decline medically

206. *Moore v. Regents of the Univ. of Cal.*, 793 P.2d 479, 519 (Cal. 1990) (Mosk, J., dissenting).

207. Meisel, *supra* note 194, at 210.

208. *Id.* at 211.

209. "An unrevealed risk that should have been made known must materialize, for otherwise the omission, however unpardonable, is legally without consequence." *Id.* at 217 n.10 (discussing *Canterbury v. Spence*, 464 F.2d 772, 790 (D.C. Cir.), *cert. denied*, 409 U.S. 1064 (1972)).

210. *Id.* at 211.

211. *Cobbs v. Grant*, 502 P.2d 1, 11 (Cal. 1972).

212. *Moore v. Regents of the Univ. of Cal.*, 249 Cal. Rptr. 494, 500-01 (Ct. App. 1988).

213. *Moore v. Regents of the Univ. of Cal.*, 793 P.2d 479, 520 (Cal. 1990) (Mosk, J., dissenting) (discussing *Morgenroth v. Pacific Medical Ctr., Inc.*, 126 Cal. Rptr. 681, 694 (Ct. App. 1976)).

appropriate treatment because of the possibility of future research.²¹⁴ Because a plaintiff's burden is so difficult, most patients seeking relief in actions for non-disclosure will fail.

Moreover, patients greatly in need of sophisticated medical treatment may be incapable of rationally considering whether to participate in medical research.²¹⁵ Patients may sense that physician-researchers want them to consent and are most interested in treating patients who also participate in their research.²¹⁶ Patients may fear that if they do not participate, their future treatment will be jeopardized.²¹⁷ Seriously ill patients are more likely to place complete trust in their physician than those with minor ailments.²¹⁸ Due to their strong desire to be cured, very ill patients often do whatever they believe will most please their physician.²¹⁹ Although patients may give consent, their choice is hardly an objective one. It has been deeply influenced by physician expectations.²²⁰ Under these circumstances, informed consent alone cannot protect patients from physician-researcher conflicts of interest.

The *Moore* dissent stated that the majority asserted that "the threat of [an informed consent cause of] action will have a prophylactic effect: it will give physician-researchers incentive to disclose any conflicts of interest before treatment, and will thereby protect their patient's right to make an informed decision about what may be done with their body parts."²²¹ Nonetheless, even if physicians disclose all information "material" to a patient's decision, including disclosure of financial interests, numerous studies demonstrate physicians' inability to

214. *Id.*

215. See KATZ & CAPRON, *supra* note 192, at 95-99. In the context of life threatening disease treatment, the authors describe the transference phenomenon as follows:

Any illness may undermine a person's normal ego strength; a crippling disease which puts a patient in a sick-bed without prospect of recovery can call forth ultimate dependence, cooperation, and devotion to the all-powerful physician who possesses the magical means of curing him. This combination of infantile regression and projection of parental image onto the physician has often been observed in treatment and research settings, particularly when the patient has sought out the physician as a specialist, especially "the outstanding specialist" in his field.

Id. at 96. Patients under these influences may not be capable of rationally weighing alternatives and are likely to simply follow the advice of their physician-expert.

216. See *id.* at 95-99.

217. See *id.*

218. See *id.*

219. See *id.*

220. *Id.*

221. *Moore v. Regents of the Univ. of Cal.*, 793 P.2d 479, 519 (Cal. 1990) (Mosk, J., dissenting).

communicate effectively with patients.²²² Physicians often obscure issues and leave out information they believe patients will not understand.²²³ Others insist on explaining consent issues in scientific jargon unintelligible to the layperson.²²⁴ Physicians may also minimize risks or indicate that participation in research is expected while discussing consent.²²⁵ Thus, it appears most unlikely that patients will fully comprehend the implications of consent.

2. WHY FIDUCIARY DUTY CANNOT BE MAINTAINED VIA INFORMED CONSENT ALONE

Traditionally, a physician's fiduciary duty to her patient has included complying with informed consent requirements.²²⁶ With the influx of private industry funds to university research, however, conflicts of interest are much more frequent and the financial gains available to researchers are often astounding.²²⁷ Industry ties may create the temptation to pursue self-interest, which may render researchers incapable of acting in the best interest of their patients. As discussed above, when explaining treatment options to patients, researchers may unintentionally obscure or leave out information.²²⁸ In *Moore*, Dr. Golde's desires to become an "entrepreneur of the new biotechnology industry" appear to have overwhelmed his sense of obligation to Moore as a patient.²²⁹ Allegedly, Dr. Golde did not merely obscure information given to Moore; he lied outright about the very purpose of Moore's continued visits to UCLA.²³⁰

Additionally, researchers may send off subtle cues indicating that they prefer patients to choose the option which also serves their research

222. See Delgado & Lescovac, *supra* note 88, at 118. See generally *id.* at 114-22 (suggesting that in some situations, intermediaries not directly associated with the research project should obtain patients' consent); Shelley E. Taylor, *Hospital Patient Behavior: Reactance, Helplessness or Control?*, 35 J. SOC. ISSUES 156 (1979).

