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Title

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Permalink

<https://escholarship.org/uc/item/16r1m372>

Journal

Hastings Center Report, 47(3)

ISSN

0093-0334 1552-146X

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Publication Date

2017-05-24

DOI

10.1002/hast.700

Peer reviewed

ESSAYS

Closed Financial Loops: *When They Happen in Government, They're Called Corruption; in Medicine, They're Just a Footnote*

BY KEVIN DE JESUS-MORALES AND VINAY PRASAD

Many physicians are involved in relationships that create tension between a physician's duty to work in her patients' best interest at all times and her financial arrangement with a third party, most often a pharmaceutical manufacturer, whose primary goal is maximizing sales or profit. Despite the prevalence of this threat, in the United States and globally, the most common reaction to conflicts of interest in medicine is timid acceptance. Some argue that even the minimal policies we do have—mostly disclosure and, in rare case, divestiture—are draconian.¹ Largely, these conflicts in medicine are managed via disclosure, although recent research suggests that this is a poor tool and may even backfire—increasing trust patients place with the discloser.² There are few calls for conflicts of interest to be banned, and, to our knowledge, no one calls for conflicted practitioners to be reprimanded.

Contrast our attitudes in medicine with public attitudes toward financial conflicts among government employees. When enforcement of rules against conflict of interest slackens in the public sector, news organizations investigate and publish their criticism.³ This phenomenon is largely absent in medicine—even when doctors are quoted in the media promoting specific drugs, their personal financial ties to the drug maker are rarely mentioned. Policies for governmental employees are strict, condemnation is strong, and criminal statutes exist (allowing for corruption charges). Yet the evidence that conflict is problematic is, if anything, *stronger* in

medicine than in the public sector. We contend that policies against conflicts of interest in medicine should be at least as strong as those already existing in the public sector.

Corruption of Governmental Officials

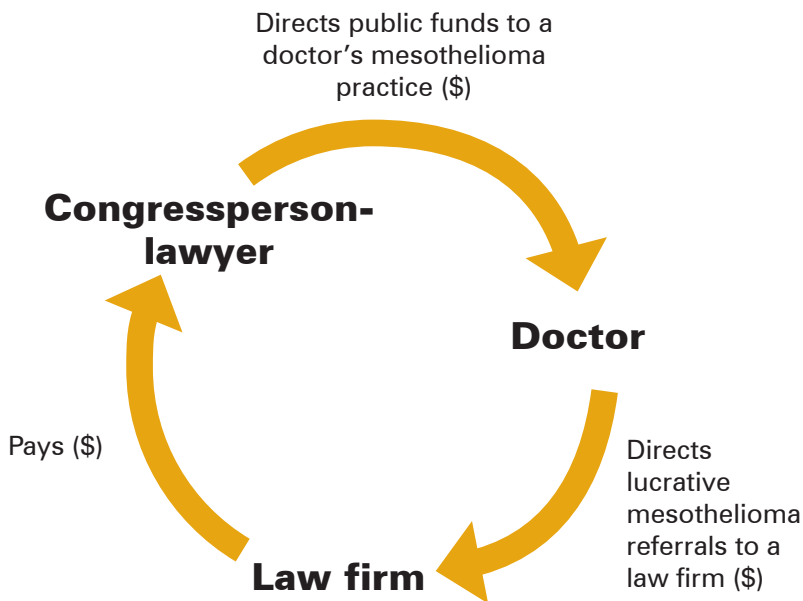
Financial conflicts for public employees can lead to widespread chastisement of an individual and sometimes to criminal charges. One prominent statute in the United States that allows financial conflicts to be prosecuted as corruption involves what is called honest services fraud. To commit this crime, a person who has a fiduciary responsibility to act in another's best interest accepts either a bribe or kickback—in other words, something of value in exchange for favorable treatment.⁴ Failure to disclose a conflict of interest could also constitute honest services fraud, although a recent U.S. Supreme Court ruling limited fraud cases brought solely for undisclosed conflict.⁵ While the charge of honest services fraud can be applied in both private and public cases, it has principally been used to prosecute governmental corruption.

