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Conflicts of Interest and Patient-Physician Trust

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Disclaimer

All events described in this case are fictional and are designed to highlight real situations in medical practice. Any resemblance to any real-life cases is purely coincidental.

Day 1: 12:17 p.m., Tuesday, July 22, 2008

“Oh, good,” you exhale in relief—the podium is still empty. Stopping short of the white coat in front of you, you glance across the long table. Turkey, roast beef, chicken salad, Italian meats! Your foot still propping open the door behind you, you look across the room. Residents chatting, laughing. Sandwiches disappearing. Another noon seminar, you grin.

But truthfully, you are still learning your way around. It’s a big hospital, bigger than where you went to school, bigger than where you trained. Just weeks ago, you had graduated from residency in internal medicine. Moving to a major city was a bit unsettling, but also exciting. Motivated by the shortage of geriatricians in the United States, you joined your first academic group practice eager to practice geriatrics and train residents to take care of the aging population.

The department chair took the podium. The first slide appeared: “Conflicts of Interest: Your Worst Nightmare.” The laughing stopped. “Don’t worry folks, lunch was on us today,” Dr. Ferguson quickly assured the crowd. The laughter returned. You recalled that yesterday’s conference was about free lunches from pharmaceutical companies.

The second slide began simply: two words—patient, physician—with an arrow pointing from one to the other that read “trust,” and another arrow in reverse, “care.” “This is where it all began, for many of you,” Dr. Ferguson remarked. Then, with one click of the mouse, the slide became satiated with words, boxes, arrows, and more arrows. “However, this is what you’re dealing with today.” You leaned forward, taking in the impressive cast of characters that would make up your professional life: medical students, residents, the university, the government, insurance companies, drug companies, medical device companies, investment groups, independent clinical laboratories, physical therapists, nursing homes...

“And in your daily interactions with them lie potential conflicts of interest—many of them financial—that could impair your clinical judgment. So listen up.” Dr. Ferguson pressed on.

He introduced the case of Jesse Gelsinger, an 18-year-old patient who died in a gene therapy experiment. The investigators had owned a company that would profit from the experiments. He introduced the case of Claudia Henschke, a renowned researcher and staunch advocate of screening for lung cancer, who failed to disclose funding from a tobacco company.

You listened intently, slowly nodding as these illustrations of conflicting interests crystallized in your mind. For the next hour, you seldom blinked as you tried to understand your academic medical center: its complexities, its breadth, its array of potential conflicts.

Discussion Questions

- What is a conflict of interest? What is a financial conflict of interest?
- Where are some areas of medicine in which conflicts of interest are likely to arise?
- How would you anticipate, confront, and deal with conflicts of interest around you?

Post-case Discussion

Legal Background on Conflicts of Interest

The Jesse Gelsinger case. In September 1999, Jesse Gelsinger, an 18-year-old patient at the University of Pennsylvania Institute for Human Gene Therapy (IHGT), died after experiencing an overwhelming immune response following infusion of an adenoviral vector in a gene therapy experiment. He was a participant in a phase I gene therapy study for ornithine transcarbamylase deficiency, a metabolic condition that causes a defect in the urea cycle. Jesse had a very mild phenotype of the disease.

After an investigation, the Food and Drug Administration (FDA) suspended all human experiments at the IHGT and restricted the subsequent work of scientists involved in the study. The violations included the following: the researchers had failed to report the deaths of monkeys that had previously been given the treatment, Gelsinger's blood ammonia levels were too high at the time of the study and should have excluded him as a participant, and the institute had failed to immediately report that two patients had experienced side effects from the gene therapy (Thompson 2000). The case was settled with fines and penalties.

Perhaps the hardest hit was the Institute's founder and director, Dr. James M. Wilson, also a leading gene therapy researcher. While members of an independent investigation of the Institute found that Dr. Wilson and his colleagues had done the best they could to follow FDA regulations, one conflict of interest stood at the forefront. According to the *New York Times*, Dr. Wilson was the founder of a biotechnology company called Genovo, which contributed one-fifth of its \$25 million annual budget to the Institute. In exchange, the company has exclusive rights to develop the Institute's discoveries into commercial products (Stolberg 2000).

The FDA subsequently conducted a random nationwide inspection of clinical trials and implemented new reporting requirements. A recent memo coauthored by Jesse's father points out that a lack of oversight at the federal level is a major concern, leaving today's patients just as vulnerable as patients 10 years ago. The authors report that an estimated 30% of human research studies are not regulated by the FDA, and that the agency was able to inspect only 1% of study sites in 2007 because of a shortage of inspectors (Gelsinger and Shamoo 2008). The authors conclude that as a result, adverse events have been underreported.

Think about how the perceived or real conflict of interest between the investigators and their biotechnology company may have affected clinical judgment. Where did the patient's interest stand in relation?

The Claudia Henschke case. In spring 2008, the *New York Times* reported that a major lung cancer study on the benefit of early spiral computed tomography (CT) screening was funded by a tobacco company (Harris 2008). The study, led by world-renowned Cornell investigators Drs. Claudia Henschke and David Yankelevitz, was published in the October 26, 2006, issue of the *New England Journal of Medicine*. The article argued for the early and frequent use of spiral CT screening, which, "[i]n a population at risk for lung cancer...could prevent some 80% of deaths from lung cancer" (Henschke et al. 2006). One of the funding organizations acknowledged at the end of the article was the "Foundation for Lung Cancer: Early Detection, Prevention & Treatment." A review of tax records uncovered that the Foundation was underwritten almost exclusively by a \$3.6 million

grant from the Vector Group, the parent company of the Liggett Group, the maker of Liggett Select, Eve, Grand Prix, Quest, and Pyramid cigarettes (Harris 2008).

Dr. Henschke was listed as the Foundation's president, while Dr. Yankelevitz was its secretary-treasurer. In addition, the medical school's dean and the vice chair of the college board of overseers were also officers (Harris 2008; Twombly 2008). The study's authors argued that the gift was publicly announced and available to grant-funding organizations as well as on the Internet; thus, the school did not try to conceal it. In their own defense, the university leadership confirmed that faculty were allowed to establish foundations without the school's approvals and that they later joined to ensure proper handling of the donations (Harris 2008). However, Dr. Jerome Kassirer, a former editor of *NEJM*, offered a harsher viewpoint: "You have to ask yourself the question, 'Why did the tobacco company want to support her research?' They want to show that lung cancer is not so bad as everybody thinks because screening can save people; and that's outrageous" (Harris 2008). Another commentator noted that "it would seem not only prudent, but imperative, for university leadership to determine the original funding source of a multimillion dollar foundation prior to endorsing it" (Moy 2008).

Other financial conflicts of interest were also evident. In a subsequent letter to *The Oncologist*, Dr. Henschke and Dr. Yankelevitz disclosed multiple pending patents related to technology used for cancer screening (Henschke and Yankelevitz 2008). They had failed to disclose these patent applications in previous papers and lectures.

According to the editors of *NEJM*, "Although the science in a submitted manuscript should be judged on its merits, one cannot fully appreciate a study's meaning without acknowledging the subtle biases in design and interpretation that may arise when a sponsor stands to gain from the report... We expect that authors will be particularly attentive to transparency in reporting if a funding entity has a vested interest in the outcome. The public's trust in biomedical research depends on it" (Schwartz et al. 2008).

This case illustrates the multiple angles from which a financial conflict of interest can take shape. Who is most responsible for such complex arrangements? Is disclosure adequate? Are academic universities equipped to police their faculty's financial relationships?

