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WHAT DOCTORS CAN LEARN FROM LAWYERS ABOUT CONFLICTS OF INTEREST

NANCY J. MOORE

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“What Doctors Can Learn From Lawyers About Conflicts of Interest,”
81 *BU Law Review* 445-456 (2001)

Nancy J. Moore

Abstract

Some physicians are receiving financial incentives for enrolling their patients in clinical studies, while others have financial interests in companies that will profit from the products under investigation. These practices are arguable permissible under both applicable law and codes of medical ethics. Further, physicians are not required even to disclose their financial conflicts when advising patients to enroll in a clinical experiment. This article explores differences between the medical and legal professions' treatments of conflicts of interest in order to explain 1) why physicians have failed to adequately address conflicts not only in clinical research, but also in other aspects of medical practice, and 2) how these conflicts should be addressed. The article concludes that physicians do not fail to recognize that there may be conflicts between their financial interests and the interests of their patients, but rather that the typical physician's response is that conflicts of interest are pervasive in medical practice and it is the ethical duty of physicians to resist temptation. Under such a broad definition of conflicts of interest, it is not surprising that physicians resist required disclosures or other precautionary measures. Lawyers, however, do not typically define "conflicts of interest" as broadly as physicians, but rather confine "conflict-of-interest doctrine" to circumstances that are unique to specific lawyers. The article further concludes that many (but not all) of the types of conflicts currently facing clinical researchers are proper subjects for regulation by conflict-of-interest doctrine. Applying this doctrine, it is clear that most cases will involve conflicts of interest that, at a minimum, must be disclosed to the patient. At least some conflicts, however, should be deemed nonconsentable, such as the receipt of financial incentives for enrolling patients in clinical studies, given the lack of benefits of permitting such payments, either to society at large or to patients themselves.

“What Doctors Can Learn From Lawyers About Conflict-of-Interest Doctrine”

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Some physicians receive financial incentives for enrolling their patients in clinical studies;¹ others have financial interests in companies that will profit from the products under investigation.² Not only are these (and other) practices² arguably permissible under both applicable law³ and codes of medical ethics,⁴ but physicians are not even required to *disclose*

¹Frances H. Miller, “Trusting Doctors: Tricky Business When It Comes to Clinical Research,” [cite, manuscript at 3, n. 12] (hereinafter “Trusting Doctors”). See also, Mark Barnes and Sara Krauss, “Conflicts of Interest in Human Research: Risks and Pitfalls of ‘Easy Money’ in Research Funding,” 9 BNA Health Law Reporter at [p. 6 of Westlaw citation 9BHLR 1378] (“Among the most criticized research compensation practices has been the payment by research sponsors of per patient “enrollment bonuses” to physicians.”).

²Miller, “Trusting Doctors,” supra note 1 at [manuscript at 16, n. 68]. See also Barnes and Krauss, supra note 1, at [p. 2 of Westlaw printout] (“Also of significant concern is that physician-researchers and/or host institutions may take ‘stakes’—such as stock options or equity ownership—in the companies whose drugs, devices, or gene therapy products are being tested by those physicians and/or those hospitals.”)

³There are no federal laws that forbid physicians from having ownership interests in products under investigation or in companies owning such products. See Barnes and Krauss, supra note 1, at [pp. 3] (stating that the most restrictive federal regulation of financial conflicts of interest merely proposes certain financial disclosure obligations on organizations and their researchers). I am unaware of any state laws to the contrary. Enrollment incentives might violate the federal Anti-Kickback Law, i.e., if they are intended to induce physicians to purchase drugs or services to be paid for by Medicaid or Medicare, but not if they “are at all related to the value of research services performed.” Id. at [p. 6]. Typically, there are actual costs associated with the research, and it may be difficult to separate actual costs from any added “incentive payment.” See, e.g., Recruiting Human Subjects: Pressures in Industry-Sponsored Clinical Research, Office of the [DHHS] Inspector General (June 2000) OEI-01-97-00195, at 17 (hereinafter “Recruiting Human Subjects”).