223. See Delgado & Lescovac, *supra* note 88, at 76-77, 115; Taylor, *supra* note 222, at 161.

224. See Taylor, *supra* note 222, at 160.

225. Delgado & Lescovac, *supra* note 88, at 76-77.

226. *Canterbury v. Spence*, 464 F.2d 772, 782 (D.C. Cir.), *cert. denied*, 409 U.S. 1064 (1972).

227. See *supra* note 63 and accompanying text.

228. See *supra* notes 222-25 and accompanying text.

229. Martin & Lagod, *supra* note 50, at 231-32 (discussing the conflict of interest present in *Moore* and noting that "[p]rofessional fame is the traditional reward of scientific research and great fortune is the new reward of biotechnology. Both are powerful attractions." (citations omitted)).

230. *Moore v. Regents of the Univ. of Cal.*, 793 P.2d 479, 485 (Cal. 1990). Moore alleged that Dr. Golde "expressly, affirmatively and impliedly represented . . . that these withdrawals of his Blood and Bodily Substances were necessary and required for his health and well-being" while denying any potential commercial or financial benefits. *Id.*

interests.²³¹ Researchers may yield to the temptation to order tests or procedures of marginal benefit to the patient to further research goals.²³² In light of these tendencies, experts have questioned whether physicians are capable of maintaining fiduciary obligations, and they suggest looking for mechanisms beyond informed consent to protect patients against conflicts of interest.²³³

Physicians have a duty to disclose conflicts of interest to their patients, but "disclosure is more helpful when . . . outside organizations assess the information disclosed and provide independent advice."²³⁴ This Comment recommends that clear statements of policy and active monitoring of research collaborations at the institutional level, including universities and government funding sources, can protect patients from physician-researcher biases. Institutions can ensure review of potential conflict situations and enforce sanctions against those who fail to comply. Moreover, institutional policies heighten awareness among researchers of situations which may pose conflicts of interest. Without oversight and enforcement mechanisms, however, disclosure to patients merely serves to allow conflicts of interest and biases to continue affecting researchers with the "consent" of patient-subjects.

IV. PROPOSED REFORM

To ensure that conflicts of interest do not undermine the integrity of university research and place unknowing subjects at risk of harm, universities and government funding sources must voice their positions regarding conflict of interest through the development of internal policy. In accordance with several prominent research organizations,²³⁵ this Comment recommends that primary responsibility for developing detailed policies to identify and manage conflicts of interest remain with individual universities.

Universities are better equipped than external regulators to evaluate university research activities.²³⁶ Universities can most easily access information about conflicts of interest by requiring faculty to document and report any industry-sponsored research activities to department heads or to university administration. On-campus faculty have the

231. Delgado & Leskovac, *supra* note 88, at 76.

232. Moore, 793 P.2d at 484.

233. See *infra* note 235. See generally Delgado & Leskovac, *supra* note 88.

234. Marc A. Rodwin, *Physicians' Conflicts of Interest: The Limitations of Disclosure*, 321 NEW ENG. J. MED. 1405, 1407 (1989).

235. See, e.g., AAMC GUIDELINES, *supra* note 5, at v; NIH Proposed Guidelines, *supra* note 16, at 1; see also Seligman, *supra* note 11, at 39 (arguing against external regulation of industry relationships at UCLA).

236. See *supra* note 235.

scientific expertise necessary to fairly evaluate research proposals on a case-by-case basis—expertise that external administrative monitors may lack.²³⁷ Moreover, universities have a direct interest in knowing about activities occurring on their campuses because universities are highly concerned with maintaining their reputations as credible research institutions. Many institutions currently collect information about university-industry collaboration, even if they have not yet developed comprehensive policies regarding potential conflicts of interest arising from industry ties.²³⁸ For these universities, developing a policy specifically addressing conflicts arising from industry ties may simply involve augmenting an existing administrative function.

Universities are also best suited to formulate policies and standards acceptable to both faculty and university administrators. Universities must consider faculty preferences and concerns when developing policies in this area in order to gain faculty respect and support for university policies.²³⁹ Otherwise, faculty may try to circumvent policies or tolerate noncompliance by others. Similarly, since each university is a unique community with distinct types of industry relationships and existing administrative structures, externally imposed policies may not address issues relevant to the particular campus or may not mesh with existing administrative systems. Thus, to operate efficiently and achieve credibility, each university must tailor policies to meet its individual needs.