A Theory of Conflicts of Interest

A conflict of interest exists under circumstances in which the professional judgment concerning a primary interest is influenced by a secondary interest (Thompson 1993). The primary interest may be the patient's health or the validity of research, while the secondary interest could take such forms as financial gain through industry relationships or equity holdings, the desirability of positive research findings, and offers of gifts or vacations.

A conflict of interest is present when conditions can allow the secondary interest to influence the primary interest, and is independent of whether behavior is actually affected by these conditions (Thompson 1993). In other words, the *circumstances* surrounding a situation determine the conflict, not the *outcome*.

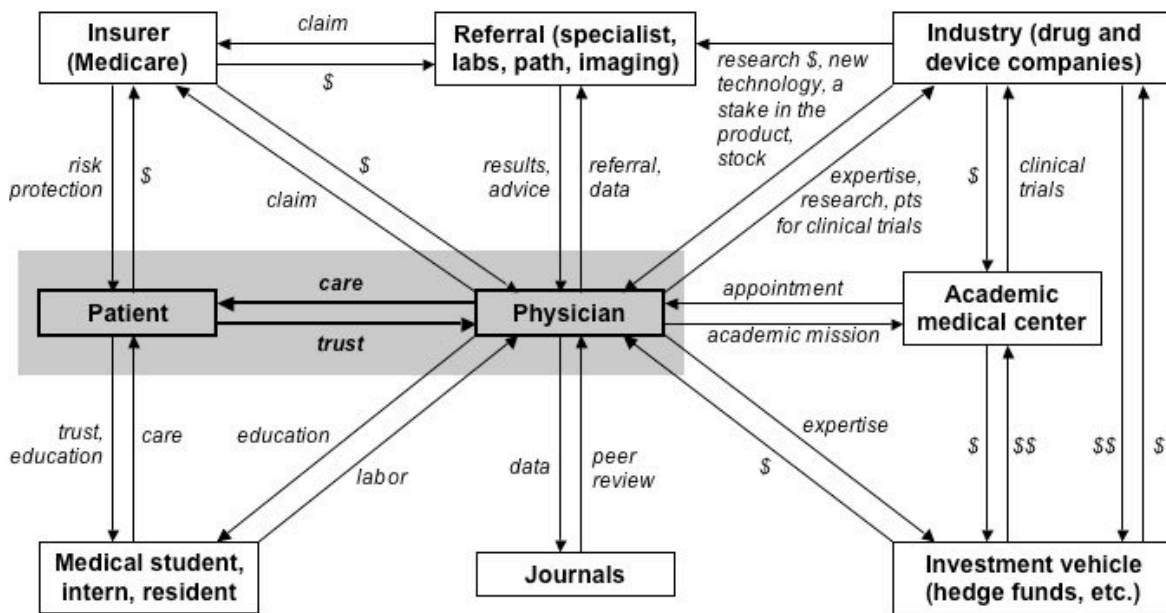
The primary interest, according to Thompson (1993), is determined by professional duties. To a physician, the primary interest most often takes the form of a patient's health, research integrity, or trainee education. The secondary interest may similarly be an inherent component of the profession

and is, by itself, an acceptable piece of clinical practice. However, the relative weight of the secondary interest in professional decisions—the appearance, or reality, that it dominates the primary interest—is what renders it problematic.

An Outline of Relationships in Medicine

The figure below could represent the second slide shown to the audience in the case narrative. It is by no means a comprehensive representation of relationships in academic medicine, but it is meant to provide a basic outline for subsequent discussion. A key question to keep in mind in the discussion of all conflicts of interest, financial or otherwise, is: How does the conflict affect the physician’s care of the patient and the patient’s trust of the physician?

Day 2 focuses on medical fraud, kickbacks, and the Stark laws and the anti-kickback statute as ways that financial conflicts of interest have been addressed in the medical marketplace. This is often a relatively unfamiliar area to medical students. Day 3 focuses on the academic-industry relationships and the broad array of conflicts in that hemisphere of medicine. Day 4 offers a brief overview of proposed solutions for addressing conflicts of interest.



Resources

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Day 2: 1:37 p.m., Tuesday, July 22, 2008

With Jesse Gelsinger still in mind, you hurry back to your office, late for your 1:30 patient. Mrs. Johnston is a 68-year-old retired high school English teacher. A pleasant woman, she was one of your first patients after you moved here. “How is your wrist?” you ask, happy to see her again.

“Oh, the wrist is coming along fine. I think I can see the physical therapist soon.” When you first met Mrs. Johnston, she had suffered a fall and broken her wrist. It was an unfortunate accident, happening as she paused to catch her breath while climbing the stairs. At the time, you were also concerned about her increasing dyspnea, but after taking a careful history and examining her, you had decided to focus on her wrist, which bothered her tremendously.

Mrs. Johnston says she is still having trouble putting on her shoes because of swelling in her ankles and lower legs. “It’s about the same as when I last saw you,” she added. She has also continued experiencing occasional shortness of breath while shopping or playing with her grandchildren. “It’s been going on for years, but I feel like I have to rest a little longer now. I still have plenty of energy during the day, but maybe not as much as I used to.”

Like last time, she denies chest pain and fever. She is a nonsmoker and has no history of MI or CAD. However, she does have a longstanding history of hypertension, usually mild. She is self-sufficient in her activities of daily living. Family history is significant for colon cancer. She is allergic to sulfa drugs and takes no medications other than calcium supplements.

On physical examination, Mrs. Johnston is well-appearing and afebrile with a BP of 155/78, HR of 78, and RR of 18. There is slight dullness to percussion over both lung bases and rales bilaterally on auscultation. An S₃ is audible with distant heart sounds. There is 2+ peripheral pitting edema with no JVD or hepatomegaly. The rest of her exam is unremarkable.

After giving Mrs. Johnston a referral to a reputable physical therapist, you explain that you would like to obtain a CBC to rule out anemia and a CXR and echocardiogram to check her heart and lungs. You also wish to start her on an ACE inhibitor to lower her blood pressure and advise her to decrease her salt intake. She is receptive to your advice and agrees to see you next month. You promise to call with lab results and wish her luck with physical therapy.

Returning to your office, you see that you have a message from the very physical therapist group to which you just referred Mrs. Johnston. “We are calling to thank you for referring your patient, Mr. Stevens, to us last week. It was your tenth patient we have had the privilege to work with, and we are delighted to participate in the care of your patients. As a token of our appreciation, we would like to present you and your group practice a \$500 contribution for general research and education purposes.”

Discussion Questions

- How would you react to the voicemail?
- How does fraud affect the health care system and the doctor-patient relationship?
- What are some remedies for dealing with kickbacks, self-referrals, and false claims?
- In what ways do you think antifraud laws may be problematic?

Post-case Discussion

Health Care Fraud

Fraud is defined as an intentional act of deception that is designed to exploit or swindle a victim. Health care fraud is seen as a significant contributor to our escalating cost and suboptimal quality of care (Kalb 1999). It is thought that physicians who have extra incentives to make referrals or utilize services contribute to the national overspending (Manchikanti and McMahon 2007). The US General Accounting Office has estimated that health care fraud accounts for 10% of health care expenditures (Kesselheim and Studdert 2008, US GAO 1992)

In 1996, the Health Insurance Portability and Accountability Act (HIPAA) established the Health Care Fraud and Abuse Control program (HCFAC) to enforce the antifraud regulations. HCFAC is run by the Department of Justice (DOJ) and the Office of the Inspector General (OIG). Single providers and groups that violate one of the health fraud statutes described below can face imprisonment and fines greatly exceeding the value of the fraudulent transaction. Moreover, violators are subject to “collateral” consequences at the discretion of the OIG, including exclusion from programs like Medicare and Medicaid, civil monetary penalties, and loss of licensure. In medicine, federal and state laws prohibit three primary types of misconduct: (1) submitting false claims, (2) paying or receiving kickbacks, and (3) making self-referrals. These are outlined below.

