

Two Cheers for Physicians' Conflicts of Interest

LANCE K. STELL, PH.D.

Abstract

This paper will attempt to demonstrate that conflict of interest is an unavoidable feature of medical practice, medical institutions, medical publications, and medical research. It also seeks to show how and why current regulations are ineffective in curbing fraud and abuse. The paper goes on to argue that, in light of the incentives incorporated into current reimbursement arrangements, physicians have to learn how to manage the conflicts they face and remain true to their fiduciary responsibility to patients.

Key Words: Conflict of interest, physician-patients relationship, fiduciary responsibility, fees, bias, professional journals, trust, HIPAA.

"...no one of his own free will chooses to...take other people's troubles in hand to straighten them out, but everyone expects pay for that..."

Plato (1)

A MEDICAL LICENSE invests the physician with social recognition, authorizing him to present himself to the public as a competent, trustworthy guardian of patients' health interests. When someone becomes a license-holder's patient, ideally, she welcomes rather than fears the physician's broad discretion to act in her best interests. This means that the physician must attend to her complaints, outline to her his findings and their significance, and define care options and their expected consequences. If his best medical judgment is that an illness is self-limiting or will respond adequately to self-care, it is his duty to say so. If she requires treatment, he may offer it. On the other hand, if his best medical judgment is that her condition requires referral to a specialist or subspecialist for fur-

ther diagnostic work-up or treatment, he must say so.

At every juncture from presenting complaint, to work-up, to care plan, to treatment, to discharge, the physician's guardianship of the patient's health interests permits benefit to the patient, but also to the physician, to the hospital, to professional colleagues, pharmaceutical and device makers, and society, very often at third party payer's or society's expense. It is no exaggeration to say that "Every physician-patient encounter is a conflict of interest. Every physician-payer encounter is also a conflict of interest" (2).

It doesn't follow, of course, that all conflicts of interest between physician and patient are equally important. Some conflicts of interest are "more equal," more problematic, than others.

Conflict of Interest: Psychological Roots and Ethical Dynamics

Plato may have been the first thinker to provide a systematic analysis of the physician-patient relationship that explains why conflicts of interest are an ineluctable feature of it. The account goes as follows:

Despite the fact that the physician presents to the public as a practitioner of the medical arts, there is "an additional art" which is not

Department of Internal Medicine, Carolina Medical Center, Davidson, NC.

Address all correspondence to Lance K. Stell, Ph.D., 102 North Main Street, Davidson, NC 28036.

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professed, namely, the art of fee-charging and fee-collecting. Since the art of medicine enables the physician to diagnose and treat disease, its practice primarily benefits the patient, not the physician. However, Plato notes that “no one of his own free will chooses to...take other people’s troubles in hand to straighten them out, but everyone expects pay for that” (1). It follows that the physician would not willingly attempt to help solve the patient’s problems were it not for his practicing the additional art that benefitted him, namely, the fee-charging, fee-collecting art.

The physician’s practice of the two arts results in mutual benefit. However, distinguishing these arts analytically and separating them in practice are not the same. How should the physician sequence the practice of these arts in time? For example, may the physician practice the money-making art “prior to” establishing a physician-patient relationship, e.g., by his assessing the ill person’s “ability and willingness to pay” (a.k.a., the “wallet-biopsy”)? After all, the money-making art remedies any reluctance the physician would otherwise have about attending to the ill. Yet this seems unfair to the ill person, because, depending on the circumstances of her illness and her access to alternative providers, she would be susceptible to extortion. On the other hand, if the physician’s practice of the fee-charging/collecting art must be delayed until the patient has recovered, her gratitude may be insufficient to motivate her to pay her bill.

Plato ignores these problems, but he insists that the physician must not practice both arts simultaneously. Once the physician-patient relationship is established, and when treating the patient, the physician must give priority to the medical art, which by definition advantages the patient, not the physician. Otherwise, the physician becomes a fraud, because by giving priority to his unprofessed art he becomes a “mere moneymaker.” In other words, what makes it non-fraudulent for the physician to profess medicine while also practicing but not professing money-making, is his perfect adherence to the fiduciary principle: “No physician, insofar as he is a physician, considers his own good in what he prescribes, but the good of the patient; for the true physician is...not a mere moneymaker” (1).

