The Ghost of Veterinary Medicine Yet to Come: Lessons Learned From Medical Business Ethics

James M. DuBois, DSc, PhD*; and Elena Kraus, BS, PhD

Medical ethics is based on the notion of fiduciary obligation, which means that physicians are expected to act in the best interests of their patients, placing their patients’ interests even above their own, should they conflict. In recent years, financial conflicts of interest in medicine have threatened this fiduciary relationship. Whereas the repercussions for patients are largely unknown, the repercussions for physicians are painfully obvious: increased paperwork and oversight, restricted relationships, and a climate of suspicion. Just as Ebenezer Scrooge learned from the Ghosts of Christmas Past, Present, and Yet to Come, veterinary medicine can learn from the past and present in the field of human medicine. Authors’ address: Bander Center for Medical Business Ethics, Saint Louis University, 3545 Lafayette Avenue, St Louis, MO 63104; e-mail: duboisjm@slu.edu.

*Corresponding and presenting author. © 2013 AAEP.

1. Introduction

A colleague and I recently offered a research integrity training program for medical researchers. Because we offered CMEs (Continuing Medical Education) credits, my co-instructor and I needed to disclose our conflicts of interest. I had none to disclose. However, I was surprised when the CME office at our university contacted me with the requirement that I, as the training program director, develop a management plan for my colleague’s conflict of interest. What was his conflict? His wife was on the speakers bureau for a pharmaceutical company. To be clear, neither my colleague nor I have prescribing privileges, and our program was not meant to address medical practice. Yet, I had to fill out a second form for this program, explaining how our program would not be distorted by my colleague’s wife’s speaking activities (it was probably my 30th conflict of interest form of the year—every publication and talk I give in medicine requires one).

I am afraid that most physicians in academic medicine have many similar stories to share—stories of oversight requirement that increase the workload with little obvious benefits to patients or research participants.

In this report, I describe the “original ethic” in medicine, examine how and why this ethic has increasingly been replaced by onerous oversight systems, and suggest that contemporary medicine is the Ghost of Veterinary Medicine Yet to Come.

The Original Ethic in Medicine

In a recent publication, colleagues and I have traced a shift from a virtue ethic in medicine to an ethic of mistrust and oversight.1 Virtue ethics had a nice,
long run in medicine. We see it articulated clearly in the writings of Sir William Osler at the end of the 19th century. We readily think of self-interest and competition as 21st-century phenomena, yet Osler wrote: “In these days of aggressive self-assertion, when the stress of competition is so keen and the desire to make the most of oneself so universal, it may seem a little old-fashioned to preach the necessity of virtue but I insist of its sake...”2 In the 20th century, the prominent Harvard physician Henry K. Beecher argued in the pages of the *New England Journal of Medicine* that “an intelligent, conscientious, compassionate, responsible investigator” provided the best protection for participants.3 Beecher considered these qualities more important even than informed consent; new regulations were not even considered as contenders. In the late 20th century, Edmund Pellegrino, who later chaired President George W. Bush’s President’s Council on Bioethics, systematically adapted Aristotelian virtue theory to the practice of medicine. In essence, the virtues of medicine are the characteristics of physicians that help them to achieve the goal—the telos—of their practice: healing, prevention, and palliation.4

Note that these goals are all patient-centered. Although it may be legitimate to earn a living or to educate the next generation of physicians, the primary goals of medicine are healing, prevention, and palliation. Thus, one of the specific virtues that Pellegrino identified is fidelity to trust: faithfully protecting the patients’ trust that physicians will act in patients’ best interests.5 This is what the courts describe as acting within a fiduciary relationship.

Given this longstanding focus on virtues in medicine, the Institute of Medicine issued a report in 2009 on “Conflicts of Interest in Medical Research, Education, and Practice.” It offered a series of recommendations that would limit the kinds of relationships physicians have and increase oversight of medical practice. However, it omitted entirely any reference to the virtue or integrity of physicians. How did this happen?

**Cases and Data That Led to the Ethic of Oversight**

The shift to increased oversight of human medicine appears to be due to two major factors: high profile cases of physician wrongdoing that involved financial conflicts of interest and growing awareness of a body of social science literature on conflicts of interest.

**Cases**

Following are two cases of physician conflicts of interest that hit the press during the past decade.