Some commentators have suggested that state or federal legislation is necessary to monitor conflicts of interest effectively.²⁴⁰ Yet even if Congress or the states passed laws regulating conflicts of interest, detailed implementation guidelines would most likely be left to universities anyway.²⁴¹ The California amendments discussed above²⁴² demonstrate that despite monitoring by the Fair Political Practices

237. One concern is that external monitors would develop a rigid list of acceptable and unacceptable arrangements without fully assessing individual proposals. Telephone Interview with Richard P. Seligman, Associate Director, Office of Contract and Grant Administration, UCLA (Feb. 1992). Often conflicts of interest can be minimized or resolved by changing some aspect of the proposal. See, e.g., AAMC GUIDELINES, *supra* note 5, at 12 (discussing potential resolution mechanisms). External monitors may be less willing or able to work out problem situations so that research proposals can go forward. In that case, valuable research may be thwarted needlessly.

238. See PHS GRANTS POLICY, *supra* note 169 (requiring universities receiving PHS funds to have a conflict of interest policy in place); Burke, *supra* note 146.

239. See *supra* note 165.

240. See generally Lescovac, *supra* note 23, at 921-22 (arguing that federal regulations would protect the public interest in the use of federal funds for research and would promote uniformity in regulation of conflicts of interest among universities).

241. See *infra* notes 242-51 and accompanying text.

242. See *supra* notes 155-65 and accompanying text.

Committee (FPPC), the FPPC requires state-supported universities to develop their own individual, detailed policies in compliance with very general state mandates.²⁴³ Perhaps the State of California recognized that one law cannot adequately account for the varying types of activities occurring on every campus within its jurisdiction.²⁴⁴

Monitoring by state agencies, such as the FPPC in California, may lend some credibility to the evaluation process.²⁴⁵ But universities can achieve credibility in other ways without state or federal agency involvement. Arbitrary decisions can be prevented by requiring tiers of review,²⁴⁶ filing reports with general university administration and faculty participation in policy development,²⁴⁷ and education regarding university conflict of interest policies. In fact, university-implemented mechanisms may be more credible than state-imposed monitoring since monitors would be on campus, rather than from an external agency bureaucracy.

The federal government currently regulates some aspects of research²⁴⁸ under grants of authority to an appropriate governmental agency such as NIH, HHS, or FDA.²⁴⁹ Undoubtedly, if Congress were to pass federal legislation aimed at managing conflicts of interest, an existing agency or a new bureaucratic arm would be authorized to implement the law. Even these powerful agencies typically leave the details of implementation to the individual research center. For instance, "PHS views its relationship with [grant] recipients as a partnership, with the recipient providing the effort and expertise necessary to carry out approved activities."²⁵⁰ Likewise, in areas of great public policy concern, such as civil rights, federal laws and subsequent agency administration

243. *Id.*

244. Since legislative history of the California Administrative Code is not kept, one cannot be certain what factors influenced the passage of the FPPC amendments.

245. See *supra* notes 159-63 and accompanying text.

246. See *infra* text accompanying notes 271-81.

247. See *supra* notes 165, 237 and accompanying text.

248. See *supra* note 166. For example, experimentation with human subjects is federally regulated by HHS. 45 C.F.R. § 46.101-.122 (1991). The regulations require that the human subject be told: (1) the purpose of the research, the procedures to be used, and whether any procedures are considered experimental; (2) the risks and discomforts involved; (3) the benefits the subject or others may receive from the research; (4) alternative treatments if treatment is involved; (5) the extent of the subject's anonymity in records that are kept; (6) compensation offered or treatment available in "research involving more than minimal risk"; (7) the name of someone with whom the subject can discuss the research, and whom the subject could contact in the event of a research-related injury; and (8) the subject's right to terminate participation at any time without losing any other benefits. *Id.* § 46.116(a)(1)-(8).

249. See *supra* notes 242-45 (for examples of regulatory authority to carry out federal legislation residing in governmental agencies).

250. PHS GRANTS POLICY, *supra* note 169, at ii.

require organizations to develop internal policies and provide assurance to the federal government that they are in compliance with general federal guidelines contained in the law.²⁵¹

An efficient means of monitoring would be to require university researchers to submit reports disclosing conflicts of interest along with applications for federal funding of research projects. For administrative and accounting purposes, federal funding sources already require grant applicants to submit detailed reports.²⁵² Through the grant review process, federal funding sources can keep conflicts of interest in check without resorting to the creation of an entirely new administrative process. Virtually every university and most research projects rely on some federal funding and would therefore be affected by funding requirements.²⁵³ Thus, requiring states or the federal government to develop detailed legislation in this area would add little.