False claims. A false claim is the improper billing of an insurer, in this case the government, by a provider. False claims can be organized into several categories: upcoding (billing the government for more care than is provided), unbundling (making multiple claims out of products or services that are meant to stand a single claim), phantom billing (billing for care not provided), falsifying documents, inflating prices, billing for unnecessary care, and billing for substandard care (Kesselheim and Studdert 2008).

The federal False Claims Act prohibits the knowing submission of false claims, statements, or certifications to the government, as well as conspiring with others or causing others to submit false claims (False Claims Act 1998). Violations carry damages up to three times the amount of the false claim and a mandatory penalty of \$5,500 to \$11,000 per claim, no matter the size of the claim (Kalb 1999).

The False Claims Act is mostly used in cases involving the billing process itself. The act does not criminalize the accidental or even negligent submission of false claims, requiring that a guilty provider must know that he or she is submitting a fraudulent claim or must otherwise demonstrate “reckless disregard” for the truth (Kalb 1999). However, this stipulation does not remove the careless provider from prosecution. The case *United States v Krizek* demonstrated, for example, that failing to review bills that upcoded services before sending them off for reimbursement is within the realm of “reckless disregard” (US v Krizek 1997).

One interesting aspect of the False Claims Act has been its extension into quality of care. It has been used in attacking suboptimal care, with the argument that claims are submitted with the implicit certification of having met legal standards for quality. Thus, submitting a claim for poor care is the same as submitting a false claim (Hoffman 1996, Kalb 1999). The government has embraced this application of the law and has expanded its role in policing deliberate denials, withholding necessary services, and providing poor quality care (Sheehan 1998).

In addition, the False Claims Act is also unique because it can be enforced by an agent acting independently—the whistle-blower. A whistle-blower can act on behalf of the United States in filing a suit alleging fraud under the *qui tam* provision of the False Claims Act. Like the DOJ, such persons are also eligible to recover three times the amount of the government’s loss plus \$5,000 to \$10,000 per false claim (Kalb 1999). This provision introduces a strong deterrent against the provider, as any person who has knowledge of fraud stands to gain personally by reporting it.

In recent years, whistle-blower activity has escalated (Kesselheim and Studdert 2008). The number of cases increased dramatically from 1996 to 2001. While it has decreased since then, the average recovery amount per case has continued to climb, because of a rise in cases against the pharmaceutical industry (Kesselheim and Studdert 2008). Throughout this period, whistle-blower recoveries averaged \$3.6 million per case, for a total of about \$1 billion recovered, and that’s only counting 72% of cases with information available. In all, three-fourths of whistle-blowers are internal employees, most often physicians or administrators (Kesselheim and Studdert 2008).

Kickbacks and the anti-kickback statute. A kickback is any bribe, rebate, or other remuneration of value designed to induce the purchase or sale of health care, including the gift offer presented in the case, which can be interpreted as an inducement for the physician to refer more patients in the future. While almost every state has its own laws against kickbacks, the federal anti-kickback statute makes it a felony for any person or group to pay a remuneration “to any other person to induce that person either to purchase a product or to refer a patient (if the cost of the product or service ultimately will be borne by one of the government health programs)” (Kalb 1999, 42 USC §1320a-7b 1998). Since the patient in this case is older than 65 years and covered by Medicare, the cost of the physical therapy is borne by the government and thus the monetary gift violates the anti-kickback statute.

Moreover, the statute prohibits the receipt or solicitation of any such payment or bribe, making the paying and receiving parties equally liable (Kalb 1999, 42 USC §1320a-7b 1998). Upon closer reading, a strict interpretation of the statute forbids a health care provider or manufacturer from transferring basically anything of value to a referral source (the physician in our case) and similarly, a referral source from receiving basically anything of value. A thing of value can also be in the form of a discount for the referred service or product, essentially rendering it a rebate. Read literally, this law is very broad and would forbid many ordinary transactions.

Thus, Congress approved a set of exceptions and “safe harbors” within which transactions may legally proceed. One such exception is payments to legitimate employees. Another is discounts that are properly disclosed and appropriately reflected in a provider’s claims (Kalb 1999).

Precedent decisions to date have established that the anti-kickback statute can be violated even if only a single purpose of the payment was to induce referrals (US v Greber 1985). In 1998, the Supreme Court held that it is enough to show a person acted with “an evil-meaning mind,” rather than with specific knowledge of violating the statute (Kalb 1999). In other words, the government needs only to prove that a defendant knew he or she did wrong, whether or not he or she actually knew about the statute (Kalb 1999).

The OIG stated in an advisory opinion: “[W]hen a laboratory offers or gives to a referral source anything of value for less than fair market value, an inference may be made that the thing of value is offered to induce the referral of business” (OIG 1999).

Self-referral and the Stark laws. A 1994 study by the US General Accounting Office showed that physician owners of diagnostic imaging services referred their patients more often and for more expensive procedures than nonowners. This amounted to 54% more MRI scans, 27% more CT scans, 37% more nuclear medicine scans, 27% more echocardiograms, and 22% more ultrasounds and X-rays (US GAO 1994).

The Stark laws regulate self-referrals, the practice by which physicians refer patients to providers of health care services or equipment in which the physician or a family member has a financial stake or compensation agreement. The Stark laws in many ways overlap with the anti-kickback statute, but there are a few important differences.

The Stark laws, also known as the Ethics in Patient Referral Act, is named after Congressman F. Pete Stark (D-CA). The law has evolved through several phases. The first, Stark I, took effect on January 1, 1992. It forbade physicians from referring Medicare patients for clinical laboratory services, such as blood tests and pathology services, if the referring physician or an immediate family member had a financial interest in, or a compensation agreement with, the provider of the laboratory service (ORA 1990). The financial interest could be either ownership or an investment. A compensation agreement could be in the form of any remuneration. Moreover, the laboratory was not allowed to bill for such services.

Stark II became effective in 1995 (ORA 1993). It extended the Stark I ban to a list of “designated health services” and to services and supplies rendered to Medicaid beneficiaries. The list included physical therapy, occupational therapy, speech-language pathology, radiology, radiation services, durable medical equipment and supplies, prosthetics, home health services, and outpatient drugs.

Penalties for Stark law violations include denial of the payment in question, refund of payment, a \$15,000 per service/claim civil penalty, and a \$100,000 civil penalty for each arrangement that is considered to be a circumvention scheme. On top of it all is a \$10,000 per day penalty for failure to produce records (Manchikanti and McMahon 2007).

Similar to the anti-kickback statute, the Stark laws were broad and required exceptions to have realistic enforcement. Otherwise, many ordinary transactions involving physicians or their family members would stand in violation. In response, Congress developed three categories of exceptions: (1) those involving ownership or investment interests, (2) those involving compensation arrangements, and (3) those involving both ownership and compensation. For a contract between a provider (or a family member) and a “designated health service” to be legal, it must satisfy one of these exceptions. Exceptions to ownership include publicly traded securities and mutual funds. Exceptions to compensation arrangements include the rental of office space or equipment, bona fide employment, and physician recruitment. Exceptions to both ownership and compensation include physician services, in-office ancillary services, and certain preventive care services, such as vaccinations (Manchikanti and McMahon 2007).

Important differences between the anti-kickback statute and Stark laws include the fact that Stark law violations are civil offenses, while anti-kickback violations are criminal (Kalb 1999). Second, Stark laws apply only to physicians (Kalb 1999). Third, one is guilty under Stark laws unless meeting an exception, whereas one does not automatically violate the anti-kickback statute for failing to meet

a particular safe harbor (Manchikanti and McMahon 2007). Fourth, Stark laws do not require intent, and a physician can violate them without knowledge of wrongdoing (Kalb 1999).

