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Corporate funding of professional foundations: just another black sheep?

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Sir Winston: Madam, Would you sleep with me for 1 million Pounds?
Unknown woman: Yes sir, I think I would.
Sir Winston: Well, how about 1 Pound?
Unknown woman: Winston! What sort of woman do you think I am?
Sir Winston: Madam, that matter has already been solved. Now we're just haggling over your price.

As a member of the pharmacy and medical device committee at a leading hospital, you are part of a discussion considering whether or not varieties of coronary artery stents should be limited and if so which ones should be chosen. The hospital representative has endorsed a particular stent from a contractual cost basis. The cardiologist member strongly recommends a particular company's product. His stated reasoning is that the recommended manufacturer contributes heavily to the Penumbral Heart and Vascular Foundation, which funds various local research projects. A number of local leading physician members are on the company's suggested speaker panels and clinical advisory board. The cost of the stent recommended by the cardiologist member would be higher than using another product, but it is argued that the prestige of the medical staff and the institution would decline with a possible reduction in referrals. What should be done?

A. Everyone has biases. Approve the recommendations of your cardiology colleague.
B. Let the deciding factor be a poll of all the cardiologists practicing at your hospital.
C. Demand that the cardiologist recuse herself and make the decision on the recommendations of cardiologist advisors who have no conflicts.
D. Conflicts aside, the product must be the best or your nationally known colleague would not be using it. Approve his recommendations.
E. Report the matter to the ethics committee of your county medical society.

From The Center for Medical Ethics and Health Policy, Baylor College of Medicine.
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These days, there seems to be a constant bombardment of dark social ills brought to light by the daily news, including family violence, hate crimes, public malfeasance, and corporate thievery. Whether this moral degeneracy is newly hatched or was conveniently ignored in the past, one can only hope the increased level of media awareness can lessen these immoralities. Physicians are hardly immune from the press finding sewage in their mainstreams, usually involving professional conflicts of interest.[1-4] These professional conflicts of interest always involve some medium of exchange, and the innovative ways some physicians appear willing to compromise professional integrity to supplement their already comfortable incomes constantly astonishes.

Reed Abelson, one of America's most talented medical sensationalists, reporting for the *New York Times*, published a recent article entitled, "Charities Tied to Doctors get Industry Gifts."[2] The article opens not with a deflectable jab but with a solid right cross to the ethical snout of medicine, beginning with the story of a cardiologist reporting at a conference in March this year that a $14,000 ultra-filtration device removed fluid better in heart failure patients than diuretics. Surprise! And a Ferrari accelerates faster than a Ford but to what avail? Although prominent researchers questioned the study's conclusions, the presenting doctor remained adamant. "We believe these results challenge current medical practice and recommendations," said Dr X, who predicted many patients might benefit."[2] Dr X did not disclose that the company making the device had donated $180,000 to a foundation she and 50 associates staffed, funded the study, and paid her a salary as a consultant, three conflictual, possibly ethical strikes.

We do not deny that this therapy could eventually become the standard of care, but look at the implications if adopted. According to the National Center for Health Statistics, 1.09 million patients were discharged (not admitted) from hospitals in the United States with a diagnosis of heart failure in 2003,[5] and because of an aging population, the number is

higher today. If universally adopted then, the therapy would have added a $15.3 billion bloat to health care. A remark attributed to Everett Dirksen mocked well those who spend huge, "A billion here, a billion there, and pretty soon you're talking real money."

The science and practice of the group, the foundation, and the data may well be legitimate, but there are quite a number of possible improprieties. Let us count the ways: personal influencing of the individual physician's research; influencing the general group practice; an affront to legitimate charities such as foundations of major medical societies and colleges; a questionable business practice of the medical company sponsors; a possible tax loophole when doing little to deserve special status; and last, but not at all least, a platform for disbursing conflicted information about medical practice.

In previous articles we decried industries' intrusions on medicine's professionalism.[6-9] Consider the least objectionable financial relationship, receiving seemingly insignificant gifts from medical companies.[7] What difference can a free medical book, a nice pen or pencil, or dinner to discuss the latest drugs or devices make? It can cloud the physician's medical judgment; that's what. It can make one choose a more expensive therapy without patient benefit, expand unsupported indications for therapies, or lead to the acceptance of the drug rep's pitch as the last word without further study. Waud[10] had the temerity to write that every kind of gift from the medical industry to physicians was a bribe, an inducement for doctors to buy instruments, contraptions, and medications that someone else finally gets billed for. This is known as *baksheesh* to anyone traveling in the mid-east, a word sharing its etymological root with *nebbish*, a descriptive insult of personal character that assumes allowing one's moral behavior to be decided by bribes is cowardly.