Moreover, governance of university research activities has traditionally been considered within the academic domain.²⁵⁴ Long-standing policies of academic freedom²⁵⁵ and institutional autonomy²⁵⁶ militate against the imposition of detailed government regulation. Outside regulation is generally not tolerated in matters of strictly

251. PHS provides the following explanation of how compliance with Title VI is managed for grant purposes:

Title VI of the Civil Rights Act of 1964 provides that no person in the United States shall, on the grounds of race, color, or national origin, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any program or activity receiving Federal financial assistance, whether directly or under a subgrant or contract arrangement. The HHS regulation implementing this requirement is contained in 45 CFR Part 80. Every domestic applicant organization is required to have an Assurance of Compliance (Form HHS-441) on file with the Office For Civil Rights, Office of the Secretary, HHS, before a grant may be made to the organization.

Id. at 4-2.

PHS does not attempt to impose its own detailed guidelines that every recipient organization must follow. Instead, recipient organizations develop policies internally. PHS reviews the Assurance forms to determine whether recipient policies and implementation mechanisms meet PHS requirements for compliance with Title VI.

252. *See supra* note 186.

253. In 1987, total federal funding of biotechnology research and development was approximately \$2.72 billion. Industry contributed less than two thirds that amount. INVESTMENT IN BIOTECHNOLOGY, *supra* note 1, at 37, 80; *see infra* note 277.

254. *But see supra* note 166 (discussing federal regulation of human subjects research).

255. *See generally* Lescovac, *supra* note 23, at 914-16 (discussing the historical development of and case law resulting in university privileges).

256. *Id.* at 918 (describing the scope of university autonomy and governmental authority to regulate universities).

university concern.²⁵⁷ If an important governmental interest is involved, however, the government may have the power to regulate.²⁵⁸ In the case of conflicts of interest, state and federal governments have general authority to regulate.²⁵⁹ But state and federal governments may lack to authority by dictate to a university the specific methods it should use to comply with funding requirements.²⁶⁰ Because more governmental regulation "potentially impinges on the free flow of information vital to informed decisionmaking," government should be cautious when establishing new regulations.²⁶¹

Regardless of other state and federal requirements, university policies should include procedures for disclosure of potential conflicts of interest,²⁶² review of research proposals,²⁶³ and control mechanisms designed to manage situations that present potential conflicts.²⁶⁴ As this Comment demonstrates, conflicts of interest arising from industry ties can influence physician-researcher behavior inappropriately. Currently available legal remedies and regulations, however, do not protect patients adequately against potential harms resulting from conflicts of interest. Therefore, universities should develop disclosure and review policies. Disclosure and review enables university officials to identify and evaluate potentially problematic situations involving industry ties. Further, universities must adopt control mechanisms to ensure that conflicts of interest are managed effectively. Lastly, universities and federal funding sources must discourage or prohibit direct financial ties between researchers and private industry because direct ties are most likely to affect physician-researchers' behavior.

257. For example, the University of California is considered a separate branch of government given authority to govern university affairs. CAL. CONST. art. IX, § 9. University affairs have been held to include: curricula, *e.g.*, *Hamilton v. Regents of the Univ. of Cal.*, 293 U.S. 245 (1934) (authorizing Regents to determine student course requirements); course credit, *e.g.*, *id.*; use of student fees, *e.g.*, *Erzinger v. Regents of Univ. of Cal.*, 187 Cal. Rptr. 164 (Ct. App. 1982) (Regents authorized to decide how tuition funds will be spent); employee salaries, *e.g.*, *San Francisco Labor Council v. Regents of Univ. of Cal.*, 608 P.2d 277, 280 (Cal. 1980) (authorizing university to ignore external wage rates); and faculty selection, *e.g.*, *Wall v. Board of Regents*, 102 P.2d 533, 534 (Cal. Dist. Ct. App. 1940) (authorizing university to select professors).

258. See *Lescovac*, *supra* note 23, at 917 (discussing constitutional analysis of government regulation of universities).

259. *Id.* (stating that state's interests in minimizing conflicts of interest in research may outweigh the interest in unrestricted scientific research).

260. *Id.* at 917-18.

261. *Id.* at 916-17.