Problems with Anti-Fraud Laws

Several unfortunate consequences of anti-fraud legislation and enforcement are worthy of note. First, it has helped transform the medical record from a clinical tool to a legal document. Second, anti-fraud law does not deal sensibly with managed care, in which underuse and misuse, rather than overuse, are the main concern (Sage 1999). In a sense, the laws constrain and penalize health care workers for entering into agreements that are logical elsewhere in our economy (Sage 1999). Third, while fraud liability has become a way of life for large hospitals and health plans, they do not alleviate the individual physician's fear of unwarranted prosecution.

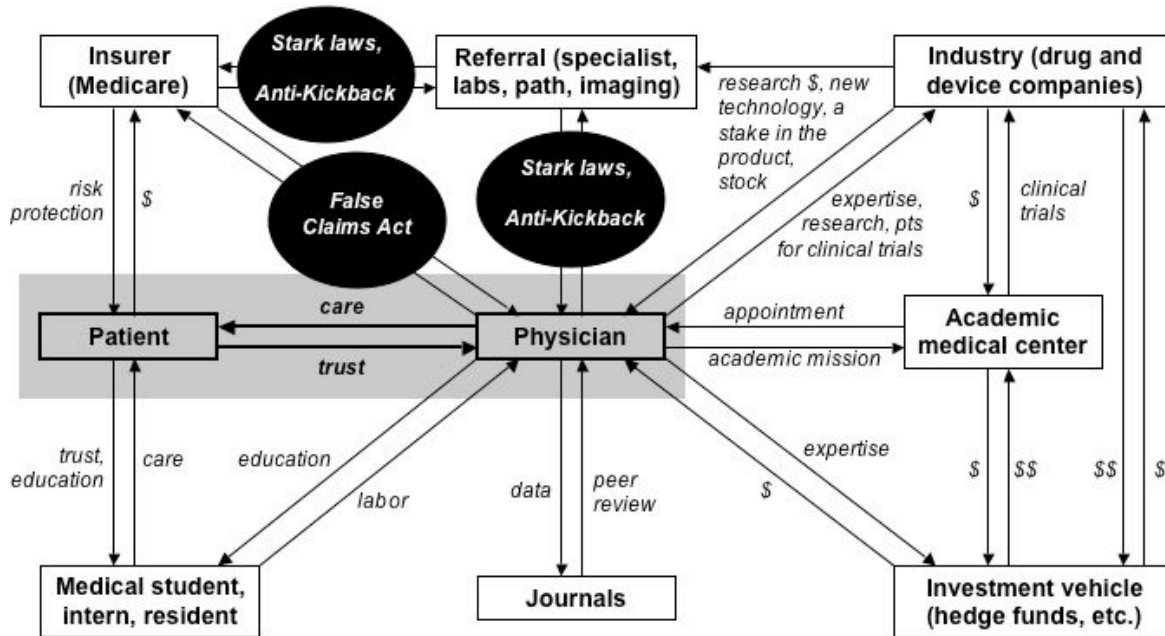
Toward their goal of decreasing health care expenditure and improving health care quality, there remain unanswered questions surrounding the laws. Perhaps the most important is whether they will produce enough savings to offset their cost of enforcement. In 2005, an estimated \$8 billion was spent unnecessarily on services in physician-owned outpatient centers (Angrisano et al. 2007). However, as Manchikanti and McMahon (2007) contend, that is still just 0.4% of the \$1.9 trillion health care budget in 2005. Moreover, with health care expenditures expected to exceed \$4 trillion by 2016, there is no evidence to suggest that switching the physician-owned outpatient services back to hospital care will cut costs (Manchikanti and McMahon 2007).

While enforcing these laws will indeed require more expenditures, there is evidence to suggest it is money well spent. From 1996 to 2005, the DOJ closed 379 health care fraud cases totaling \$9.3 billion, with recovery amounts rising sharply from 2002 to 2005 (Kesselheim and Studdert 2008). It has been calculated that the government's return on investment is \$15 recovered for every \$1 invested in enforcement efforts (Kesselheim and Studdert 2008; Meyer, 2008). With increasing prosecution experience in medical fraud cases and increasing incentives for states to get involved as well, the government may further increase its efficiency in the years ahead.

Preserving the Doctor-Patient Relationship

Health care fraud needs to be addressed because it introduces financial conflicts of interests into clinical judgment, which ultimately displaces the primary interest of the physician's work. It may also damage patients' trust of the medical profession, which may be the greatest cost of all. Anti-fraud laws, after all, are intended to steer physician interests in line with patient interests.

Inherent in their goals is an effort to ensure that when a clinical decision is made, whether for a treatment or a referral, the only factors influencing that decision are those most immediate to the condition and care of the patient. In other words, the care that is warranted solely by clinical considerations is the care that should be chosen. It is, under usual circumstances, what the patient would prefer, and so these anti-fraud laws seek to align the physician's decision-making along these preferences. In essence, they are a guardrail helping to prevent the physician from veering towards incentives well-designed to hijack their primary interest—incentives founded upon the benefit of entities other than the patient. Their primary interest, we recall, is the patient's welfare.



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Day 3: 8:00 a.m., Thursday, October 7, 2010

Two years after beginning your appointment, you have a strong patient base and meaningful longitudinal relationships with your patients. You enjoy teaching in the medicine rotations for third-year students and rounding with interns and residents each month. As the principal investigator of several successful clinical studies, you were recently appointed to assistant professor of medicine. Last year, you served as a coinvestigator on a clinical trial examining a new ACE inhibitor and loop diuretic combination drug for the treatment of heart failure. The combo drug was designed to have fewer side effects related to ACE inhibitor (particularly hyperkalemia) and loop diuretic (hyperuricemia), with improved survival compared with each drug alone.

When the study began, Mrs. Johnston had come back to see you. She had reported that for six months after her wrist healed, she was able to restrict salt intake, remain active, and follow her medications, which included a loop diuretic, potassium-sparing diuretic, and the initial ACE inhibitor. However, she was concerned that her symptoms had worsened. She apologized for missing her last two appointments with you and reported worsening dyspnea on exertion. On examination, Mrs. Johnston was stable with a BP of 160/72, HR of 80, and RR of 16. She had gained 10 pounds since you met her in 2008, and her bilateral ankle edema had not subsided. Pulmonary rales were still evident over both bases with a faint S₃ heart sound. After carefully considering your options, you discussed the new combination drug trial with Mrs. Johnston. You first disclosed your role in the trial and then explained to her that the study randomizes patients to either the combination drug or the traditional regimen that she was taking at the time. Thus, there would be no risk of being placed on a placebo. As a phase III trial, the combo drug had passed safety and efficacy tests in healthy volunteers.

Mrs. Johnston had thought deeply about the trial. She had picked apart every sentence of the informed consent language and exhausted your knowledge of pharmacology. “I have trusted you with my health the last two years, and if you think this will be worthwhile, I will be happy to participate,” she had said in the end. You promised your diligence in her follow-up.

During this past year, the study went on at 22 academic medical centers across the country. It was double-blinded. You submitted periodic site reports to the data safety monitoring board set up by the pharmaceutical company. You have enrolled 27 of your patients to date, most of whom, like Mrs. Johnston, trusted your judgment. Along the way, you had heard through several colleagues that the company that manufactures the combination drug was a committed supporter of research projects at your academic medical center, contributing toward basic science research, continuing-education programs, and training grants for residents. You had begun to suspect that the relationship between your academic medical center and the company was more complex than the clinical trial arrangements.