**Case 1**

Dr. Gleason was charged with promoting a drug for purposes not approved by the federal government. Gleason promoted Xyrem as a drug for depression and pain relief at hundreds of speeches and seminars. (The Food and Drug Administration had approved Xyrem only for the treatment of narcolepsy.) Jazz Pharmaceuticals paid Dr. Gleason generously for these services—more than $100,000 in 1 year. Gleason told audiences that “table salt is more dangerous” than Xyrem. However, the active ingredient in Xyrem is gamma-hydroxybutyric acid (GHB), a fast-acting central nervous system depressant that can suppress breathing and cause coma or death during an overdose. It was designated as a Schedule 1 controlled substance after highly publicized cases in 2000 in which women died or were raped after GHB was slipped into their drinks.6

**Case 2**

Dr. Chan, a neurosurgeon, earned $200,000 a month and amassed $10 million performing spinal fusions. He was charged by the Federal Bureau of Investigation with demanding and receiving thousands of dollars in kickbacks from medical-device manufacturers. A Medtronic hardware representative accused Dr. Chan of switching to a different supplier after the new company agreed to offer him cash kickbacks and alleged that Dr. Chan did many unnecessary surgeries simply for profit. One of several malpractice cases against Dr. Chan involved fusion surgery on a man in his 80s who had only weeks to live with terminal cancer and who would not have benefited from the procedures.7,8

These cases were part of a string of highly publicized cases involving unnecessary procedures, fraud, abuse,9–12 and medical research biased by significant financing from for-profit companies.13 Spurred by these cases, some people suspected that they were the tip of the iceberg and began studying systematically physicians’ relationships to industry.

**Social Science Data**

Several review articles have found that financial relationships between physicians and the drug and device industries are ubiquitous14,15 and have measurable effects on physician diagnosis and treatment patterns16 as well as the design, results, and publication of biomedical research.17–19 Additionally, when physicians own the companies that provide services, they use these services more often than do other physicians.20

At the same time, most physicians insist that their practice of medicine is not affected by such financial relationships, even though they believe that their peers’ behavior is negatively affected.21 How is this possible? Perhaps the answer lies in the social science research that was reviewed by the Association of American Medical Colleges (AAMC) and the Institute of Medicine (IOM).22,23 An appendix to the IOM report entitled “How psychological research can inform policies dealing with conflicts of interest in medicine” concluded the following:

Research shows that when individuals stand to gain by reaching a particular conclusion, they
tend to unconsciously and unintentionally weigh evidence in a biased fashion that favors that conclusion. Furthermore, the process of weighing evidence can occur beneath the individual's level of awareness, such that a biased individual will sincerely claim objectivity.24

The last point is particularly important. It helps to explain how physicians may think they are prioritizing their patients' well-being even as financial factors bias their decisions.

Life in an Era of Oversight and Suspicion
Despite calls for professional self-regulation, physicians have been unable to preempt outside restrictions.25 Regulation in the areas of physician self-referrals and referrals for goods and services has come in the form of federal anti-kickback and Stark laws (see Table 1). Senator Charles Grassley (R-Iowa) became a watchdog for the US government in cleaning up federally funded research. His call for investigations and audits at medical practices, hospitals, and academic institutions kept the issue at the forefront of the news and prompted the codification of the Physician Payment Sunshine Act as well as a revamping of the National Institutes of Health (NIH) conflict of interest guidelines.26–29

To inspire confidence and show that physicians could in fact self-regulate, numerous medical institutions,30 medical journals,31 and medical organizations, including the AAMC, the IOM, and even the Pharmaceutical Manufacturers of America, released various reports and guidelines on the interaction of physicians with for-profit industries.24,32–36 Unfortunately, the imposed regulations are often vague, arbitrary, and burdensome, provoking physician discontent and the perception of slowing the progress of science.37,38

Who's Complaining?
Ironically, patients are not the ones who have complained and insisted on tighter regulations in medicine. When confronted with conflict-of-interest scenarios, most patients believe that physicians in general would be biased by financial conflicts of interest—but not their own physician.39 At the same time that medicine has grown more distrusted in regulatory circles, the public has expressed growing trust: In 1976, medical doctors saw 56% of Gallup poll respondents rate their honesty and ethical standards as high or very high; but this percentage has steadily climbed over the past two decades, reaching 70% in 2012.40 (As an aside, the 2012 rating of physicians' ethics is 7 times higher than the ratings received by the members of Congress, who increasingly oversee the practice of medicine.)

2. Conclusions
Veterinary medicine is not immune to problems with conflicts of interest. I am not an expert in this arena, but, after conducting the briefest of literature reviews, my co-author and I identified several stories addressing business practices in veterinary medicine. For example, veterinarians are becoming targets in the controversy surrounding the use of prescription drugs in racehorses and the clear financial incentives to keep unhealthy horses racing.41–43 Politicians such as Governor Cuomo of New York,43 groups such as the Jockey Club,44 and individual veterinary professionals45 are calling for investigations and regulations to decrease apparent conflicts of interest and prescription violations by equine veterinarians at America’s racetracks.44,46,47

Although we could be mistaken, we have the impression that veterinary medicine is not as heavily regulated as human medicine. The American Association of Equine Practitioners’ “Ethical and Professional Guidelines” provide excellent guidance to equine veterinarians, just as the American Medical Association’s “Code of Medical Ethics” has since 1847. In this regard, veterinary medicine seems to be in a position roughly analogous to the position of medicine in the 1990s and early 2000s.