⁴The American Medical Association’s Principles of Medical Ethics do not address conflicts of interest, either in practice or in research. See AMA, Principles of Medical Ethics, in Rena A. Gorlin, Codes of Professional Responsibility 341 (4th ed.1999). There are two advisory opinions of the AMA Council on Ethical and Judicial Affairs that generally address a physician’s ethical responsibilities in clinical research. One opinion sets forth comprehensive guidelines for physicians engaging in clinical investigation of new drugs and procedures; it does not mention conflicts of interest, financial or otherwise. Opinion 2.07, Current Opinions of the Council on Ethical and Judicial Affairs, in Gorlin, supra, at 350. The other opinion specifically addresses conflicts of interest in biomedical research; rather than providing guidelines directly for physicians, however, it simply states that “[a]ll medical centers should develop specific guidelines for their clinical staff on conflicts of interest,” and further, that these guidelines should include a rule that “once a clinical investigator becomes involved in a research project for a company or knows that he or she might become involved, she or he, as an individual cannot ethically buy or sell the company’s stock until the involvement ends and the results of the research are published or otherwise disseminated to the

their financial conflicts when advising patients to enroll in a clinical experiment.⁵ Indeed, a recent essay discussing the basic requirements for ethical research fails to even mention the risks of harm to patients that are presented by conflicts of interest on the part of a clinical researcher.⁶

Professor Miller understandably characterizes as a “startling omission” the medical profession’s failure to address conflicts of interest between clinical researchers and their patients.⁷ As one who has previously studied the differences between the medical and legal professions’ treatments of conflicts of interest,⁸ I am not nearly as startled as Professional Miller. After all, unlike the legal profession, the medical profession lacks a strong tradition of regulating

public.” Opinion 8.031, Current Opinions of the Council on Ethical and Judicial Affairs, in Gorline, *supra*, at 389. Although the rationale for the suggested guideline is not given, I assume that the intent is to prohibit illegal insider trading. Thus, the suggested guidelines do not prohibit physicians from having financial ties to companies whose products they are investigating; rather, they merely require that such ties be disclosed to the medical center where the research is conducted. *Id.* The suggested guidelines also require that “any remuneration received by the researcher from the company whose product is being studied must be commensurate with the efforts of the researcher on behalf of the company,” *id.*; this guideline does not clearly prohibit incentive payments, as it appears to permit compensation for more than the actual costs of a physician’s participation in a clinical study.

One medical association recently adopted a flat ban on physicians from having ownership interests in companies whose products they are testing, but this position is clearly the exception and not the rule. See *infra* note [] & accompanying text.

⁵As Professor Miller notes, federal law requires only that physicians disclose financial conflicts to the institution sponsoring the study; it does not require disclosure to the subjects of the investigation. See Miller, “Trusting Doctors,” *supra* note 1 at [12/20 manuscript at 19]. See also note 4, *supra* (discussing AMA advisory opinion suggesting similar guidelines for institutions sponsoring clinical research). But see *Moore v. Regents of the University of California*, 51 Cal 3d 120, 793 P. 2d 479 (1990), a common law breach of fiduciary duty case discussed by Professor Miller. See Miller, “Tricky Business,” *supra* note 1 at [12/20 manuscript at 19]

⁶Ezekiel Emanuel, David Wendler and Christine Grady, “What Makes Clinical Research Ethical,” 283 J. Am. Med. Ass’n 2701 (2000), discussed in Miller, “Trusting Doctors,” *supra* note 1 at [12/20 manuscript at 15].

⁷Miller, “Trusting Doctors” *supra* note 1 at [12/20 manuscript at 16].

⁸See Nancy J. Moore, “Entrepreneurial Doctors and Lawyers: Regulating Business Activities in the Medical and Legal professions,” in Roy G. Spece, Jr., David S. Shimm, Allen E. Buchanan, eds., *Conflicts of Interest in Clinical Practice & Research* 171 (1996) (hereinafter “Moore, “Doctors and Lawyers”). I have also compared the medical and legal professions’ treatments of confidentiality. See Nancy J. Moore, “Limits to Attorney-Client Confidentiality: A ‘Philosophically Informed’ and Comparative Approach to Legal and Medical Ethics,” 36 Case Western Reserve Law Review 177 (1985-86) (hereinafter “Attorney-Client Confidentiality”).

conflicts of interest in medical practice generally.⁹ Indeed, the AMA Principles of Medical Ethics make no mention of the subject;¹⁰ nor is it typically addressed in standard treatises and casebooks on medical ethics.¹¹

Both doctors and lawyers believe that trust is essential to the success of the professional relationship.¹² Why then have physicians failed to adequately address conflicts not only in clinical research, but also in other aspects of medical practice? And if physicians (or others)¹³ were to address these conflicts, would the practices in question be prohibited altogether or would it be sufficient for physicians to proceed with the informed consent of their patients? The purpose of my brief response to Professor Miller's provocative article is to suggest possible answers to these questions, based on a comparison between the medical and legal professions'

⁹Moore, "Doctors and Lawyers," supra note 8 at 179.