Obviously, “true physician” is not a description of any real-life person, but rather an abstract, ideal physician who is making a medical decision for his one and only patient. Inso-

far as this ideal physician has other patients, they are abstracted away, so neither he nor we consider the time-tradeoffs in caring for more than one patient. He serves his patient tirelessly. He considers only one thing when applying the medical art to the patient’s situation—the patient’s good—and nothing else. The true physician’s single-mindedness reflects his perfectly just, well-ordered soul. His self-control renders him unsusceptible to all incentives that bid to motivate his rendering less or more treatment than the medical art directs. In particular, financial incentives cannot motivate the true physician to undertreat or to overtreat or to otherwise influence his medical judgment.

All human physicians fall short of Plato’s ideal, “true physician.” Human physicians have many patients and suffer from chronic time-management problems. They lack perfect self-control. The prospect of reimbursement may well influence their medical judgment to some degree, resulting in overtreatment or undertreatment rather than “right treatment.”

Implications of the Incentive Principle

If “pay,” whether denominated in financial or in nonfinancial terms, tips the balance of motivation between a physician’s being “unwilling” to his being “willing” to “take [the patient’s] troubles in hand to straighten them out” (presumably, a good result of incentives) then it is reasonable to expect that “amount” and “kind” of compensation will exert recurrent influence on the physician’s motivation and judgment, making a difference between the physician’s being “grudgingly willing to attend,” “reluctantly willing to attend,” and “eagerly willing to attend, at all times” (a more troublesome result).

- The promise of fee-for-service (FFS) reimbursement at customary and reasonable rates creates a well-appreciated incentive for the physician to accept and serve as many FFS-sponsored patients as possible. Less obviously, it creates an incentive for the physician to avoid subspecialist referral. The aggressive utilization-bias created by FFS reimbursement does not necessarily benefit patients sponsored by it. One study of well-insured cancer patients found that they received worse care and more dangerous treatments than uninsured patients (3).
- The bias against referral created by FFS also creates an incentive for subspecialists

to pay primary care physicians for referrals. Although fee-splitting is regarded as unethical in the U.S., it is widely practiced in Japan, where subspecialists pay up to \$2,500 (U.S. equivalent) per referral.

- Fee-splitting is an economic corrective for the primary care physician's incentive to treat beyond his capability. Prohibiting fee-splitting advantages primary care physicians as a group. It disadvantages subspecialists and patients who might have benefitted from referral or who might have avoided iatrogenesis associated with primary care physicians treating beyond their ability.
- The incentive to overtreat FFS-sponsored patients advantages the physician's self-pay and nonpaying patients by enabling cross-subsidization of their care. The ability to cost-shift marginally effects the physician's willingness to attend to self-paying and nonpaying patients. It may also cause the physician to overestimate how much *pro bono* care he provides.
- Steadily declining Medicare reimbursement to physicians will reduce physicians' willingness to care for Medicare-sponsored patients (4). The effect will be marginal, not categorical. Rather than causing the wholesale discharge of Medicare patients from a physician's practice, declining reimbursement will tend to influence his willingness to accept the next Medicare-sponsored patient into his practice. As the number of Medicare-sponsored patients in a physician's practice decreases, his increasing reluctance to accept new Medicare patients will affect most persons not yet Medicare eligible, including those of his current patients who are now otherwise-sponsored.
- Since the medical standard of care is defined by reference to what the average member of the profession in a particular community does in particular circumstances, and since financial reimbursement exerts influence on the medical judgment of the average member of the profession, medical indications for a procedure may be influenced (more or less) by the prevailing reimbursement scheme. For example, cataract surgery is performed on approximately 1.4 million patients per year. The procedure accounts for Medicare's largest expenditure,

and is performed at lower rates in pre-paid settings than in fee-for-service settings. It follows that whether cataract surgery is medically indicated varies somewhat with reimbursement models (5). Another example: Physicians tend to avoid screening for and diagnosing substance abuse disorders, because they rarely receive reimbursement for treating it. To the extent that society relies on the medical profession's diagnostic data to estimate the incidence of substance abuse, it will underestimate the incidence of substance abuse (6).