262. See *infra* part IV.A.

263. See *infra* part IV.B.

264. See *infra* part IV.C.

A. Disclosure of Potential Conflicts of Interest

As a part of the approval process for research projects and contracts, universities should require faculty to disclose all relevant personal interests, as well as pertinent interests of immediate family members, to appropriate university officials.²⁶⁵ Relevant interests may include ownership interests, external professional positions, consulting agreements, gifts, honoraria, or loans involving industry. Complete disclosure is essential to the management of conflicts of interest because without full information, universities remain unaware of the types of arrangements in which faculty are involved. Since university policies must stay abreast of trends in collaborative arrangements, universities should require faculty members to disclose all relevant interests annually, regardless of whether the faculty member has submitted new grant applications, proposals, or project renewals.²⁶⁶

Although some universities have claimed that requiring disclosure of all financial interests of researchers and their immediate family members would be overly burdensome,²⁶⁷ such disclosure is essential to uncovering conflicts of interest. Even a well-intentioned researcher may be subconsciously affected by the fact that a son, daughter, or spouse stands to gain financially from positive research findings. If researchers are not required to disclose their immediate family members' financial ties, less well-intentioned researchers need merely place an investment in another family member's name to avoid scrutiny by university officials. Such circumvention of the review process defeats the purpose of disclosure and review requirements, which is to uncover conflicts of interest. Instead, universities should promote complete openness and honesty throughout the disclosure and review process.

Disclosure is important not only as a means of identifying conflicts of interest but also because it demonstrates a researcher's good faith and integrity.²⁶⁸ Revealing all potential conflicts and allowing careful review implies that one has nothing to hide and is willing to comply with an objective standard of appropriate faculty-industry collaboration. If universities reinforce norms of honesty and openness about research relationships, inappropriate behavior will more likely be discouraged.

265. See AAMC GUIDELINES, *supra* note 5, at 11; NIH Proposed Guidelines, *supra* note 16, at 4; Seligman, *supra* note 11, at 28 (advocating faculty disclosure of any financial or other personal interests in industry research sponsors held by the faculty member, his or her spouse, or dependents).

266. AAMC GUIDELINES, *supra* note 5, at 11; NIH Proposed Guidelines, *supra* note 16, at 4. *But see* UCLA Policy on Disclosure of Financial Interest in Private Sponsors of Research (Apr. 1984) (on file with author) (requiring disclosure only before final acceptance of a grant or contract, or when funding is renewed).

267. COMMITTEE ON CONFLICTS OF INTEREST, *supra* note 4, at 54.

268. AAMC GUIDELINES, *supra* note 5, at 10.

Full disclosure allows researchers to maintain their credibility as principled, unbiased scientists. Since all potential conflicts in a disclosure model are subject to university scrutiny, those evaluating a researcher's findings can be more confident that findings are objective, rather than the outgrowth of bias. Similarly, full disclosure allows others to determine for themselves whether a researcher's personal interests may have influenced his treatment decisions or research findings. Thus, journal publishers or lecture audiences should require researchers to disclose any financial ties when presenting their research findings.²⁶⁹ For example, had the *JAMA* article and editorial discussing the effectiveness of Retin-A²⁷⁰ disclosed the authors' significant financial ties to a Retin-A manufacturer, readers would have been on notice that the authors' enthusiasm may have been overzealous. As a result, physician-researchers would have been more likely to look for other more objective research findings or perform independent research in attempts to replicate the authors' findings prior to prescribing Retin-A. Further, failure to disclose conflicts may significantly impact the choices community physicians make in treating their patients. Undoubtedly, many physicians who read the Retin-A article trusted the reported results and began treating patients with Retin-A. That treatment may have been inappropriate. Ultimately, the public suffers from the failure to disclose conflicts of interest.

B. Review of Potential Conflicts of Interest

Following disclosure, designated university personnel should review all privately and federally sponsored research agreements. Each university should adopt a review process appropriate to its own administrative structure. However, proposals should be subject to several levels of review, such as given by department heads, faculty committees, and university officials.²⁷¹

1. INITIAL REVIEW

Initial review of new research proposals or contracts could be conducted by department heads.²⁷² Scientific expertise is essential to proper evaluation of research proposals. Due to their knowledge of a specific research area, department heads are better able to evaluate

269. See COMMITTEE ON CONFLICTS OF INTEREST, *supra* note 4, at 68 (advocating that scientific journals require that authors sign a sworn statement that they have no conflicts of interest, or disclose any conflicts of interest).

270. See *supra* notes 134-37 and accompanying text.

271. AAMC GUIDELINES, *supra* note 5, at 11-12.

272. *Id.*

situations that could be problematic than non-scientist administrators or scientists knowledgeable in other areas.²⁷³ As a result, department heads would serve most effectively as a first-level screen to identify proposals involving conflicts of interest that university officials should examine more closely.²⁷⁴ In addition to scientific expertise, department heads would need to become well-versed in university policy and federal, state, and local requirements regarding conflict of interest.²⁷⁵

Under pressure from the university to obtain private funds, department heads may be biased toward allowing conflicts of interest to remain. However, the desire to maintain a clean departmental record provides department heads with competing incentives to comply with university policies. In addition, university policies should be sufficiently detailed to minimize room for discretionary decisions. If department heads are given little latitude, bias is less likely to enter the decision-making process.