Consider a recent example: Sheldon Silver was the speaker of the New York State Assembly from 1994 to 2015 when he was convicted of corruption charges.⁶ Concurrent with his work in public office, Silver worked as a lawyer in a personal-injury law firm in New York City, a job from which he received more than three million dollars in referral fees. Many of his referrals involved cancer patients who had been exposed to asbestos and directed to Silver's law firm upon the advice of Robert Taub, a physician who directs the mesothelioma research center at Columbia University.

Kevin De Jesus-Morales and Vinay Prasad, "Closed Financial Loops: When They Happen in Government, They're Called Corruption; in Medicine, They're Just a Footnote," *Hastings Center Report* 47, no. 3 (2017): 9-14. DOI: 10.1002/hast.700

Figure 1.

The Flow of Money in a Case of Political Corruption



During a federal investigation, prosecutors uncovered that Silver, as speaker, used his discretionary control of a state health care fund to direct \$500,000 to Taub's research. In short, prosecutors alleged that Silver directed public money to Taub because Taub sent lucrative referrals to a law firm that employed and, thus, paid Silver. A closed financial loop provided the prosecution's evidence of honest services fraud. (Figure 1 represents the financial relationship.) Among jurors who convicted Silver, one had initially felt that the state grant money Silver directed to Taub was just "goodwill,"⁷ but she later changed her mind.

The juror's comment illustrates the difficulty with such cases: how does one know that the financial relationship was the reason the public funds were used as they were? One can imagine the doctor objecting to the charge by asserting that the referrals were made to that firm simply because its lawyers were excellent. The speaker could have insisted that few doctors were conducting cutting-edge mesothelioma work and this was in fact the best use of public money. Finally, his position with the New York State Legislature was a part-time job, so it is reasonable that he would also work for that firm. In other words, someone might argue that every link along the financial chain was merely coincidence and that the arrangements did not amount to quid pro quo.

Both these objections and the nature of the financial relationship have analogues in medicine. As public officials have a fiduciary responsibility to citizens, physicians have a fiduciary responsibility to patients—a duty to act always and inexorably in their patients' best interest. Physicians are paid for providing services to patients, just as public-sector

employees are paid for performing their duties. Physicians may also choose to engage in financial relationships with other entities that create a situation similar to the one in which Speaker Silver was involved. Moreover, one often hears physicians make comparable objections to questions about their financial relationships as the speaker might have mounted about his. Physicians argue, for instance, that the drugs they prescribed were selected, not because of the physicians' relationships with pharmaceutical companies, but because those were the best drugs, and the physicians insist that they took money from the companies, not in exchange for prescribing certain drugs, but because they had valuable medical information to contribute to the pharmaceutical companies. In other words, the same kinds of challenges with adjudicating the motives behind a single case exist in medicine as in government.

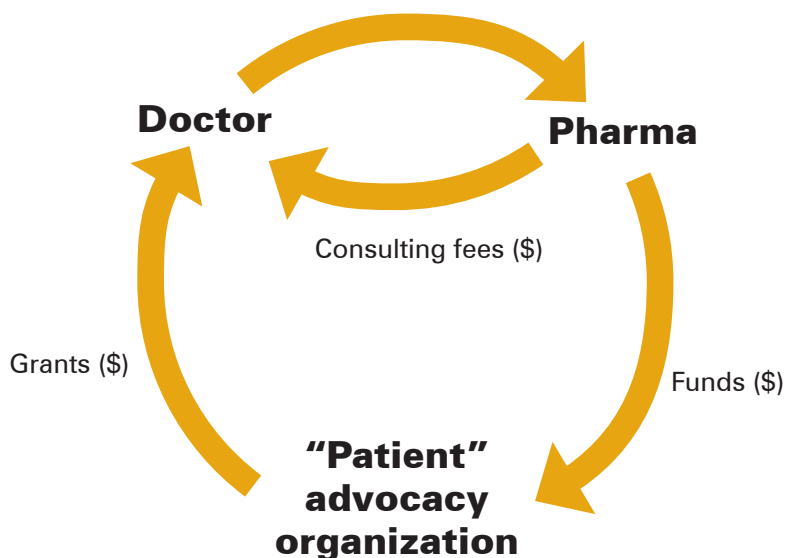
Consider the financial arrangements of many academic hematologist-oncologists. They often prescribe or recommend costly oncologic drugs of marginal benefits and real risks.⁸ They also often take part in powerful guidelines groups like that of the National Comprehensive Cancer Network, which promulgates a list of drugs that the Centers for Medicaid and Medicare Services must pay for by law.⁹ These academic doctors have tremendous influence over the use of cancer drugs and their coverage by federal payers, both in their practices and beyond.