- As a rule, Medicare does not pay for patient-administered prescription drugs. However, it will reimburse hospitals for intravenous (IV) prescription drugs administered to Medicare beneficiaries. Medicare will also reimburse physicians for the IV prescription drugs they administer to outpatients. Both hospitals and oncologists obtain cancer drugs directly from pharmaceutical companies at wholesale prices. As a result, both hospitals and oncologist have an incentive to favor IV administration of medications over "patient administration" whenever there is a choice. Indeed, it is hard to justify keeping a patient in the hospital if she does not have at least one IV line. However, when a physician orders IV chemotherapy for an inpatient, nurses administer the drugs which the hospital has procured. The hospital rather than the physician bills Medicare for the drugs at retail prices. On the other hand, the oncologist may bill Medicare at retail prices for the cancer drugs he has obtained wholesale, provided that he infuses them in an outpatient setting. Obviously, as inpatient care reimburses less well, outpatient oncology becomes more attractive. Making outpatient cancer care more attractive to oncologists may be welcomed by patients but not by hospitals. Hospitals have an incentive to call attention to the Medicare "loophole" that allows physicians to bill at retail prices for prescription drugs they administer by IV to outpatients. Furthermore, the social interest in adverse-event monitoring and peer review are more difficult to manage in an outpatient setting.

Medical Ethics, Made (Too) Simple

Perhaps disillusioned by the scope and depth of physicians' self-interest (7) and the overall commercialization of medicine (8), one

state medical board has announced an absolutist corrective: “zero tolerance” for physicians’ conflicts of interest:

...patients...come to the physician in a vulnerable condition, believing that the physician has knowledge and skill that will be used for their benefit. Patient trust is fundamental to the relationship thus established. It requires that...there be no conflict of interest between the patient and the physician or third parties. (9)

Norman Levinsky has weighed in similarly (10): “Physicians are required to do everything that they believe may benefit each patient without regard to costs, or other societal considerations.... It is society, not the individual practitioner, that must make the decision to limit the availability of effective but expensive types of medical care.”

Unfortunately, as Plato’s 2500-year-old analysis makes plain, “zero-tolerance” for physicians’ conflicts of interest is equivalent to “zero-tolerance for physicians.”

Levinsky’s idealistic-sounding nostrum for ethically challenged doctors, “You must do whatever benefits the patient...” rationalizes the physician’s “doing everything” when expectable patient benefit is small or speculative, but also when expectable physician benefit is much larger and more certain, not to mention outsized financial gains accruing to his hospital, or to medical supply companies, pharmaceutical companies and device makers. Rather than reminding physicians that declining marginal benefit for patients should not provide ethical cover for ignoring the obvious incentive effects of comparatively larger gains for themselves, Levinsky would make physicians’ willful ignorance of their disproportionate gains into a virtue rather than a vice.

Conflicts of Interest in the Nonprofit Sector?

In 1991, Genentech, a for-profit biotechnology industry leader, contributed \$2.5 million to the American Heart Association (AHA, a private, nonprofit corporation) for construction of its national headquarters in Dallas, Texas. In the mid-1990s, the AHA launched a health care initiative to reduce morbidity and mortality secondary to “brain attack,” its campaign term for acute ischemic stroke. The AHA touted the

promising results of a clinical trial of a new bioengineered fibrinolytic agent, tissue plasminogen activator (tPA). The AHA estimated that tPA might save as many as 400,000 lives per year, reduce stroke-related morbidity, and perhaps even reverse paralysis secondary to stroke. During the 1990s, Genentech’s contributions to the AHA exceeded \$11 million. Genentech’s support was not disinterested: it had developed and patented tPA and intended to market it. In 1996, the FDA approved tPA (Alteplase) for use in ischemic stroke. The expert panel that issued the favorable recommendation (eight to one) contained only one member not known in advance to favor tPA approval. His professional history was uniquely devoid of ties to Genentech. By contrast, six of the eight supporting panel members had financial ties to Genentech, four of the eight supporting experts were members of Genentech’s paid-speakers bureau, and two of the eight had received research support from Genentech (11).