Universities should develop a standard roster of review questions or criteria to maintain uniformity in the evaluation.²⁷⁶ As part of the process, reviewers should ask how research proposals compare to institutionally mandated standards.²⁷⁷ Generally, reviewers should examine proposals to determine whether conflicts of interest are present. Reviewers may also need to contact university legal counsel, research administration, government relations, or other appropriate departments to obtain informed opinions on particular proposals.²⁷⁸

Under this type of system, industry involvement in the development of a cell-line, as in the *Moore* case, would have been reviewed by a departmental expert familiar with what such a project entailed.²⁷⁹ Undoubtedly, under review, Dr. Golde's conflicts of interest would have been identified and would have been subjected to further review. At a minimum, Dr. Golde would have been required to provide a thorough explanation of the research methods and to obtain proper consent, prior to continuing Moore's involvement. At that point, Moore

273. *Id.*

274. *Id.*

275. *Id.*

276. For example, the University of California campuses employ six criteria in evaluating research proposals. *See supra* note 159; *see also* AAMC GUIDELINES, *supra* note 5, at 13-15 (outlining review questions for use in evaluating research proposals).

277. For example, if the university determines that having stock options in a company sponsoring one's research is absolutely forbidden, the researcher's disclosure statement should be checked to determine whether stock options are part of the package.

278. AAMC GUIDELINES, *supra* note 5, at 11.

279. Dr. Golde's research activities involving Moore began in 1976, six years before UCLA instituted its conflict of interest policy. *Moore v. Regents of the Univ. of Cal.*, 793 P.2d 479, 481 (Cal. 1990). Consequently, UCLA did not subject Dr. Golde's research proposal or industry ties involving Moore to its current conflict of interest review.

would have been free to exercise his choice regarding whether to participate in further research at UCLA. Certainly, informed consent doctrine favors respecting a patient's freedom of choice prior to conducting any medical or research procedure over compensation after harm has occurred.²⁸⁰

2. SECONDARY REVIEW

Secondary-level review would entail scrutiny by a committee comprised of university officials, such as deans or other top administrators.²⁸¹ The committee's role would be to make a final decision about whether a significant conflict of interest exists. If a conflict is found, then the committee would determine whether the proposal is wholly unacceptable, permissible with some modification, or permissible as is. In addition, the committee could be responsible for periodic follow-up reviews in situations where proposals were approved subject to modification. For example, a review committee might approve a proposal on condition that the primary investigator divest certain personal interests related to the project or remove himself from certain aspects of the research. Continued monitoring by the review committee would ensure that these conditions were maintained throughout the course of the project.

C. Mechanisms for Management of Conflicts of Interest

A range of control mechanisms is essential to effective management of conflicts of interest.²⁸² To minimize conflicts, universities might require that contracts between the university or faculty member and a private entity be negotiated by a neutral party. Project approval could be made contingent on making research results, procedures, and samples fully available to other researchers. Similarly, policies could require methods

280. In cases where proper consent has not been sought, patients may bring a tort action for nondisclosure. See Meisel, *supra* note 194 (for a history of the nondisclosure action for failure to obtain informed consent). The function of tort law is to compensate "individuals . . . for losses which they have suffered within the scope of their legally recognized interests generally . . . where the law considers that compensation is required." W. PAGE KEETON ET AL., PROSSER AND KEETON ON THE LAW OF TORTS § 1 (5th ed. 1984). Thus, by recognizing a tort action for failure to obtain informed consent, the law has stated that lack of consent is compensable. One important role of tort law is the prophylactic role of preventing future harm. Once defendants are held liable, they and others like them have strong incentive to prevent future similar harms. In addition to compensating the victim, one reason for imposing liability is to deliberately provide incentives to avoid the particular harm. Thus, by imposing liability on those who fail to obtain informed consent, tort law has provided legal incentives for maintaining the policy of informed consent. *Id.* § 4.

281. AAMC GUIDELINES, *supra* note 5, at 11.

282. See *id.* at 15.

of eliminating researcher bias, such as peer review of research design and third party selection of research participants. Regardless of which specific control mechanisms universities utilize, they must develop mechanisms that serve to manage or monitor potential conflicts of interest.²⁸³

Likewise, prompt and effective disciplinary proceedings for those who behave inappropriately are an essential component of any university policy for managing conflict of interest.²⁸⁴ Disciplining researchers who fail to uphold university policy sends a strong message to other researchers as well as to the public that unethical or inappropriate behavior will not be tolerated. The case examples discussed above suggest that some researchers may have fallen into the trap of believing that if everyone else is doing it, it must be all right. In order to prevent the acceptance of conflicts of interest as part of the modern research environment, cases of inappropriate behavior must be exposed and researchers disciplined accordingly.