Now, consider the common, potential financial conflicts of interest in which academic oncologists may become involved. Over 80 percent of NCCN authors receive direct personal payments from drug companies, and nearly 50 percent receive research funding from the pharmaceutical industry (research funding, of course, has indirect career benefits).¹⁰ Moreover, many of these academics also receive funding from patient-advocacy organizations, which themselves receive pharmaceutical funding, with estimates ranging from 30 to 71 percent.¹¹ (Figure 2 depicts this relationship.) Thus, the movement of money in physicians' and public employees' financial conflicts of interest makes a similarly closed loop (see figures 1 and 2).

In both cases, it is difficult, if not impossible, to show that any individual decision would have been made differently had it not been for the financial relationship. However, in the case of financial conflict of interest in medicine, many well-done epidemiological studies have demonstrated a bias—that financial relationships between physicians and pharma consistently cause a distortion of the evidence or its interpretation. At the same time—to our knowledge, which is based on a literature search—there is no empirical evidence that

Figure 2.**The Flow of Money in Cases of Medical Financial Conflict of Interest**

Heavily prescribes a costly drug when data about it is unclear; advocates for the drug to be recommended in medical guidelines (\$)



public-sector financial conflicts of interest are biasing. One may argue that, if anything, our policing of and penalties for financial conflict of interest in medicine should be intensified. This is not to say that harmful conflicts of interest in the public sector are rare or policing and penalties adequate, but what we can say for certain is that, in medicine, conflict is generally ubiquitous and penalties absent. There may be room to reduce conflict in both areas and is certainly much room to improve the situation in medicine.

What We Know about Physicians' Conflicts of Interest

Financial conflict of interest in medicine has been studied for at least thirty years.¹² In a nationwide evaluation conducted ten years ago, 94 percent of surveyed physicians reported ties to the pharmaceutical industry.¹³

As figure 2 illustrates, financial relationships that constitute conflicts of interest in medicine often form a closed loop, and empirical data suggest that it is a positive feedback loop. Consider recent studies showing that doctors with greater financial payments from pharmaceutical companies are more likely to prescribe costly brand-name drugs (including statins) over generic alternatives.¹⁴ These financial arrangements raise the question of whether doctors are, to a degree, violating their fiduciary responsibility to patients—by preferentially using more costly, branded drugs. In contrast to

what is known about conflicts of interest in government, that similar conflicts in medicine are linked to altered patterns of behavior has been empirically demonstrated.

In another example of a closed financial loop, clinicians with direct ties to drug manufacturers are frequently part of developing and authoring guidelines recommending the use of agents for treatment of type-2 diabetes produced by the very same manufacturers.¹⁵ Given the lack of comparative data on the appropriate use of these agents,¹⁶ the potential for bias is great. This relationship looks like the one represented in figure 1. Just as Silver could have insisted that he directed state grant money to Taub because the latter was doing unusually valuable work in the treatment of mesothelioma, physicians may argue that their decision to recommend those drugs was based on their best interpretation of the evidence, yet we cannot be sure that is true. Further evidence shows that doctors with financial ties to makers of diabetes medications were less likely to be concerned about potential postapproval safety issues¹⁷ and that editorialists with

financial ties were more likely to emphasize poorer evidence of the medical benefits of a widespread, lucrative drug when a randomized trial found that it was harmful.¹⁸ Evidence for a reinforcing loop is greater in medicine than in politics.