Discussion

- How do financial conflicts of interests between academics and industry take shape?
- In what ways can they affect individual decision-making? Institutional decision-making?
- How do patients and physicians feel about financial conflicts of interests between academic medicine and industry? How do you feel about them?

Post-case Discussion

Framing the Problem

Conflicts of interest in any segment of the research protocol can jeopardize research integrity in favor of financial interests to industry. There is strong evidence that publications by researchers with ties to industry are much more likely to favor industry products than those by researchers without such ties (Ridker and Torres 2006, Bekelman et al. 2003, Bodenheimer 2000). In the individual investigator-industry relationship alone, conflicts of interest can arise in study design, data collection and analysis, authorship of publication, content of publication, and the decision of whether to publish results at all.

For example, in formulating study design for a clinical trial, drug companies may use a variety of techniques to increase the favorability of results. They could test a drug in a healthier population with fewer health conditions, compare a drug to an insufficient dose of a competing drug, or use surrogate endpoints that may not accurately reflect clinical endpoints (Bero and Rennie 1996, Rochon et al. 1994, Johansen and Gotzsche 1999, Bodenheimer 2000). Rochon et al. (1994) found that in almost half of nonsteroidal anti-inflammatory drug trials, the competing drug was given at a lower dose. Johansen and Gotzsche (1999) reported that trials for the antifungal agent fluconazole compared the drug to oral amphotericin B, which is better absorbed intravenously.

The key question here is whether clinical investigators will be inclined to speak up and address these flaws in research design in the face of financial support from industry? Would you?

More than biasing the content of research, conflicts of interest may actually motivate researchers to undertake projects entirely on the basis of whether there is available industry funding, rather than on scientific importance (Angell 2000). Blumenthal (2003) argues that of greatest concern are financial conflicts that “result in economic gains to investigators and universities above and beyond reimbursement for the costs of research, such as the income that results from consulting, equity-holding, patenting and licensing.”

These economic gains may in themselves be enticing to the investigator. Additionally, however, they may be difficult to walk away from, even if one wished to do so. Bodenheimer (2000) offers a quote from a physician experienced in industry-funded drug trials to demonstrate this point:

Companies can play hardball, and many investigators can't play hardball back. You send the paper to the company for comments, and that's the danger. Can you handle the changes the company wants? Will you give in a little, a little more, then capitulate? It's tricky for those who need money for more studies.

Investigators, Institutions, and Industry—The Extent of Relationships

Relationships between academic institutions and industry are ubiquitous. In an editorial in the *New England Journal of Medicine*, former editor Dr. Marcia Angell writes:

For financially struggling medical centers, it means cash. For the companies that make the drugs and devices, it means access to research talent, as well as affiliation with a prestigious “brand.” The time-honored custom of drug companies’ gaining entry into teaching hospitals by bestowing small gifts on house officers has reached new levels of munificence. Trainees now receive free meals and other substantial favors from drug companies virtually daily, and

they are often invited to opulent dinners and other quasi-social events to hear lectures on various medical topics. All of this is done with the acquiescence of the teaching hospitals (Angell 2000).

As early as 1994, companies spent about \$1.5 billion to support some 6,000 projects in the life sciences in US universities (Blumenthal et al. 1996). At the time, that amounted to 14% of the total funding for academic research in the life sciences (Blumenthal 2003).

A review of 37 studies documenting financial relationships between industry and investigators or institutions showed that about one-fourth of investigators had industry ties, and two-thirds of institutions held equity in start-up companies that funded research conducted at the institutions (Bekelman et al. 2003). The authors found a statistically significant association between industry funding and pro-industry findings in publications, as well as an association between industry funding and restrictions on publication and data sharing. That relationships with industry reduce the openness of communication is also evident in a 1996 industry survey, which found that more than half of biomedical company executives admitted that their research agreements with universities restricted the open communication of results (Blumenthal 2003).

In a 2000 case study of the University of California, San Francisco, faculty members, Boyd and Bero found that 7.6% of faculty investigators had personal financial ties with the sponsors of their research. These financial ties took the form of paid speaking engagements (\$250 to \$20,000 per year), consulting agreements (<\$1,000 to \$120,000 per year), positions on an advisory board or board of directors, and holding equity in the company (Boyd and Bero 2000).

In 2007, Campbell and colleagues published a national survey of 459 medical school department chairs at 140 institutions, which found that 67% percent of departments and 60% of department chairs have relationships with industry. In this study, nonclinical departments were more likely to enter into relationships with industry than clinical departments, which the authors attribute to the likely greater degree of licensing and product development activities associated with nonclinical departments. Clinical departments, on the other hand, were far more likely to receive discretionary funding to purchase equipment and support research seminars, graduate medical education, and continuing medical education (Campbell et al. 2007).

One argument in favor of institution-industry relationships is that they facilitate the movement of drugs and devices from the laboratory to the market, ultimately benefiting patients. A corollary argument is that this is justified by the Bayh-Dole Act of 1980, which encourages academic institutions to patent their discoveries and share royalties from the products with their faculty.

Another argument, pointing to reality, is that academic institutions simply need the money to operate—conduct research, support education, and compete academically (Angell 2000). In 2007, for example, funding for new grants from the National Cancer Institute decreased by more than \$12,000,000 from 2006 (NIH 2007). Recent cuts in Medicare reimbursements also compound the financial difficulties. A 2007 article in the *Washington Post* reported that pharmaceutical and medical device companies pay for two-thirds of the cost of continuing medical education in medical schools and teaching hospitals (Williamson and Lee 2007). Campbell and colleagues (2007) also found in their survey that 65% of clinical departments received industry money for continuing education and 37% for residency and fellowship training programs. Interestingly, the majority of department chairs

surveyed were confident that such relationship with industry had no effect on their professional activities (Campbell et al. 2007).

Indeed, it is undeniable that industry funding plays an important role in promoting research and product development (Moy 2008). But this recognition also raises two very important questions: first, what is being sacrificed for this arrangement that is also valuable to us—to doctors, to patients, and to the medical profession? And second, if indeed these relationships influence the behavior and judgment of investigators and institutions alike, at what point do we say enough; at what price are we giving away too much for the research help and product development? The price, of course, is clinical judgment. It is patient welfare. It is the integrity of medicine. And so these are, in a way, moral questions, which at the very least deserve our attention.

Investigators, Institutions, and Industry—The Impact of Relationships

The extent of institution-industry relationships suggests that working with industry has brought many benefits to investigators and universities. The evidence says the same. Beneficiaries of the funding claimed that industry support involved less red tape and brought more prestige to their schools (Blumenthal et al. 1996). Industry-funded researchers were more likely to be involved in technology-transfer activities like patenting and licensing than were researchers who adhered to the traditional path of publications and scientific presentations (Blumenthal 2003, Blumenthal et al. 1996, Cohen et al. 1994). In addition, universities were granted 131% more patents and 158% more licenses in 2000 than in 1991, with their corresponding income from licensing jumping from \$121 million in 1991 to \$997 million in 2001 (Blumenthal 2003).

An early survey of more than 1,200 faculty members at 40 major universities found that researchers with industry support published more, applied for more patents, and earned more than colleagues without industry support (Blumenthal et al. 1986). They were also more likely to withhold research findings from the public in order to protect their proprietary value (Blumenthal et al. 1986). Ten years after this initial study, Blumenthal and colleagues surveyed more than 2,000 faculty members at 50 leading research universities and found a similar set of associations: faculty with industry support had more peer-reviewed publications, reported more trade secrets, and engaged in more commercial transactions (Blumenthal et al. 1996). They engaged in more administrative activities as well.