The Committee on Government Operations Report criticized several prominent research universities for failing to effectively deal with cases of physician misconduct or inappropriate behavior.²⁸⁵ Among problems identified were delayed investigation, cover-up or denial of any wrongdoing, and retaliation against whistle blowers.²⁸⁶ Because universities are at risk of losing grant funding if wrongdoing is found,²⁸⁷ there is strong incentive to employ tactics such as delay and cover-up, thereby lessening the likelihood that wrongdoing will be found. Universities often further obscure the real problem by labeling questionable faculty behavior as a mistake or a case of overly optimistic reporting of findings.²⁸⁸ However, scandals arouse suspicion within the scientific community and in the public. Failure to publicly acknowledge and confront the conflict of interest issue further erodes the public trust in

283. The AAMC suggests a number of control mechanisms to facilitate management of conflict of interest, such as negotiation of research affiliations or contracts by a neutral party, subjecting a research plan to independent peer review prior to beginning research, incorporating mechanisms designed to eliminate researcher bias within the research design, requiring that projects be supervised by someone without conflicts of interest, ensuring that means are available to verify results, sharing data and materials openly with other independent researchers, publication of findings, and acknowledgment of any outside sponsorship. *Id.*

284. *See id.* at 10; COMMITTEE ON CONFLICTS OF INTEREST, *supra* note 4, at 69 (recommending NIH impose penalties against institutions that fail to thoroughly investigate allegations of scientific misconduct).

285. *See* COMMITTEE ON CONFLICTS OF INTEREST, *supra* note 4, at 61-63.

286. *Id.* at 28-38, 47-50, 61-62. *But see id.* at 15-16 (discussing the University of California at San Diego's effective handling of an investigation).

287. *Id.* at 69.

288. *Id.* at 62.

the institution. Furthermore, if misconduct and subsequent cover-up are discovered, government funding sources may withdraw funds not only from the specific project in question, but may fail to renew funding to that department or university as a whole.²⁸⁹ Given that government funding constitutes a large portion of any institutional research budget,²⁹⁰ loss of research funding is a high price to pay for covering up a faculty member's misconduct.

Similarly, victimizing the whistle blower shifts the focus of inquiry away from potential wrongdoers and onto the loyalty of the whistle blower. Instead of penalizing those who identify inappropriate faculty behavior, individuals should be encouraged to eliminate wrongdoing by bringing it to the attention of proper university authorities. Outlining specific procedures for disciplining faculty is outside the scope of this Comment. However, with proper procedures in place, those suspicious about possible wrongdoing can be assured that their concerns will be investigated effectively without jeopardizing their own careers.

D. Per Se Prohibitions

Finally, government funding sources, as well as universities, should strongly discourage or prohibit certain kinds of affiliations between faculty and private industry.²⁹¹ Government funding sources should not provide funds for projects in which clearly inappropriate relationships exist. Universities or federal funding sources could prohibit university researchers from holding equity interests or options in companies sponsoring their research. Likewise, faculty interests in companies affected by the outcome of research should not be allowed. At a

289. If grantees fail to comply with conditions of the grant, PHS may suspend or terminate the grant or take other available legal remedies. In addition, HHS can disqualify or suspend individuals and institutions from eligibility to receive grants or other forms of financial assistance or contracts under HHS discretionary programs. Following any suspension or termination, all HHS components are informed via the HHS Alert System. Any sanctions imposed on the individual or institution are also reported to the HHS Alert System. PHS GRANTS POLICY, *supra* note 169, at 8-21.

290. In fiscal year 1989, total funding for scientific research was approximately \$21 billion; 51% of this amount was government funding. Carey, *supra* note 7, at 148. In 1987, companies contributed an estimated \$1.5 billion to \$2.0 billion in biotechnological research and development. This amount constituted approximately two thirds of the amount invested by the federal government in 1987. INVESTMENTS IN BIOTECHNOLOGY, *supra* note 1, at 80.

291. COMMITTEE ON CONFLICTS OF INTEREST, *supra* note 4, at 68 (recommending PHS restrictions on financial ties to industry where researchers are conducting evaluations of a product or treatment produced by the industry sponsor); NIH Proposed Guidelines, *supra* note 16, at 4. *But see* COMMITTEE ON CONFLICTS OF INTEREST, *supra* note 4, at 71 (noting one scholar's opinion that if funders or universities restricted financial ties, many scientists would leave academic research, and consequently the potential fruits of their efforts would be lost).

minimum, university researchers should not enter into consulting agreements or receive honoraria or other payment from private sources if their university research involves evaluating the effectiveness of a product developed by the private company.

