SOUNDING BOARD

UNDERSTANDING FINANCIAL CONFLICTS OF INTEREST

THE problem of conflicts of interest began to receive serious attention in the medical literature in the 1980s.[1,2] Studies have described a wide range of conflicts involving physicians, medical researchers, and medical institutions (the most comprehensive is by Rodwin[3]). Among the areas of concern are self-referral by physicians,[4-6] physicians' risk sharing in health maintenance organizations (HMOs) and hospitals,[7] gifts from drug companies to physicians,[8,9] hospital purchasing and bonding practices,[3] industry-sponsored research,[10,11] and research on patients.[12] Yet the concept of conflict of interest itself has been inadequately analyzed, and consequently its elements, the purposes of regulation, and standards for assessment are still often misunderstood.

ELEMENTS OF CONFLICTS OF INTEREST

A conflict of interest is a set of conditions in which professional judgment concerning a primary interest (such as a patient's welfare or the validity of research) tends to be unduly influenced by a secondary interest (such as financial gain). Conflict-of-interest rules, informal and formal, regulate the disclosure and avoidance of these conditions.

The primary interest is determined by the professional duties of a physician, scholar, or teacher. Although what these duties are may sometimes be controversial (and the duties themselves may conflict), there is normally agreement that whatever they are, they should be the primary consideration in any professional decision that a physician, scholar, or teacher makes. In their most general form, the primary interests are the health of patients, the integrity of research, and the education of students.

The secondary interest is usually not illegitimate in itself, and indeed it may even be a necessary and desirable part of professional practice. Only its relative weight in professional decisions is problematic. The aim is not to eliminate or necessarily to reduce financial gain or other secondary interests (such as preference for family and friends or the desire for prestige and power). It is rather to prevent these secondary factors from dominating or appearing to dominate the relevant primary interest in the making of professional decisions.

Conflict-of-interest rules usually focus on financial gain, not because it is more pernicious than other secondary interests but because it is more objective and more fungible. Money is easier to regulate by impartial rules, and it is also generally useful for more purposes. It is therefore a mistake to object to the constraints on financial gain by complaining that there are other kinds of influence (e.g., "an interest in obtaining provocative results" or pressure to favor "previously published findings of colleagues, friends, or researchers in collaborating groups"[13,14]) that can have equally bad or worse effects on professional judgment. Just because we cannot do much about the other secondary interests, it does not follow that we should do little about financial gain. (This point also applies to types of financial interests; we might choose to proscribe one type, but not another.[15])

It is also a mistake to treat conflicts of interest as just another kind of choice between competing values, as occurs with ethical dilemmas involving termination of care, confidentiality, or the use of human subjects in research. To do so dilutes the concept of a conflict of interest and encourages the attitude that conflicts are so pervasive that they cannot be avoided. In ethical dilemmas, both of the competing interests have a presumptive claim to priority, and the problem is in deciding which to choose. In the case of financial conflicts of interest, only one of the interests has a claim to priority, and the problem is to ensure that the other interest does not dominate. This asymmetry between interests is a distinctive characteristic of conflicts of interest.

REASONS FOR REGULATING CONFLICTS OF INTEREST

A common criticism of rules governing conflicts of interest is that they unfairly punish ethical physicians and researchers for the misdeeds of the few unethical ones. Rules regulating conflicts in research are said to be a "serious insult to the integrity of scientists" who have any financial connection with industry.[13] "To ascribe a conflict of interest automatically in such situations amounts to an assumption that the sponsor's interests have influenced the investigator . . . and that the research findings are different from what they would otherwise have been."[13]

Similarly, rules regulating self-referral are said to assume falsely that physicians prescribe drugs or order diagnostic tests in which they have a financial interest without regard to whether the drugs or tests are in the patient's interest.[16] Critics argue that, on the contrary, patients benefit in the long run because a physician's financial interest in the facility to which he or she refers patients creates a strong incentive to ensure that it provides high-quality care.[15,17]

Criticisms of this kind rest on a mistaken view of the basic purposes of conflict-of-interest rules. The first purpose is to maintain the integrity of professional judgment. The rules seek to minimize the influence of secondary interests (such as personal financial gain) that should be irrelevant to the merits of decisions about primary interests (such as the care of a patient or the conduct of research). The rules do not assume that most physicians or researchers let financial gain influence their judgment. They assume only that it is often difficult if not impossible to distinguish cases in which financial gain does have improper influence from those in which it does not. It is difficult even in

one's own case, and all the more so in the case of people one does not know personally, to determine what motives have influenced a professional decision. Given this general difficulty of discovering real motives, it is safer and therefore ethically more responsible to decide in advance to remove insofar as possible factors that tend to distract us from concentrating on medical and scholarly goals.