However, not all outcomes were beneficial. The study also found that faculty who received more than two-thirds of their funding from industry were less productive and published less-influential articles than did their peers who did not receive as much support from industry (Blumenthal et al. 1996). Thus, perhaps there is a ceiling, at least from an academic career point of view, on how much benefit individual investigators can derive from industry.

The impact of relationships between academic medicine and industry has not gone unnoticed. Institutions have responded in many ways to prevent their influence, which is a topic of the final day of this case. For now, it may be reassuring to note that, in general, the academic community is aware of the risks of industry influence. In a 2005 survey of 2,400 faculty who had recently published clinical research, Mello and colleagues found that 92% believe it was inappropriate to allow industry sponsors to veto decisions to publish (Mello et al. 2005a). In a different survey of 107 institutions, 85% of administrators reported that they would not approve contracts that gave industry control over the decision to publish (Mello et al. 2005b).

At the same time, these surveys also uncovered causes for concern. About 4 in 10 investigators who run clinical trials report they are accepting of provisions that allow companies to insert their own statistical analyses into papers (Mello et al., 2005a). Institutions, too, varied considerably on whether companies could draft manuscripts, insert their own analyses, or prohibit investigators from sharing results (Mello et al., 2005b). Being involved in clinical trials, being a junior faculty, and having high levels of industry funding were all associated with greater willingness to accept contracts with pro-industry stipulations (Mello et al., 2005a). Why these characteristics have an association with greater tolerance of industry influence is something we should also think about.

Examples of Academic-Institutional Relationships That May Influence Research Integrity

Ghost authorship. One way in which academic-industry relationships have encroached on the integrity of research is through the publication process. Ghost authorship—the practice whereby industry personnel prepare manuscripts in the name of academic investigators—is not uncommon. In a 1998 survey of 809 corresponding authors across six major peer-review US medical journals, all of which follow the International Committee of Medical Journal Editors (ICMJE) criteria, Flanagan et al. found that 11% of studies had evidence of ghost authorship, another 21% had evidence of honorary authorship, and 2% had evidence of both. In a telling editorial, Brennan describes the way this practice works: “The caller said that I would not really have to do much work on this project. I would discuss the matter with them, and they would then have a professional writer compose the editorial, which I could modify as I saw fit. I would earn \$2,500 for what was estimated to be several hours of work.” (Brennan 1994)

Honorary authorship is defined as a guest or gift authorship, in which an individual who does not meet authorship criteria is named as an author (Rennie and Flanagan 1994, Rennie et al. 1997). Ghost authorship, on the other hand, is defined as a failure to name as an author someone who made significant contributions to the preparation or writing of the manuscript (Rennie et al. 1997).

A recent case study of industry documents from litigation involving the drug rofecoxib shows that in the practice of ghost authorship, recruited authors are often placed first or second on the authorship list (Ross et al. 2008). The manuscript, meanwhile, is prepared by the drug company or medical publishing companies. This happened in both clinical trial articles and review articles, and the attributed author often did not disclose industry support (Ross et al. 2008).

Ultimately, the concern of ghost authorship is the direct undue influence of the peer-reviewed literature, which serves as the evidence basis for clinical treatment decisions. Recall the Claudia Henschke case, which raised the same concerns even though it did not directly involve ghost authorship. Journals grant authorship on the assumption of integrity and accountability, which translates into public trust in the evidence and interpretations provided. Influence from industry in this process creates a conflict of interest that not only jeopardizes the integrity of research, but also potentially damages public trust in the medical profession.

Academic institutions and the investment industry. In addition to pharmaceutical companies and medical-device manufacturers, conflicts of interest also exist between academic institutions and a separate—though not unrelated—industry. Almost 10% of US physicians have a formal relationship with the investment industry (Topol and Blumenthal 2005, Bodow 2001). Among investment entities that seek physician advice, the biggest proportion now seems to come from

hedge funds, which traditionally bet on the success or failure of stocks using high-risk strategies (Maler 2005, Topol and Blumenthal 2005).

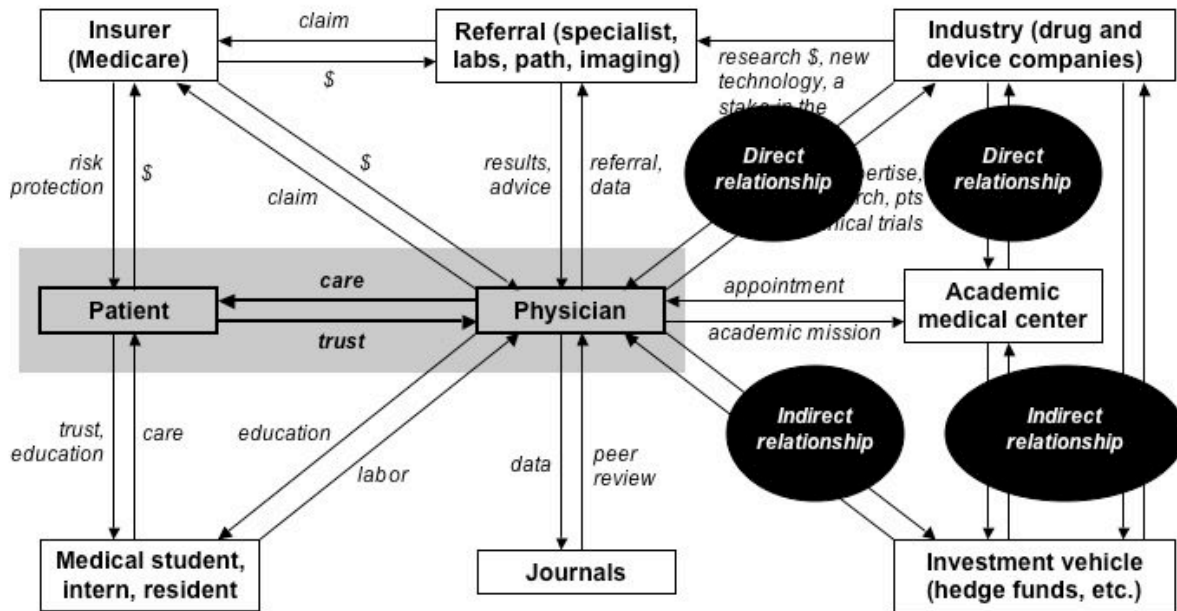
As much as one-third of hedge fund investments are directed at pharmaceutical, medical-device, and other biotechnology or life-sciences companies (Topol and Blumenthal 2005). This situation then completes the indirect relationship between clinical researcher or academic institution and industry, establishing financial conflicts of interest not unlike those found in direct academic-industry relationships. Investment firms have an incentive for obtaining expert advice or inside information from physicians. According to a Pulitzer Prize-winning *Wall Street Journal* article by Anand and Smith, physicians are paid as much as \$1,000 per hour for consulting with the investment industry. In fact, there is an entire industry for managing such consultation agreements and relationships. Topol and Blumenthal (2005) cite an example of one such company based in New York, which has contracts with more than 60,000 physicians and 50 asset-management firms; similar companies exist in other major cities, often conducting business with physicians and investment firms over the Internet.

Like direct academic-industry relationships, such indirect relationships equally jeopardize the objectivity of clinical judgment. Referring back to Thompson's (1993) theory of conflicts, the primary interest of patient well-being is compromised. According to Topol and Blumenthal (2005), physicians have traditionally not considered investment relationships to be a conflict of interest. Is it enough to merely require disclosure of such relationships in papers?