¹⁰Id. As note earlier, there are several advisory opinions of the AMA Council on Ethical and Judicial Affairs that address conflicts of interest in clinical research. See supra note [4]. See also infra notes [] & accompanying text. In addition, a section of the AMA Code of Medical Ethics entitled "Fundamental Elements of Patient-Physician Relationship," that contains a statement that patients are entitled "to be advised of potential conflicts of interest that their physicians might have." Gorlin, supra note [], at 341-342. This section was adopted by the AMA in 1990. I have been unable to locate any opinions of the Council on Ethical and Judicial Affairs addressing this proposition.

¹¹See, e.g., Barry Furrow, et al. *Health Law* (2d ed. 2000) (containing no entry for conflicts of interest in index nor any discussion of physician conflicts in the chapter on research); Robert M. Veatch, *A Theory of Medical Ethics* (1981) (containing no entry for conflicts of interest in index). But see Arthur L. France, *Bioethics: Health Care, Human Rights, and the Law* (1999) (containing brief section on conflicts of interest in medical research, limited to discussion of common law breach of fiduciary duty set forth in *Moore*; additional reference in index to conflicts of interest refers generally to disclosure obligations of physicians); Terrance C. McConnell, *Moral Issues in Health Care: An Introduction to Medical Ethics* 4-44 (1982) (containing no entry for conflicts of interest in index, but does have a section entitled "Confidentiality and Conflicting Loyalties," including a case study raising what lawyers would view as a classic conflict of interests between two patients).

¹²See, e.g., Miller, "Trusting Doctors," supra note 1, at [12/20 manuscript at 5-7 (discussing role of "trusting" in physician-patient relationship); Charles W. Wolfram, *Modern Legal Ethics* 146 (1986) (discussing role of trust in attorney-client relationship).

¹³For a discussion of the extent to which the medical profession is regulated by legislative and administrative bodies, in addition to self-regulation through medical codes, see Moore, "Doctors and Lawyers," supra note [] at 181-184. The legal profession has been granted far more ability to regulate itself than has the medical profession. Id.

historical responses to conflicts of interest in professional practice.

Physician Failure to Address These Conflicts

According to Professor Miller, “[m]any clinicians bridle at the notion that doctors are easily tempted to be ‘unethical’ when their self-interest is directly involved.”¹⁴ Additionally, they “resist precautionary measures that they believe unfairly taint the whole profession for the misdeeds of a few.”¹⁵ To lawyers like Professor Miller and me, such thinking on the part of physicians reflects a fundamental misunderstanding of the underlying purpose of both fiduciary law¹⁶ and conflict of interest rules, such as those adopted by courts for the legal profession.¹⁷ These legal regulations are designed to hold fiduciaries to a higher standard of conduct than non-

¹⁴Miller, “Trusting Doctors,” supra note 1, at [12/20 manuscript at 10] (citing “Conflict of interest: the new McCarthyism in Science,” 269 J. Am. Med. Ass’n 2782)(1993).

¹⁵Id. Physicians responded similarly to a proposal to ban referrals of patients to health care facilities in which the physicians have an economic interest. See Moore, “Doctors and Lawyers”, supra note [] at 178-179: “Thus, physicians who voted to reverse their original vote banning self-referrals apparently did so because they were angered by the implication that they could not be trusted to act professionally in caring for their patients. These physicians understand that it is unethical to recommend unnecessary procedures or to refer patients to inappropriate facilities; however, they ‘object to the implication that every physician that [sic] is involved in some kind of facilities is guilty of a violation of ethics.’” (Footnotes omitted.)