Why not simply judge professional decisions by their results? One reason is that many treatment or referral decisions are never reviewed by anyone other than the physicians directly involved. Neither is the market an adequate test of results; it provides only limited protection against the harmful effects of conflicts of interest.[15] In the conduct of research, peer review of results offers greater protection. But the objectivity of a particular piece of research is not the only concern, as many commentators suppose it is.[13] The more far-reaching issue, which peer review does not normally address, is the choice of topics and the direction of research — for example, the tendency of industry-sponsored researchers to put more emphasis on commercially useful research than basic research.[18] Nor do conflict-of-interest rules encourage one to "focus attention on the circumstances of the writer rather than on the substance of the writing and thereby stifle objectivity."[14] There is no reason that one cannot consider both the circumstances and the substance. Furthermore, the point of the rules is to eliminate or reduce certain kinds of circumstances so that the scholar can concentrate on substance.

The second purpose of conflict-of-interest rules depends even less on the assumption that physicians neglect patients or researchers produce biased results because of the influence of financial gain. That purpose is to maintain confidence in professional judgment. The aim is to minimize conditions that would cause reasonable persons (patients, colleagues, and citizens) to believe that professional judgment has been improperly influenced, whether or not it has.

Maintaining confidence in professional judgment is partly a matter of prudence. To the extent that the public and their representatives distrust the profession, they are likely to demand greater regulation of practice and research and are likely to supply fewer resources for both. Patients may be less likely to trust physicians generally. Since the actions of individual physicians and researchers can affect public confidence in the whole profession,[19] individual professionals have an obligation, both to the public and to the profession, to make sure that their own conduct does not impair their colleagues' capacity to practice medicine or conduct research.

A failure to avoid a conflict of interest may therefore be wrong even when one is not influenced by secondary interests at all. When professionals do not take reasonable precautions to avoid situations of conflict or do not observe rules regulating such conflicts, they have acted unethically. Contrary to the view of some commentators,[14] a charge of a conflict of interest may indeed constitute an accusation, even in the absence of an otherwise improper motivation.

Standards for Assessing Conflicts of Interest

Standards for assessing conflicts of interest identify factors that make conflicts more or less problematic. The severity of a conflict depends on (1) the likelihood that professional judgment will be influenced, or appear to be influenced, by the secondary interest, and (2) the seriousness of the harm or wrong that is likely to result from such influence or its appearance.

In assessing likelihood, we may reasonably assume that, within a certain range, the greater the value of the secondary interest (e.g., the size of the financial gain), the more probable its influence. Below a certain value, the gain is likely to have no effect; this is why de minimis standards (which define that value) are appropriate for some gifts. Also, the value should generally be measured in relation to typical income and to the scale of the practice or research project.

Also affecting likelihood is the scope of conflict, in particular the nature of the relationship that generates the conflict. Longer and closer associations increase the problem. A continuing relationship as a member of the board or a limited partner of an industrial sponsor, for example, creates a more serious problem than the acceptance of a one-time grant or gift.

The extent of discretion — that is, how much latitude a physician or researcher enjoys in exercising professional judgment — partly determines the range of probabilities. The more routine the treatment or the more closely it follows conventional professional practice, the less room there is for judgment and hence for improper influence. Also, the less independent authority the professional has in a particular case, the less latitude there is for improper influence. A conflict involving a laboratory technician, for example, is generally less severe than one involving a principal investigator.

In assessing the seriousness of a conflict, we consider first the value of the primary interest — the effects on a patient's welfare or the effects on the integrity of the research. These effects include not only the possibility of direct harm to the patient or the research, but also the indirect harm that results from a loss of confidence in the judgment of the physician or researcher.

The greater the scope of the consequences, the more serious the conflict. Beyond its effects on the particular patient or research project, a conflict may have effects on the practices of other physicians or on the research projects of colleagues. Questions such as these should be considered: Will this physician's association with a commercial laboratory raise doubts about the objectivity of all the physicians in his or her hospital or HMO? Will the fact that this drug company is sponsoring this research project tend to undermine confi-

dence in the results of the work of other scholars in the institution and their ability to raise funds from other sources? Claims of physicians' independence or academic freedom should not be allowed to obscure the fact that the actions of any particular physician or scholar may substantially affect the independence of colleagues.

Finally, the more limited the accountability of the physician or researcher, the more serious the conflict. If the decision of a physician is reviewable by colleagues or authorities (who do not themselves have conflicts of interest), then there is less cause for concern. But the reviewers must be, and must be seen to be, genuinely independent and effective. Even if professionals are accountable for particular decisions, however, they may escape scrutiny for the cumulative effects and broader policy implications of their decisions. The informal norms and policies of a hospital or HMO represent judgments that, no less than explicit decisions in particular cases, may be improperly influenced by secondary interests.