Patient attitudes toward financial conflicts of interest. Three studies show varying degrees of patient attitudes toward financial conflicts of interest. Through in-person interviews with 253 patients participating in cancer-research trials, Hampson and colleagues (2006) found that 90% of patients expressed little worry about financial ties between researchers or institutions and drug companies. Eighty-two percent of patients interviewed reported that they would have enrolled in the trial even if the drug company had paid the investigator royalties for speaking, and 76% reported being willing to enroll even if the researcher owned stock in the company. Similarly, 77% and 79% would do so if their cancer center had owned stock in the company or received royalty from the company, respectively. Forty percent of patients wanted disclosure of the oversight system for researchers, while 31% wanted disclosure of the investigators' financial interests.

A subsequent study by Gray et al. (2007) showed that 44% of 102 advanced cancer patients in phase I clinical trials reported concern about financial conflicts of interest. A slight majority (52%) believed that financial conflicts of interest should be disclosed to patients in clinical trials. Interestingly, a greater majority of patients (61%) believed that intrinsic conflicts of interest were a more serious concern than financial conflicts. Patients reported a greater amount of concern about investigators who did research for "selfish" reasons or who used patients as "guinea pigs" than about investigators who reaped financial rewards. In the end, a majority of patients would still be willing to participate after learning of conflicts of interest.

In a third study, Kim et al. (2004) surveyed potential research participants online and found that a great majority of respondents felt financial conflicts of interest should be disclosed (64% to 87%). More respondents were concerned with individual than institutional conflicts of interest. Across the different scenarios presented, a majority were still willing to participate.



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Day 4: 8:03 a.m., Friday, October 8, 2010

Looking at the charts of your 27 enrolled patients neatly stacked on your shelf, you wonder how they may react upon learning of the financial relationships between your institution and the pharmaceutical company that manufactures their trial drug. You had followed protocol and meticulously walked each patient through the informed-consent process, answering all of their questions. However, you are still uneasy. Something about the arrangements just does not feel right. You wanted the best for your patients. You wanted to run a good clinical trial.

Were the two wishes ever in conflict?

Your first patient this morning canceled, so you take your curiosities to the medical library, eager for answers. Are there any checks and balances in place against conflicts of interest? What is my department doing to ensure that my coinvestigator and I are doing this study properly and ethically? What is my institution doing to protect itself from conflicts of interest?

As a clinical researcher, you were trained in patient-confidentiality issues and informed-consent procedures through your institution's HIPAA certification program. While designing clinical studies, you had multiple interactions with your hospital's institutional review board and are now familiar with IRB rules and regulations as well. Through preparing manuscripts for peer-review journals, you also became familiar with the uniform requirements of the International Committee of Medical Journal Editors (ICMJE). Despite this knowledge, you remain uneasy over your contractual obligation with the pharmaceutical company in your trial and its financial relationship to your institution.

Reading through articles on the scope of financial conflicts in medicine, its prevalence in the academic setting, and editorials from prominent physician-leaders, you begin to ask different questions than before. You begin to focus on the incentives behind the scenes.

- “If my institution had refused to accept its donation for research and education, would the pharmaceutical company have chosen another site to conduct its trial?”
- “If my institution had refused to accept pharmaceutical donations, would it have been able to open the new Center for Neurology and Behavioral Sciences across the street?”
- “If I were not a coinvestigator in this clinical trial, would I have been so eager to enroll Mrs. Johnston and the other 26 patients into the study, even given their clinical indications?”

You imagine that there would be sobering answers to these questions. You read on, hoping to discover something that would reassure you that the sacred space occupied by the physician-patient relationship is protected from conflicts of interest.

Discussion Questions

- Who should regulate financial conflicts of interest?
- What do you think regulation should consist of?
- What are some advantages and limitations of disclosure?
- What do you know about your institution's policies for dealing with conflicts of interest?
- What are some strengths and weaknesses of your institution's policies?

Post-case Discussion

The Purpose of Regulation

In his seminal 1993 paper, Thompson proposes two main reasons to regulate conflicts of interest. The first is to maintain the integrity of professional judgment. Referring to the primary and secondary interests, Thompson argues:

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.... 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 second purpose of regulation is to maintain confidence in professional judgment. “The aim,” Thompson writes, “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 (Thompson 1993).” Recall that in Thompson’s theory, a financial conflict of interest is a condition, not a behavior. It can exist regardless of whether researchers who stand to benefit from them actually do benefit.

Individual Disclosure

One of the major themes in proposals to prevent financial conflicts of interest is independence between researchers and industry (Angell 2000, Bodenheimer 2000). Angell (2000) writes, “Cooperation should be at arm’s length, with both sides maintaining their own standards and ethical norms.”

But given the existence of a financial conflict of interest, the one frequent remedy to deal with it is disclosure. Disclosure is a central tenet of IRB policies, ICMJE uniform requirements for manuscript submission, and academic institutions’ self-imposed regulations on their own faculty investigators. The ICMJE uniform requirements, which have been adopted by most peer-review medical journals, state in no uncertain terms that, “When authors submit a manuscript, whether an article or a letter, they are responsible for disclosing all financial and personal relationships that might bias their work. To prevent ambiguity, authors must state explicitly whether potential conflicts do or do not exist” (ICMJE 2007).

During 2001 and 2002, the Association of American Universities (AAU) and the Association of American Medical Colleges (AAMC) published national policy recommendations dealing with conflicts of interest in individual investigators. In 2004, the US Department of Health and Human Services (USDHHS) released guidelines for human-subject protection stemming from financial conflicts. Disclosure is a common theme. The AAMC recommends that, “Disclosure...should include an explanation of the fact that the financial interest in question has been reviewed by the conflict of interest committee, approved subject to committee oversight, and determined by both the committee and the IRB not to pose any additional risk to the welfare of research subjects or the integrity of the research” (Task force on financial conflicts of interest 2001).

Simply put, physicians should disclose to patients their financial stake, and scholars should disclose to readers their financial support, Thompson (1993) argues.

There are at least two notable goals of disclosure. The first is derived from the ethical principle of autonomy. Patients and research participants should be provided information that is important for making informed decisions (Weinfurt et al. 2006). In theory, disclosure allows independent minds to exercise independent judgment over their decisions, free from coercion and other undue influence. The disclosed information should contain all conflicts of interest, and the information should be delivered in a clear and usable way (Weinfurt et al. 2006).

The second goal of disclosure, and most relevant to this case, is to deter researchers from having significant conflicts of interest (Weinfurt et al. 2006). If researchers are made to believe that the conflicts of interest, if publicly known, would reflect unfavorably upon their work, then they are more likely to avoid having such conflicts altogether.

A third goal may simply be to comply with requirements and protect against legal threats (Hall et al. 2003, Resnik 2004, Weinfurt et al. 2006).

Disclosure, however, is not without its limitations. Those who receive disclosure may not have the capacity to correctly interpret the information, nor may they be in a position to do anything about it (Rodwin 1989). Disclosure on its own may generate more anxiety for patients and more suspicion for the audience of research, as it presents a problem but fails to offer any solutions for dealing with it (Rodwin 1989, Thompson 1993). Frequently, it is a release of responsibility but not a path toward truly informed consent.

Institutional Responses

Although the initial AAU, AAMC, and USDHHS guidelines focused on individual conflicts of interest, they also urged medical schools to act at the institutional level. The 2001 AAU guidelines warned that, “The existence (or appearance) of such conflicts can lead to actual bias, or suspicion about possible bias, in the review or conduct of research at the institution. If they are not evaluated or managed, they may result in choices or actions that are incongruent with the missions, obligations, or values of the university.”

In 2002, the AAMC released a second report that addressed institutional conflicts of interests. This report called for a “credible separation” between decisions involving technology transfers or investment and decisions involving research programs, all the while warning that even when credible separation has been achieved, certain financial relationships with commercial sponsors should be examined closely (Task force on financial conflicts of interest 2002).