¹⁶As Professor Miller notes, although it is generally believed that physicians owe fiduciary duties to their patients, there is some question whether fiduciary law applies to the same extent to physicians as it does to other fiduciaries. Miller, “Trusting Doctors,” supra note 1, at [12/20 manuscript at note 24 & accompanying text. Professor Miller has been a strong proponent of applying a stricter application of fiduciary principles to physician behavior. See, e.g., Frances H. Miller, “Secondary Income From Recommended Treatment: Should Fiduciary Principles Constrain Physician Behavior?”, in Bradford H. Gray, ed., *The New Health Care for Profit* 153 (1983).

¹⁷See, e.g., American Bar Association, Model Rules of Professional Conduct, Rules 1.7-1.12 (2000). See generally, Wolfram, supra note [], at 312-494.

fiduciaries in order to preserve the trust that is the hallmark of the fiduciary relationship.¹⁸

Nevertheless, given physicians' historical attitudes toward both ethics in general and conflict of interest problems in particular, such thinking is not at all surprising.

Unlike rule-oriented lawyers, physicians traditionally have viewed the subject of professional ethics as a matter of "individual conscience,"¹⁹ that is, a "subject over which well intentioned individuals can, and often do, disagree."²⁰ Beginning with the Hippocratic oath, medical codes have emphasized the "discretion" of the individual physician to decide what conduct is ethically required in particular cases,²¹ as well as the status of codes as providing not rules, but rather standards of conduct,²² or perhaps merely guidance²³ or a basis for moral reasoning.²⁴ As a result, even with respect to confidentiality---a subject directly addressed by the

¹⁸See generally Tamar Frankel, "Fiduciary Law," 71 Calif. L. Rev. 795 (1983) (providing a comprehensive discussion of the underlying justifications of fiduciary law); Wolfram, *supra* note [], at 313-314 (discussing the underlying justifications of lawyer conflict of interest rules).

Other papers in this conference have questioned both the necessity and the desirability of using fiduciary law for these purposes. I take no position here on that extraordinarily interesting issue. For purposes of this paper, I take as a given the application of the traditional fiduciary model to physician-patient and attorney-client relationships.

¹⁹Moore, "Attorney-Client Confidentiality," *supra* note [8], at 183.

²⁰Marc A. Rodwin, "The Organized American Medical Profession's Response to Financial Conflicts of Interest: 1890-1992," 70 *Milbank Quarterly* 703,705 (1992)(discussing physician view of conflicts of interest "as matters of *personal* ethics").

²¹Moore, "Attorney-Client Confidentiality," *supra* note [8], at 183.

²²*Id.* (citing AMA reaffirmance of status of Principles of Medical Ethics"not as 'laws, but standards of conduct which define the essentials of honorable behavior for the physician").

²³*Id.* (citing "the rider habitually attached by the British Medical Association when giving 'advice' to its members [that] explicitly states that it is open to the doctor to act in accordance with the dictates of his conscience").

²⁴*Cf.* Nancy J. Moore, "The Usefulness of Ethical Codes," 1989 *Annual Survey of American Law* 7, 12 (discussing the views of philosopher John Ladd, who views ethics as "an open-ended, reflective and critical intellectual activity,' one which cannot be captured in the promulgation of even voluntary rules, guidelines or standards").

AMA Principles²⁵--- physicians have failed to formulate relatively specific standards, for example, to determine when it is permissible to disclose information to protect the welfare of others.²⁶

Although conflicts of interest are not addressed in the AMA Principles, a current opinion of the AMA Council on Ethical and Judicial Affairs provides as follows:

Under no circumstances may physicians place their own financial interests above the welfare of their patients. The primary objective of the medical profession is to render service to humanity; reward or financial gain is a subordinate consideration. For a physician unnecessarily to hospitalize a patient, prescribe a drug, or conduct diagnostic tests for the physician's financial benefit is unethical.²⁷

It is not the case then that physicians simply fail to recognize that there may be conflicts of interest between their financial interests and the interests of their patients. Rather, the typical physician's response is that conflicts of interest are pervasive in medical practice and that it is the ethical duty of physicians (and other professionals) to resist temptation.²⁸ Thus, in an article cited by Professor Miller, a physician objects to medical journals requiring disclosure of conflicts of medical researchers because conflict of interest is "a nearly universal circumstance."²⁹ Indeed, it includes the interest of both government and academic scientists "in obtaining provocative results, since publicity and prominent publication may bring the rewards

²⁵AMA Principles of Medical Ethics, Principle IV, in Gorlin, supra note [], at 341.