Remedies

Historically, the trend has been from less to more extensive control of conflicts of interest — from individual discretion to collective regulation. The more severe the conflicts, the more justifiable are more extensive forms of control.

Relying on the good character of individual physicians and scholars to ensure that they avoid conflicts, or deal with them judiciously when they arise, is the least intrusive procedure. It also has the advantage of maintaining conditions of mutual trust between physicians and patients and between scholars and their public. It is, however, more effective in face-to-face relations that continue over time — in small communities, for example, in which patients know their physicians personally. It is less likely to be adequate in large organizations and in the impersonal encounters or distant relationships that characterize much of the practice of modern medicine and medical research.

Regulation by the profession provides more assurance than individual discretion that conflicts will be avoided. As compared with government regulation, it also has the advantage of involving those who know and care personally about professional practice. Rules are more likely to fit the special circumstances of the clinic and the laboratory when they are written by those who know these circumstances well and who have a personal stake in maintaining the integrity of the profession. The disadvantage of relying exclusively on the profession is that physicians, not only individually but also collectively, confront a conflict between their primary interest in maintaining the integrity of the profession and their secondary interest in promoting the economic welfare of its members. Unlike many other professions, the medical profession did not formally address conflicts of interest in its codes until the 1980s, and even then it in effect left the problem to the discretion of individual physicians.[3] Only in 1991 did the American Medical Association declare that self-referral, for example, was "presumptively inconsistent" with a physician's obligation to patients.[6]

The growing role of governments in regulating conflicts of interest is in part a response to the failure of physicians and scholars to deal adequately with the problem and in part a result of the greater stake that society has in medical practice and research. Despite the claim of some physicians that ethics cannot be legislated,[20] law and morality overlap and interact in many ways, most of which are mutually reinforcing. The chief advantage of government regulation is that it includes more people in the process of making and enforcing the rules, thereby reducing the problem of conflicts of interest on the part of the profession itself. An important disadvantage is the uniformity and procedural complexity that normally characterize the legal process. These create difficulties in matching the rules to the variety of conflicts that may arise and could even decrease the probability that violations will be prevented or punished.

Whether the responsibility for dealing with conflicts of interest falls to individual physicians and researchers, the profession, or governments, disclosure is the remedy most commonly prescribed. A physician is required, for example, to tell patients about his or her financial interest in the laboratory to which they are being referred and to let them decide whether to go to a different laboratory. A scholar is expected to indicate the sources of financial support for the research. Disclosure may be more or less public; the information may be provided to colleagues, hospital or HMO administrators, professional boards, state boards, or the general public. An advantage of disclosure is that it gives those who would be affected, or who are otherwise in a good position to assess the risks, information they need to make their own decisions.

A deficiency of disclosure is that those who receive the information may not know how to interpret it and may not in any case have reasonable alternative courses of action in the circumstances.[15,21] Disclosure could even exacerbate some of the indirect consequences of conflicts, such as the effects on confidence in the profession or in the research enterprise. By itself, disclosure may merely increase levels of anxiety, causing patients and readers generally to suspect physicians and researchers but providing no constructive ways to restore trust. Disclosing a conflict only reveals a problem, without providing any guidance for resolving it.

Because of the limitations of disclosure, more stringent methods of enforcement deserve consideration, especially in cases of more severe kinds of conflict of interest. Other methods (roughly in order of increasing stringency) include mediation (devices such as

blind trusts that insulate the physician from the secondary interest),[10,15] abstention (an analogue to judicial recusal that would have physicians or researchers withdraw from cases in which they have substantial secondary interests), divestiture (which would eliminate the secondary interest), and prohibition (which would have physicians or researchers withdraw permanently from fields in which they have substantial secondary interests).[15,22,23]

Conclusions

The problem of conflicts of interest in medicine is more complex than is often recognized. A more systematic framework is desirable for specifying and applying rules to regulate conflicts. A better understanding of the nature of conflicts of interest and a clearer formulation of standards could increase confidence in the medical profession. Physicians and scholars could then concentrate more fully on their main missions — treating patients, teaching students, and conducting research.

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I am indebted to those who participated in the Clinical Ethics Lecture Series, sponsored by the Harvard University Division of Medical Ethics and Massachusetts General Hospital, Boston, at which an earlier version of this article was presented, especially Dr. David Blumenthal, Dr. Linda Emanuel, and Daniel Steiner.

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