We speak from outside the field of equine veterinary medicine and thus are not in a good position to assess working conditions or to make predictions about the field. Nevertheless, we will offer a few tentative conclusions from these brief reflections.

1. Returning to the leitmotif adapted from Dickens, the Ghost of Medicine Present may be the Ghost of Veterinary Medicine Yet to Come: If this is true—if veterinary practice is currently less regulated than medicine and coming under increasing scrutiny—then we would warn: Provide ethical leadership and self-regulate or else others will do it for you (and probably very badly).

2. One’s clients are not a good gauge of whether external oversight is forthcoming. As noted above, patient trust appeared to be strong and growing at the very time when Congress and regulatory bodies increased oversight.

3. Because individuals are generally unaware of how self-serving biases affect their judgments and behaviors, “self-regulation” cannot occur only at the individual level; professionals must police professionals. It is not enough for individuals to try very hard to behave well. To avoid the fate of medicine, professional associations of veterinarians may need to create and enforce reasonable rules.

4. Good business ethics often build on good clinical practice. In a fee-for-service system, practitioners generally earn more by providing more procedures. Meeting inappropriate patient demands for treatment—or client demands in veterinary medicine—can be profitable. Yet, many scandals in medical business ethics have arisen from providing unnecessary or inappropriate treatments—
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<th>Rule</th>
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<tr>
<td>NIH Conflict of Interest Rules, 42 Code of Federal Regulations (CFR)</td>
<td>All applicants for or recipients of Public Health Service (PHS) funding</td>
<td>Responsibilities of institutions regarding investigator financial conflicts of interest. Information is collected and managed by the institution and provided to the public only when requested. Reports must be given to the PHS.</td>
<td>Depends on the situation. Remedies could include fines and suspension of funding, which can end a researcher’s career.</td>
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<td>Physician Payments Sunshine provisions of the Patient Protection Affordable Care Act</td>
<td>All US drug and medical device manufacturers covered under Medicare, Medicaid, or State Children’s Health Insurance Program (SCHIP)</td>
<td>A federal database of all payments and transfers of value made to physicians and teaching hospitals. The Department of Health and Human Services will post information received on a publicly available, searchable on-line database starting September 30, 2013. Databases will be updated on June 30 annually thereafter.</td>
<td>Fines of up to $10,000 will be charged for each failure to report, not exceeding $150,000 annually.</td>
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<td>Anti-kickback laws</td>
<td>All physicians practicing in the United States</td>
<td>Prohibits paying, soliciting, or receiving any remuneration (kickback, bribe rebate) in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made under Medicare or a State healthcare program.</td>
<td>Felony conviction results in a fine of not more than $25,000 and imprisonment for not more than 5 years, or both.</td>
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<td>Stark Laws</td>
<td>Federal law</td>
<td>Govern physician self-referral for Medicare and Medicaid patients. Prohibits physicians from referring Medicare patients for certain designated health services to an entity with which the physician or a member of the physician’s immediate family has a financial relationship, unless an exception applies.</td>
<td>Denial of payment or refund of monies received, payment of civil penalties of up to $15,000 for each service provided in violation of the law, and 3 times the amount of improper payment received from the Medicare program, exclusion from the Medicare program and other State programs, and payment of civil penalties for attempting to circumvent the law of up to $100,000 for each circumvention scheme.</td>
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<td>False Claims Act</td>
<td>Federal law pertaining to those who bill for medical services</td>
<td>Any person who knowingly submits false claims to the government, causes another to submit a false claim to the government, or knowingly makes a false record or statement to get a false claim paid by the government is liable for damages. Includes a qui tam provision that allows people who are not affiliated with the government to file actions on behalf of the government (whistleblowing).</td>
<td>One who is liable must pay a civil penalty of between $5500 and $11,000 for each false claim and 3 times the amount of the government’s damages.</td>
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that is, treatments that are neither the standard of care nor based on evidence. As a general rule, the right of patients and parents to decline treatment has few exceptions; however, patients generally have no right to demand treatments that a physician considers contrary to good clinical practice.\(^{48}\) For example, a competent patient may choose to decline antibiotics to treat strep throat, but a physician has no obligation to prescribe antibiotics to treat a viral infection. I imagine that similar rules of thumb are useful in guiding clinical practice in veterinary medicine.

The first step to sensible rule-making is to clarify to whom your primary fiduciary obligation exists. Veterinarians are in a tough position, analogous to the position of pediatricians. The person communicating with you and paying bills is your client but not your patient. Your patients do not sue; your clients can. Your patients will not go to another veterinarian; your clients can. These are facts that can shift allegiances away from your patients.

In discussions of ethics, there are rarely easy answers, but I do believe that deep and realistic consideration of the tensions between the interests of the provider, client, and patient is the starting point for any sound business ethic within veterinary medicine.

References and Footnotes