²⁶Moore, "Attorney-Client Confidentiality," supra note [], at 186.

²⁷AMA Council on Ethical and Judicial Affairs," Opinion 8.03, in Gorlin, supra note [], at 388.

²⁸This is also the view of at least one philosopher of medical ethics, who believes that one solution to conflict of interest problems is to better reduce physicians' inclinations to give in to temptation. See Edmund L. Erde, "Conflicts of Interests in Medicine: A Philosophical and Ethical Morphology," in Spece et al., supra note [8], at 12, 29.

²⁹"Conflict of Interest: The New McCarthyism in Science," 269 J.A.M.A. 2782 (1993), in Miller, "Trusting Doctors," supra note 1 at [12/20 manuscript at n. 48].

of promotion and further research funding.”³⁰

Given such a broad definition of “conflict of interest”,³¹ it is not surprising that physicians resist either required disclosures or other “precautionary measures.” After all, conflicts of interest in this broad sense may be the “central problem” of professions, perhaps even their “defining characteristic.”³² And if, “[b]y definition, the function of a professional is to serve interests beyond the professional’s own self-interest,”³³ then any attempt to regulate *all* such conflicts does indeed appear to be a daunting, nigh impossible task.

But lawyers do not typically define “conflicts of interest” so broadly. Of course, lawyers understand that there is pervasive conflict between the interest of lawyers and their clients and that with respect to most of these conflicts, there is little to be done other than to rely on lawyers’ professionalism, that is, their willingness to exercise self-restraint.³⁴ But for lawyers, there is a difference between conflicts of interest in this broad sense and conflicts of interest in the narrower sense reflected in both fiduciary law and ethics codes. What I will call “conflict-of-interest doctrine” does not purport to regulate circumstances that are common to all lawyers, but only those circumstances that may be unique to specific lawyers. In other words, conflict-of-interest doctrine in law does not address the largely unavoidable conflicts, but only those that

³⁰Id. at 2783.

³¹See also Erde, *supra* note [28] at 30 (“to have a conflict of interest is to be in a situation in which one might plausibly be thought to do something immoral due to a motivation that might tempt most role holders or this individual”).

³²Geoffrey C. Hazard, Jr., “Conflicts of Interest in the Classic Professions,” in Schimm et al., *supra* note [8], at 85.

³³Id.

³⁴Cf. *id.*

can be avoided or removed, by permitting (or requiring) clients to seek other lawyers---that is, lawyers who are not burdened with a particular conflict of interest.³⁵

Why lawyers, and not physicians, have developed this narrower conflict-of-interest doctrine is at least partly a function of the frequency with which these types of conflicts arise in legal, but not medical practice.³⁶ Certainly lawyers confront far more conflicts between multiple clients, including not only current, but also successive clients.³⁷ Moreover, it has not been until fairly recently that physicians have acquired a wide variety of particular financial interests that conflict with the health of their patients.³⁸ Lacking a strong historical experience of such conflicts, physicians have been ill-equipped to distinguish between those conflicts that are pervasive in medical practice and those that are not.

Regulation of Conflicts in Clinical Research

As noted above, some types of conflicts are largely unavoidable for medical researchers; for example, conflicts that arise from the researcher's interest in career advancement through

³⁵Cf. Michael D. Bayles, Professional Ethics 78-79 (1983) (distinguishing between "largely unavoidable conflict[s]", such as those between a professional's interest in income and leisure and a client's interest in services, and conflicts of interest "with respect to specific professionals, clients and problems," which "can usually be avoided or removed").

³⁶In addition, lawyers are understandably more aware of the lawyer's role as fiduciary and the significance of conflict-of-interest doctrine in fiduciary law.

³⁷See, e.g., Bayles, *supra* note [] at 81 ("Physicians do not have as many conflicts of interest between clients as lawyers, because the health of one does not ordinarily adversely affect the health of others.")

³⁸See, e.g., Arnold Relman, "The New Medical-Industrial Complex, 303 N.Eng. J. Med. 963 (1980). But see Rodwin, *supra* note [20] at 704 (noting medical profession's long history of conflicts of interest involving "fee-splitting, physician's dispensing of drugs they prescribe, and other self-referral practices").

provocative results.³⁹ For these conflicts, we must indeed rely on the professionalism (i.e., self-restraint) of physicians to put the interests of their patients ahead of their own financial (or other) interests.⁴⁰ But the types of conflicts Professor Miller addresses—financial incentives for enrolling patients in clinical studies and ownership interests in a product under investigation—are neither unavoidable nor common to all physicians. Therefore, they are proper subjects for regulation by conflict-of-interest doctrine. So, what would such doctrine provide?