Contrasting Views on Conflicts of Interest

While the threat to a fiduciary interest is present in both cases, society is more tolerant of financial conflict in medicine. Why?

One reason may be the pervasive nature of and physicians' early habituation to such relationships. A systematic review found that 40 to 100 percent of medical students had interactions with the pharmaceutical industry.¹⁹ Eight studies within the review established that more frequent contact led to more positive perceptions of the industry.²⁰ This contact was financial, with the majority of students receiving lunch or educational materials. Favorable attitudes toward industry interactions appeared to change during medical training (when drug companies start to interact with doctors-to-be), as clinical students were more likely than preclinical students (53 to 71 percent compared to 29 to 62 percent) to report that promotional information was helpful in learning about new drugs.²¹

Consider, too, the pervasiveness of financial conflict of interest. In the case of oncologists on the NCCN guidelines' committee, over 80 percent receive financial payments from

Financial arrangements between physicians and pharmaceutical companies raise the question of whether doctors are violating a fiduciary responsibility to patients—by preferentially using more costly, branded drugs.

drug makers. Nearly 70 percent of speakers at the oncologists' national meeting in 2015 had financial ties to drug makers.²² Other surveys suggest that 30 to 60 percent of guideline authors receive payments (for personal or research use) from the pharmaceutical industry.²³ Underreporting of conflict in this arena has also been documented.²⁴ Finally, some studies show that over 90 percent of doctors have financial ties to manufacturers of medical products.²⁵

Professional medical societies also have financial conflicts of interest due to their arrangements with the industry. Of 154 Italian medical societies, 65 percent received private sponsorship for their last conference, 29 percent had manufacturers' logos on their webpage, and 36 percent had industry-sponsored satellite symposia at their last conference.²⁶ A large study showed that financial relationships between organizations that produce medical guidelines and individuals who sit on guidelines committees are common and that poor disclosure of conflict is linked to more positive statements about patented biomedical products.²⁷

Conflicts of interest surrounding guidelines do not produce concerns just about treatment but also about disease classification and diagnostic tools. As of this writing, 69 percent of the *Diagnostic and Statistical Manual of Mental Disorders-5* task force members report having ties to the pharmaceutical industry. This represents a relative increase of 21 percent over the proportion of *DSM-IV* task force members with such ties.²⁸ Thus, the frequency with which the loop is closed among doctors (as illustrated in figure 2) is certainly high, and it may exceed the frequency with which it occurs among government employees, although reliable data are lacking. Simply because of the prevalence of these closed financial loops in medicine, we may be inured to their threat.

Another reason financial conflicts of interest in government and in medicine are thought of differently may be doctors' long-standing trusted position in society. The public continues to place high (though declining) trust in physicians,²⁹ while it has much less trust in elected officials.³⁰ Despite this fact, the public remains concerned about financial ties that researchers or institutions have with drug companies. In an Australian study, 70 percent of the patient-participants indicated that they wanted to know about these financial relationships.³¹ Nevertheless, according to one study of American cancer patients, 82 percent of patients would have enrolled in a trial even if the drug company had paid the researcher for speaking, 75 percent if the company's payment to the researcher had been for consulting, 70 percent if the researcher

had received royalty payments from the company, and 76 percent if the researcher had owned stock in the company.³² What we can take from this information is that patients have such great faith in physicians that they give them the benefit of the doubt even though they are concerned about the distortive power of financial conflicts. This may in part explain the divergent treatments of conflicts of interest in politics and in medicine, though it does not justify it.