The next item on the list to trot out are the paid pseudoconsultancies and "marketing research" payments.[9] "Somewhere along the way, though, the medical manufacturers' marketing departments shouldered their way into the process, and introduced the techniques of advertising and salesmanship to what medical professionals had been led to believe was a relationship built on their scientific and clinical expertise. Though told otherwise, it was no longer just the doctor's expert opinions and research programs that were sought, it was his influence as a sales broker for expensive products he ordered at his patients' expense." Industrial money, disguised as research support, can easily be slipped into the marketing department, as the subject of the *New York Times* exposé appears to have done.[3] A paid medical consultant necessarily becomes the functional equivalent of a company employee, and companies, not surprisingly, expect their employees' loyalty, the thorny rose of commercialization.

But why bring the matter of physician/industrial conflicts of interest forward once again? Because the formation of tax-free charitable foundations is the latest, perhaps greatest, conflict of interest blemish on professionalism yet devised. Payments to such foundations create possible conflicts of interest, though not in the direct form that payments to physicians as consultants or members of speakers' bureaus do. Setting up such foundations is at risk for becoming a subterfuge conceived of by physicians, not industry, that could lead to the plethora of unethical behaviors identified above, touching on every aspect of a physician's professional life. In this scenario, the physician's economic self-interest in the foundation is substantial if he is receiving research support from it. His relationship with the company in question is thus an indirect conflict of interest, but no less substantial as a result. Foundations can become legal vehicles for transferring industry money to physicians that flies beneath the moral radar by posing as a charitable undertaking. When receiving funds from a "foundation," one may delude themselves into thinking that because of the intermediary there is no conflict, but only a psychosis would allow forgetting who funded the "foundation" and who could withdrawal future funding.

There have been numerous examples of gross distortions when scientific objectivity has not been scrupulously maintained. To prevent this problem, academic health centers have established conflict of interest policies, but these usually do not address indirect conflicts of interest that are created when payments are "laundered" to parties or entities other than the investigator.[11] The newly emerging forms of indirect conflicts of interest need to be disclosed to professional organizations and hospitals and responsibly managed so that they do not distort the decision-making processes of health care organizations.

The syllogism for option A would read: All humans have biases and must make decisions regardless. All physicians are humans. Therefore, physicians must, because of their human nature, make biased decisions. This assumes that conflicts of interest are both unavoidable and also that they cannot be responsibly managed. The conflict of interest in this case is avoidable; other conflict-free cardiologists could be asked to advise the committee. Important institutional decisions should be made by individuals who are unbiased on the specific matter being discussed.

Option B is what used to be done when cost-plus reimbursement was in vogue. Then the hospital administrators spared no expense in having huge inventories of different types of prosthetic joints, heart valves, vascular grafts, and other supplies, but we live in a different world today. Provided there is no evidence-based clinical advantage of one therapy over another, cost merits consideration, being important enough to be mentioned first in the American College of Surgeons Task Force on Professionalism's recommendations.[12] Science's foundation is not democracy. It is unlikely that evidence-based consensus would be reached by taking a poll. In addition, taking a poll does not responsibly manage conflicts of interest; depending upon the conflicts of interest of those polled, associated politicking might lead to less effective management of conflicts of interest.

Option D assumes that conflicts of interest are indirectly proportional to clinical competence when, in fact, "human nature" may make it just the opposite. The higher

one climbs in professional acclaim, the more infallible they may believe they are. The faulty reasoning of this option undermines it as a responsible strategy for managing conflicts of interest.

Option E is very premature. There is no evidence of the cardiologist behaving improperly. Anyone who serves on institutional advisory committees has the obligation to contribute their expertise and advice toward questions in their sphere of knowledge. Serious unmanaged conflicts of interest are morally wrong without proof of wrongdoing but are not censurable per se.

Financial conflicts of interest disorder scientific objectivity and they abound.[9] Some knowledgeable sociologists describe the current societal state as a "creed of greed," and from the incessant trials of top level corporate crooks, doubt of this resides only with the most naive and uninformed.[13] Whatever, retention of medicine's exalted professional status, inherited from physician's collective efforts across the previous centuries, conflicts of interest need to be dealt with by more than simple disclosure, although even simple disclosure has been a repeated problem with authors at one of the most prestigious American journals.[14] The editor of the *Journal of the American Medical Association*, Dr DeAngelis, publishes names of nondisclosing violators, when discovered, and notifies deans at their medical schools. But continued failures of authors to disclose have led criticisms of her efforts. Perhaps, a special journal for publishing conflicted data is needed with the articles available for citing only after nonconflicted confirming articles are published.

To protect the scientific and ethical integrity of the committee's deliberations and recommendations and of the hospital's purchasing practices and policies, the conflicted cardiologist should not be allowed to participate in deliberations and recommendations. There is surely expertise in his specialty from colleagues without direct or indirect conflicts of interest. If no such expertise is available within the medical staff of the hospital, it should be obtained on a consultancy basis. Option C, rarely chosen in practice, is our selection.

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