Under conflict-of-interest doctrine in legal ethics, a conflict exists if there is substantial risk that the representation of a client will be materially and adversely affected by the lawyer's own interests or by the lawyer's responsibilities to another client, a former client or a third person.⁴¹ Interests include not only financial interests, but also personal interests, such as personal relationships (e.g., the opposing party is the lawyer's spouse) or deeply held religious or political beliefs.⁴² The mere presence of some conflicting interest is not sufficient to trigger conflict-of-interest analysis; rather, an analysis is triggered only when the interest is of such a

³⁹See supra note [] & accompanying text. See also Arnold S. Relman, "Economic Incentives in Clinical Investigation," 320 N.Eng. J. Med. 933 (1989) (conceding that professional ambition in medical scientists creates risk of bias, but arguing that it also has "a redeeming social value absent from the pursuit of economic self-interest" and, in any event, "interest in professional advancement, unlike the pursuit of private gain, cannot be prevented by legislation or any social action").

⁴⁰See, e.g., Hazard, supra note [] ("self-control" as one of several techniques used to address conflicts of interest facing professionals.)

⁴¹American Law Institute, Restatement (Third) of the Law Governing Lawyers § 121 (1998). Conflict-of-interest doctrine, including not only disciplinary rules, but also the law of disqualification and civil liability based on breach of fiduciary duty, is restated in Chapter 8 of the new Restatement of the Law Governing Lawyers. See generally Nancy J. Moore, Restating the Law of Lawyer Conflicts," 10 Geo. J. Legal Ethics 541 (1997) (hereinafter "Lawyer Conflicts") (reviewing the proposed final draft of entire chapter). For purposes of this article, the most relevant provision of lawyer disciplinary codes is the rule generally addressed to concurrent conflicts of interest. See ABA Model Rules of Professional Conduct, Rule 1.7(b) ("A lawyer shall not represent a client if the representation of that client may be materially limited by the lawyer's responsibilities to another client or to a third person, or by the lawyer's own interests....").

⁴²See Restatement (Third) of the Law Governing Lawyers, supra note [41], § 125, cmt. c.

magnitude that it might materially impair the lawyer's ability to consider alternative courses of action, discuss all relevant aspects of the representation with the client, or otherwise represent the client competently and diligently.⁴³

Having identified a potentially disqualifying conflict, the lawyer must then determine whether the representation may proceed with the adequately informed consent of the client or whether the conflict is nonconsentable.⁴⁴ Some conflicts are specifically prohibited, such as preparing instruments giving the lawyer a substantial gift from an unrelated client⁴⁵ or making an agreement giving the lawyer media rights to information relating to an ongoing representation.⁴⁶ More typically, however, particular conflicts are found to be nonconsentable when the lawyer cannot reasonably conclude that the lawyer will be able to provide effective representation.⁴⁷ Underlying any conclusion that a conflict is nonconsentable is the belief that a client who would give consent in such a case is unlikely to have fully understood or appreciated the risks or has not felt free to reject the representation.⁴⁸

Applying this doctrine to the circumstances addressed by Professor Miller, I think it clear

⁴³Id.

⁴⁴See Moore, "Lawyer Conflicts," supra note [] at 548-49 (describing the important steps an individual lawyer should take in analyzing a potentially impermissible conflict of interest).

⁴⁵See ABA Model Rules, Rule 1.8(c).

⁴⁶See ABA Model Rules, Rule 1.8(d).

⁴⁷Under the disciplinary code, a conflict is nonconsentable unless "the lawyer reasonably believes the representation will not be adversely affected." ABA Model Rules, Rule 1.7(b)(1). See also Restatement (Third) of the Law Governing Lawyers, § 122(2)(c) (notwithstanding informed consent of client, lawyer may not represent a client if "in the circumstances, it is not reasonably likely that the lawyer will be able to provide adequate representation to one or more of the clients).