Conflict and Pharma-Funded Research

The comparison between financial conflicts of interest in medicine and in government would be incomplete without discussing the fact that research sponsored by the drug industry consistently provides a more favorable impression of its products. When compared to trials funded by not-for-profit organizations, trials funded by for-profit companies are significantly more likely to recommend a new treatment over the over the standard of care,³³ namely, a treatment offered by the given company. Industry-funded trials report positive outcomes in 85 percent of publications, compared with 50 percent for government-funded trials and 71.9 percent for trials funded by nonprofit or nonfederal organizations.³⁴ Reviews of the literature have shown that industry-funded trials are up to four times more likely to report findings supporting their product than are trials without financial conflict of interests.³⁵ Industry-sponsored economic analyses are 1.8 times (82 percent [28 out of 34] versus 45 percent [21 out of 47] of analyses; $P = .003$) more likely to report favorable qualitative cost estimates.³⁶ Favorable results seen in pharma industry-sponsored research are exaggerated via the following strategies: selective funding of trials on drugs considered to be superior to the competition, poor-quality research, poor selection of an appropriate comparator, and publication bias and ghostwriting.³⁷ There is no analogy for this in government. It would be as if military manufacturers provided their own analyses of foreign policy and made recommendations about when to wage war.

When Financial Conflicts in Medicine Become Criminal

At times, financial conflict of interest in medicine does constitute a crime. Searching news articles for reports of kickbacks reveals numerous examples of physicians sentenced to prison or fined for receiving money in exchange for refer-

ring patients to particular health care services. All of these cases contain a positive feedback loop, similar to that in forms of public-sector corruption. One article describing a physician who was paid to refer patients to a particular laboratory service notes, “Such referrals are illegal in medicine because of the potential that doctors will put their financial interests ahead of the needs of their patients.”³⁸ Worse, however, is the absence of practical difference between these kickback schemes and the problem of financial conflict of interest. The difference appears to be a matter of statistical probability; kickbacks imply quid pro quo, while in cases of conflict of interest in medicine, doctors are statistically likely to alter patient-treatment behavior in ways that benefit the pharmaceutical companies from which they receive payments. Yet this distinction does not matter to patients—in both cases, the fiduciary responsibility is threatened.

Possibly, financial conflict of interest in the public sector also does not constitute a crime.³⁹ The rules governing most federal positions, however, are very strict and reliably regard financial conflict as a kind of corruption.⁴⁰ Moreover, when financial entanglements among elected officials are not classed as corruption, news organizations investigate.⁴¹ Yet, this same phenomenon is largely absent in medicine: even when doctors are quoted in the media about specific drugs, their personal financial ties to the drug maker are rarely mentioned.

Can anticorruption statutes be used to prosecute physicians? Although such cases are rare, there is precedent.⁴² Yet, as a practical matter, other statutes, such as the Medicare and Medicaid Anti-Kickback Statute, have provided alternative paths for prosecutors. Future prosecutors may wish to extend the charge of honest services fraud to cases involving the fiduciary relationship between doctors and patients. After all, there is no relevant difference between conflicts of interest in medicine and in the public sector with respect to the intent or scope of this law, which governs all fiduciary relationships.

A Call for Tougher Policies and Equal Consequences

When public sector employees put themselves in financial relationships where their impartiality toward the public good is pitted against their personal financial interest, corruption charges may be brought. When doctors put themselves in similar financial relationships and there is epidemiological evidence for biased decisions, society's condemnation and punishment are mild or absent—in all but the most extreme cases. As of 2016, conflict-of-interest policies principally mandated disclosure, and in 2016, Harvard Medical School loosened its policies to permit more financial conflicts of interest.⁴³

The prevalence of conflict, doctors' early inculcation to a conflicted culture, and a high degree of trust in doctors can account for why we treat financial conflict of interest in medicine and this form of corruption among public officials differently. They do not, however, justify our divergent treatment of them. Although a recent U.S. Supreme Court narrowed

the breadth of corruption law, the current legal formulation remains far stronger than our policies concerning financial conflict of interest in medicine and may again be changed over time. At a minimum, financial conflict-of-interest policies in medicine must be strengthened to better mirror our attitudes toward and policies on political corruption. The status quo of financial conflict is untenable and threatens the fiduciary relationship between doctor and patient.

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