Equity interests, fees, and gratuities enable researchers to benefit financially as a direct result of positive research findings. In many cases, researchers conducting privately sponsored research are already under tremendous pressure to report positive findings because continued research sponsorship may depend on findings beneficial to the sponsoring company. With the added factor of personal financial interests involved, researchers are likely to become quite concerned about losing the value of their investment as well as maintaining their research sponsor.²⁹² These combined pressures may result in a real inability to evaluate findings objectively or an overwhelming temptation to report findings inaccurately. Of greatest concern is the likelihood that researchers receiving payment from a private source while simultaneously evaluating a product of the source, will be unable to remain objective. Consequently, findings would tend to overstate the product's effectiveness and minimize possible negative side-effects or risks.²⁹³

As the TIMI trials illustrate,²⁹⁴ researchers could potentially manipulate the stock market to increase their own rewards through an incomplete or biased release of results. Even the best-intentioned researcher is likely to be affected by the prospect of large financial gains.²⁹⁵ "The real problem is that if you have money in it, your judgment is warped even if you're honest."²⁹⁶ More importantly, biased reporting of research results may mislead the medical community about the effectiveness of a certain drug, device, or treatment modality. Had the authors of the TIMI trial reports revealed their equity relationships with Genentech, other scientists and physicians would at least have been alerted that the results might be biased. Better yet, if the TIMI researchers had not had a financial stake in the value of Genentech stock, there would

292. See *supra* notes 59-61 and accompanying text.

293. See *supra* parts II.B.3, 5 (discussing the TIMI trials and Retina-A examples).

294. See *supra* part II.B.3.

295. Although most commentators on conflict of interest guidelines have been concerned with the impact of large financial gains on researcher objectivity, one study suggests that small gifts or honoraria, such as \$100 to take part in a symposium examining a drug's effectiveness, may actually have a greater biasing effect on researchers' attitudes. According to the study, researchers may perceive large financial gains as a bribe, and would therefore be consciously aware of the risk of selling out. Conversely, researchers may view small financial benefits as inconsequential, and therefore not guard against potentially biasing effects. COMMITTEE ON CONFLICTS OF INTEREST, *supra* note 4, at 66-67.

296. *Id.* at 56 (quoting Dr. Leon Eisenberg in *PHYSICIAN'S WEEKLY*, May 14, 1990).

have been no incentive to report incomplete and biased results, and therefore no suspicion surrounding their activities.²⁹⁷ Future patients and the public at large may suffer real harm as a result of inflated positive research findings. To prevent such harm, universities should strive to minimize situations in which flagrant conflicts are most likely to arise. Therefore, universities should seriously consider prohibiting direct equity relationships in industry sponsors.

V. CONCLUSION

Although universities are beginning to critically examine the scope and nature of university and faculty relationships with industry, they also need to clarify which types of relationships are acceptable and which are not. Allegations that universities prefer to deny or cover up suspicions of wrongdoing provide disturbing evidence that unchecked activity may be tolerated. Incidents such as *Moore* and the others described above are undoubtedly occurring in some research institutions.²⁹⁸ These examples and universities' recent focus on conflicts of interest in industry-sponsored research²⁹⁹ suggest that some researchers are being unduly influenced by ties to industry and, as a result, patients are being harmed. This Comment argues that individual universities must take responsibility for activities occurring on their own campuses by formulating and implementing comprehensive policies. University policies should include mechanisms for disclosure, review, and management of potential conflicts of interest. Further, by exercising their tremendous power of the purse,³⁰⁰ federal funding sources can command compliance with conflict of interest policies. By discouraging or prohibiting direct financial relationships between faculty members and private industry, both universities and federal funding sources can greatly reduce the prevalence of physician-researcher conflicts of interest.

[O]bjectivity and vested financial interest do not make good bedfellows. . . . [One can't] expect the average researcher to be any less immune to the siren song of making a fast fortune. . . . If you can't bring yourself to part with your stock or fat consulting fee, then you shouldn't expect anyone to trust what you have to say about the effectiveness of a drug, device, or medical product. Disclosure is not enough. Complete medical divestiture must be the moral rule governing medical testing.³⁰¹

297. See *supra* text accompanying notes 100-21.

298. See *supra* part II.B.

299. See *supra* note 19 and accompanying text.

300. See *supra* note 7.

301. COMMITTEE ON CONFLICTS OF INTEREST, *supra* note 4, at 57 (quoting Caplan, *supra* note 152).