⁴⁸See Moore, "Lawyer Conflicts," supra note [] at 557. For a defense of the paternalism underlying these rules, see generally Nancy J. Moore, "Conflicts of Interest in the Simultaneous Representation of Multiple Clients: A Proposed Solution to the Current Confusion and Controversy," 61 Tex. L. Rev. 211 (1982) (hereinafter "Conflicts of Interest").

that most cases will involve conflicts of interest that, *at a minimum*, must be disclosed to the patient. For example, unless the financial incentive is de minimus (and thus not much of an “incentive”), surely there is substantial risk that physicians who receive payments for enrolling their patients in clinical studies will be biased, either consciously or unconsciously, in favor of recommending a patient’s participation. Such risk is also present when physicians have a significant financial interest in the product under investigation. At the very least, patients of these physicians are entitled to the information indicating possible bias; information that might lead them to seek either a new physician or a second opinion before deciding to participate in a clinical study.⁴⁹

The more difficult question will be whether disclosure is sufficient or whether the conflict should be deemed nonconsentable. At least one medical association has come out in favor of an outright ban on physicians having ownership interests in companies whose products they are testing.⁵⁰ Nevertheless, it is anticipated that other physician and hospital associations will oppose such a ban, on the ground that the risk of bias is “greatly outweighed by the advantages to medical science and patients’ interests in allowing these physicians to continue to have incentives to develop and test new devices.”⁵¹ This argument may be especially strong in

⁴⁹One philosopher suggests that disclosing conflicts of interest to patients is not an adequate remedy because it does not resolve the conflict or solve the problem. See Erde, *supra* note [] at 28. He further believes that the primary effect of disclosing conflicts would be “to be very distrustful and very assertive in largely implausible ways.” *Id.* But his definition of conflicts is so broad as to include virtually every motivation that might tempt a physician to put the physician’s own interests above the patient’s interests. See *supra* note []. Given such a broad definition of conflicts of interest, disclosure is clearly not a workable solution, as it would serve merely to undermine the patient’s trust in the professionalism of the physician.

⁵⁰See Barnes and Krauss at p. 2 (noting that the American Society of Gene Therapy “adopted a policy that its members engaged in gene therapy research should have no equity, stock options or other ownership interests in the companies whose products they are testing in clinical trials”).

⁵¹*Id.*

the case of medical devices, given the difficulty of finding someone other than the physician-inventor who is willing to conduct the tests.⁵² But the potential benefit to society at large is not necessarily a sufficient reason to permit such practices. After all, the *risk* is not to society at large, but rather to individual patients. Using legal ethics as a guide, the more important questions may be whether there are any potential benefits to the patients themselves and whether their consent is likely to have been sufficiently informed and voluntary.⁵³

Professor Miller strongly suggests that there are no benefits to the patient-subjects, because clinical trials are experiments, not therapy.⁵⁴ But patient-subjects may have a different view. First, there is at least *some* possibility that *some* of them will be benefitted by the trial itself.⁵⁵ Second, even if it is unlikely that any individual trial will benefit a particular subject, participation in these trials helps bring to market new drugs or devices, some of which may provide a future benefit to these patients. Finally, the possibility of providing a future benefit to other persons suffering from similar ailments may itself be a benefit to those asked to participate in a clinical trial. Of course, the limited nature of these potential benefits must be understood, or the consent will not have been sufficiently informed and voluntary. The concepts are not complex, but there is some concern that aside from what is written in “informed consent

⁵²Cf. id. (“physician-researchers are often the primary inventors of new devices, co-own intellectual property rights to those devices with their institutions, and are the primary clinical researches in regard to their own devices”).

⁵³See Moore, Conflicts of Interest, *supra* note [] at 226 (waiver of some conflicts recognized because of potential benefits of representation to client), 236-240 (justification for making some conflicts nonconsentable is concern that consent is not truly informed and voluntary).

⁵⁴See Miller, “Trusting Doctors,” *supra* note 1, at [11-13]

⁵⁵See id. at [13] (“With hindsight a research subject’s health may indeed turn out to be improved by participating in an experimental study, but the chances are statistically slim in most experimental protocols.”).

documents,” financially-conflicted investigators may, consciously or unconsciously, distort the information when talking to patients.⁵⁶

Aside from the adequacy of the disclosure, there is concern that the dual role of physician-investigators adversely impacts the voluntariness of patient consent.⁵⁷ As the Office of the Inspector General has noted, “[p]atients may be reluctant to contradict their doctor’s wishes by refusing participation in a trial, or may agree to participate because they trust and respect their physician, who they believe is looking out for their best interests.”⁵⁸ But as Professor Miller astutely observes, patients are not nearly as “trusting” as they once were.⁵⁹ Moreover, once they know that their physician has a financial interest in the product under investigation, they are unlikely to have the same blind trust that they might have had in the absence of such information.