The American Heart Association never published the dissenter’s opinion, which pointed out that the AHA’s initial enthusiasm for tPA was based on only one trial, and that a statistical analysis of that trial’s results showed that chance alone could explain the “finding” of tPA’s apparent efficacy.

Subsequently, no fibrinolytic trial demonstrated that tPA confers a mortality benefit in treatment of acute ischemic stroke. On the other hand, several studies found an association between tPA and increased mortality. More worrisome, one fifth of patients initially diagnosed with stroke by expert teams were found subsequently not to have suffered stroke. And patients falsely diagnosed “positive” for stroke who receive tPA emergently are exposed to risk unbalanced by benefit (12).

Nevertheless, in August of 2000, the AHA upgraded its recommendation for tPA from “optional” (class II b) to “definitely recommended” (class I). Having won FDA approval and treatment-guideline support from the AHA, Genentech has no interest in funding a comparative efficacy study matching tPA against streptokinase (a very cheap, generic fibrinolytic agent). One of its scientists explained, “We don’t know how another trial would turn out. And if we don’t come out ahead, we would have a [tremendous] self-inflicted wound” (13).

Clinical trials sponsored by drug companies are much more likely to report positive results than trials that have nonprofit sponsors. Does this suggest that physicians who conduct drug-

company-sponsored clinical trials have a conflict of interest which increases the likelihood of their producing positive results for a fee? Perhaps.

However, it is estimated that drug development costs resulting in FDA approval average \$500 million per drug (14). If so, wouldn't a drug company have an obvious incentive to use adverse selection to withhold from clinical trials any drug/device antecedeately regarded as unlikely to win approval?

Similarly, suppose that nonindustry funding sources are comparatively indifferent as to whether otherwise rigorously designed study proposals might yield negative results. Wouldn't it be likely *a priori* that more of its sponsored studies would fail to find benefit or would be equivocal?

Also, nonfinancial conflicts of interest may distort judgment as much as or more than financially based conflicts. An interest in winning desirable academic appointments, in securing tenure and promotion, in publishing articles in prestigious journals, in vindicating one's pet theories, sheer animus, etc., may bias judgment just as powerfully as funding from an interested party.

Seeking Unbiased Professional Judgment: The Professional Journals

Professional journals are imperfect bias filters. They may eliminate some biases, but also add some of their own.

The professional credentials that qualify an editor or reviewer to evaluate a manuscript submitted for publication also make it more likely that he or she will have conflicts of interest with its authors. Review-process opacity renders readers unable to discern whether publication decisions may have been marginally influenced by shared mentorship, favor-repayment, political loyalty, frank envy, or even retaliation against professional rivals or a study's sponsors. Editors with their own record of professional achievement vary in their susceptibility to think less well of a manuscript that ignores their own or friends' contributions to the field or treats such contributions dismissively, without "due respect."

Drummond Rennie, a longtime medical journal editor himself and a sturdy critic of the medical literature's quality, has written (15):

"...there seems to be no study too fragmented, no hypothesis too trivial, no lit-

erature citation too biased or too egotistical, no design too warped, no methodology too bungled, no presentation of results too inaccurate, too obscure, and too contradictory, no analysis too self-serving, no argument too circular, no conclusions too trifling or too unjustified, and no grammar and syntax too offensive for a paper to end up in print."

Conclusion

It follows from Plato's analysis of fiduciary relationships that incentives sufficiently strong to forge them also present a hazard to them. If perfect adherence to the fiduciary principle as modeled by the "true physician" is used as a standard, then every trust-bearing agent, including all real-world physicians, must be continually out of compliance, more or less.