Attempting to understand the scope of institutional responses, Ehringhaus and colleagues (2008) surveyed the leadership of the 125 accredited allopathic medical schools in the United States. Specifically, they examined the degree to which the AAU and AAMC recommendations have been adopted. The authors reported that of the 86 schools that participated in the survey, 30 have adopted policies applicable to the institution’s financial interests, while 55 have adopted policies concerning financial interests of individual senior officials. Policies overseeing midlevel officials were adopted by 55 schools; for IRB members, 62 schools; for governing board members, 51 schools (Ehringhaus et al. 2008). According to the authors, this reflects special attention paid to people who have a direct role in protecting human research subjects.

In an examination of the Institutional Review Board (IRB) and institutional policies of 120 US academic medical centers, Weinfurt et al. (2006) found that 57 (48%) academic centers explicitly mentioned disclosure of financial conflicts to research participants as a possible way to manage these conflicts. However, there was little agreement on how to go about disclosing the conflicts. Strategies included describing how research was funded in the informed-consent language and asking investigators to discuss financial conflicts of interest with potential research participants. The authors discovered that “most academic medical centers that explicitly discussed disclosure of conflicts did not recommend or require a great deal of information beyond the name of the sponsor. Even statements that included information about the nature of the relationship were brief, mentioning only that a sponsor supports the research.”

It is generally recognized that the adoption of institutional conflict-of-interest policies across US academic medical institutions is far from complete (Ehringhaus et al. 2008, Rothman 2008). At the same time, however, the movement toward adoption has not been received with exclusive applause from the research community. There is a growing discontent among researchers that conflict-of-interest policies are stifling progress. A 2005 letter in *NEJM* articulates many of these frustrations (Stossel 2005):

No evidence points to a diminution of the public’s trust in the biomedical research enterprise because of the increase in academic–industrial interactions. Americans responding to a Harris poll conducted periodically since 1977 consistently rank scientist and physician as the most prestigious occupations. Subjects volunteer enthusiastically to participate in clinical trials. Public-opinion surveys commissioned by Research!America, a not-for-profit research-advocacy organization, indicate that Americans want more, not less, cooperation at the state and national level among funders and performers of health research. A 2005 national survey by Research!America shows that 73 percent of the respondents think that government, universities, and the pharmaceutical industry do not work together to develop new treatments, and 95 percent believe that they should. When asked whether scientists should benefit financially from their discoveries, 69 percent of the respondents thought they should be allowed to do so. The public trusts physicians and scientists because they deliver results — not because they disdain profit...The intense energy currently dedicated to demonizing academic–industrial research relationships should be redirected toward developing better ways to identify and facilitate the type of partnerships that have brought more good, by far, than harm.

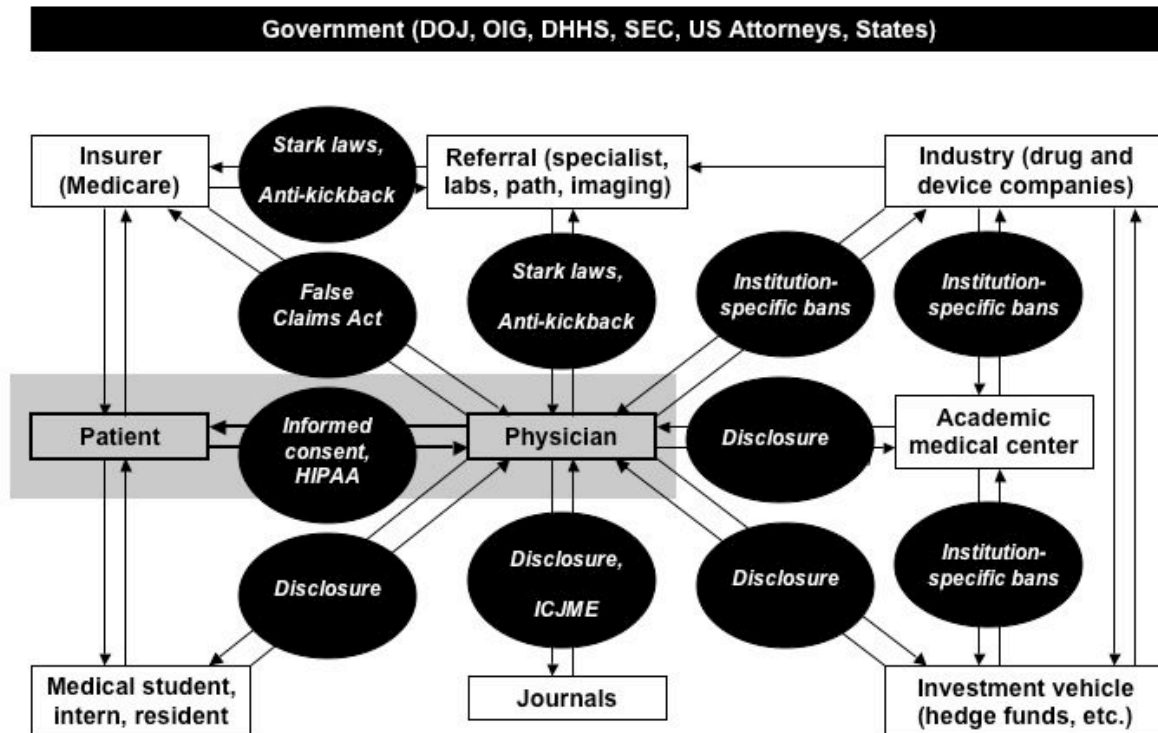
A 2005 study from the University of Michigan concluded that HIPAA regulations have led to a significant decrease in the number of patients available for prospective and retrospective research (Armstrong et al. 2005). The authors reported that in a registry of patients, consent for follow up declined from 96% before HIPAA to 34% after HIPAA.

Government Responses

In 1996, Congress passed the Health Insurance Portability and Accountability Act (HIPAA), a multifaceted legislation that has evolved into a cornerstone of academic research protocols across US institutions. Briefly, Title I of HIPAA regulates individual and group health insurance plans. Title II deals with health care fraud and medical liability reform. It includes the all-important privacy rule, which took effect in 2003 and has established the nationwide protocol for handling protected health

information. Title II also includes a complementary security rule, which dictates security standards for electronic health data.

In addition to HIPAA and addressing medical fraud through enacting the False Claims Act, Stark laws, and anti-kickbacks statute, the government has also accompanied academic institutions in an overall effort to address safety, accountability, and financial conflicts of interest in medicine. The NIH, Centers for Medicare and Medicaid Services, and law enforcement, including the Department of Justice, Office of Inspector General, DHHS, and US attorneys, have each played a role. The following is a brief summary of institutional and government responses.



Conclusion

Financial conflicts of interest are as much a product of profit seeking as they are an unfortunate vice of our complex, decentralized medical marketplace. There are no doubt steps that individuals and institutions can take to prevent them, but it is also unlikely that any entity alone—even the government—can abolish them entirely. On the one hand, this case has tried to demonstrate the versatility of financial conflicts: that they are widespread throughout professional relationships in health care and that they can intrude on professional judgment and patient welfare in various ways. On the other hand, this case has also tried to acknowledge that relationships between academic medicine and industry serve an important role in driving product development and technological innovation in health care, ultimately benefiting patients. As physicians-in-training, we must ask ourselves whether the vast array of conflicting interests is a worthwhile price for the innovation; whether we should tolerate risking patient welfare to benefit patient welfare; or whether there are ethical absolutes that we do not question. How deep of an encroachment into that sacred space between physician and patient—one delicately balanced on trust—is acceptable for us?

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