Disclosure might be sufficient in the case of physicians with ownership interests in the products under investigation. The argument is much stronger, however, for banning the payment (or receipt) of financial incentives for enrolling patients in clinical studies. It is hard to even imagine what the benefits might be of permitting such payments, either to society at large or to patients themselves.⁶⁰ Of course, physicians are entitled to be reimbursed for the actual costs of

⁵⁶See “Recruiting Human Subjects,” supra note [3] at 22. Cf. Fred C. Zacharias, “Waiving Conflicts of Interest,” 108 Yale L. J. 407, 422 (1998) (speculating that code provisions providing for certain nonconsentable conflicts might be explained by a distrust of the information and explanation given by lawyers with “a vested economic interest in retaining their clients”).

⁵⁷See “Recruiting Human Subjects,” supra note [3] at 22.

⁵⁸Id. at 23.

⁵⁹See Miller, “Trusting Doctors,” supra note 1, at [8-10].

⁶⁰This lack of a benefit is most striking when an additional payment per subject enrolled is offered as the enrollment deadline nears and additional subjects are still needed, in which case it seems obvious that the payments are made solely to encourage speedy enrollments. See “Recruiting Human Subjects,” supra note [3] at 17.

participating or conducting a clinical trial, and it may well be difficult to separate such costs from “incentive” payments.⁶¹ On the other hand, if cost reimbursement payments are difficult to distinguish from “incentive” payments, then it is unrealistic to expect patients to assess the significance of the information disclosed, particularly if the information consists of either a general statement that the physician is receiving an unspecified payment for each patient enrolled or even a specification of the total per-patient dollar amount. This particular conflict is no doubt best managed by simply preventing it altogether.⁶²

Conclusion

I do not suggest how or even by whom⁶³ these conflicts will be resolved. I do suggest, however, that physicians are woefully ignorant of the importance of developing a workable conflict-of-interest doctrine for medical practice. Such a doctrine would apply not only to the clinical research issues addressed by Professor Miller, but also to conflicts issues that arise in everyday clinical practice.⁶⁴ These conflicts may not occur with the same frequency that they do

⁶¹See *id.*

⁶²Cf. *id.* at 2 (discussing how various conflicting financial interests “must be managed, declined, disclosed or altogether prevented”).

⁶³See Moore, “Doctors and Lawyers,” *supra* note ___ at 182-184 (discussing the greater role played by legislative and administrative bodies in regulating physicians than in regulating lawyers).

⁶⁴For example, one medical ethicist discusses a case in which a physician learns that his patient, David, is a homosexual. Five years later, he learns that his long-time patient Joan is engaged to marry David. The case is treated as one involving “conflicting loyalties, a case where the physician must divulge confidential information about one patient in order to benefit another patient.” McConnell, *supra* note [11] at 42-43. The author dismisses his own analogy to lawyers’ conflict-of-interest doctrine by noting that “this sort of conflict cannot be anticipated by the medical worker,” and then proceeds to resolve the conflict in favor of disclosure. *Id.* at 42-43. Of course, unanticipated conflicts arise quite frequently in legal practice, and conflict-of-interest doctrine addresses this problem, by requiring that the lawyer withdraw from representing both clients when informed consent is impossible,

in legal practice; nevertheless, physicians must be prepared to deal with them in a manner calculated to preserve the trust placed in them by their patients. Trusting physicians (and lawyers, too) may be a tricky business, but it is the business of professionals to encourage and nurture that trust or they may well find themselves bereft of their “professional” status.

as it would be in this case. See ABA Model Rules, Rule 1.7, Comment [2] (stating that when a conflict arises after representation has been undertaken, the lawyer should withdraw from the representation) & Comment [5] (stating that if one client refuses to consent to disclosure necessary to permit the other client to give an informed consent, the lawyer may not request consent to the conflict).