Conflict-of-interest management is an exercise in practical, "second-best ethics." The problem is that we have no consensus about "an acceptable rate of noncompliance." Flagrant abuses of trust that come to public notice invite speculation that similar cases are going undetected. The speculators are not necessarily disinterested either.

Thomas Hobbes's "state of nature" argument proved that trust and anxiety are inversely related. Where there is no basis for trust whatsoever, there is no rational limit on our anxiety, and we can never invest too much in precautionary measures. Once there is a rational basis for social trust (provided by some type of social contract), public anxiety declines and the perceived need for precautionary measures goes down. Still, should social trust decrease for some reason, social anxiety would increase and the public's willingness, collectively and individually, to invest in precautionary measures would go up. Declining social trust in the medical profession, therefore, has fueled a growth market in precautionary measures, especially in regulation and enforcement. The Health Insurance Portability and Accountability Act (HIPAA) is the latest example.

This federal law criminalizes any "scheme or artifice" to defraud, or obtain money by false pretenses from any health plan (federal or otherwise). The prohibitions are sweeping in their scope. For example:

- Federal law is violated if even one purpose (as opposed to a primary or sole purpose) of a payment, whether received or given, is in exchange for or to induce the referral of pa-

tients or the ordering, purchasing, or recommending of items or services. It “may” be a defense that the improper purpose was “incidental,” “minor,” or “not material” (16).

- Although courts recognize that some benefits received or given by providers may be *de minimis*, any payment or other benefit may violate the law when the amount is sufficient to influence the physician’s reason or judgment (17).
- The fact that a fee charged is reasonable will not serve as a defense if the intent underlying the arrangement that generated it can be shown to be an exchange of payment for referrals (18).
- There need not be proof of an agreement to make referrals, or to order, purchase, or recommend medical items or services. Intent may be inferred from the circumstances of the case (19).
- The mere potential for increased charges to, or a payment to be made by, a federal health care program may be sufficient for the law to be violated; no actual payment is necessary as long as the challenged charge for an item or service might be reimbursed by a federal health care program (20).
- The fact that an arrangement is “common” in the health care industry is not a defense to a kickback violation (21).

These prohibitions are so sweeping that virtually every financial relationship in the health care industry potentially violates federal law. The magnitude of threatened penalties, despite the unlikelihood of their imposition on any one of the million health care providers in the United States, creates an incentive for each of them to invest in precautionary measures to reduce the hazard of federal prosecution. The resulting redistribution of resources does nothing to improve care quality, nothing to reduce the incidence of medical errors, nothing to improve access to health care.

On the contrary, to guide the redistribution of resources, the federal government encourages providers to adopt “voluntary compliance programs” and to self-disclose improper billing. Law firms have opened new sections of their practices to market precautions to their client-providers. No “money-back guarantee” accom-

panies these products. There are at least two competing trade associations that credential HIPAA compliance officers. Hospitals may now purchase insurance against the consequences of filing false claims—an irony, since a predicate of insurance is uncontrollability of risk.

It might be argued that these anti-kickback and anti-fraud provisions effectively offset physician and other provider incentives to take unfair advantage of their trust, and that as a result, providers will become more trustworthy. But if the number of law enforcement actions are an index to provider trustworthiness, the trend looks bad. For the past 6 years, civil, criminal and administrative fraud enforcement has logged an increasing number of cases.

It has been repeatedly asserted that 10% of health care spending (\$1.15 billion in 1998) is lost to fraud, waste and abuse. Since this percentage has not been revised in more than a decade, aggregate losses from “fraud and abuse” must be growing inexorably with increases in health care spending. Indeed, the sweepingly broad definition given to unlawful provider conduct implies that the only restraint on the number of enforcement actions is the size of the enforcement budget.

Plato claimed that a society’s rate of increasing injustice correlated with its number of lawyers. More lawyers create more regulations and proliferate causes of action, leading to citizens spending more and more of their time in litigation. Incentives create relationships. One cheer. Conflicts of interest create occasions for regulatory oversight. Two cheers?

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