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ETHICS CASE

Donations of Expensive Equipment for Resident Training

Commentary by Ashvini K. Reddy, MD

As the newly appointed director of a retina fellowship at an academic center, Dr. Bayes took his educational responsibilities most seriously, advocating for trainees to have access to interesting cases and the newest technology.

One afternoon, Dr. Bayes received a phone call from Mr. Clements, a surgical device representative for VitreSure, a company specializing in surgical retina platforms and equipment. Dr. Bayes agreed to speak with Mr. Clements about the possibility of purchasing the VitreSure surgical machine for the residency training program.

As agreed, the two met one week later. Dr. Bayes explained to Mr. Clements that, while his institution did have a surgical machine already, it was an older model, and getting approval for funds to purchase a new system could be difficult. There was need for a new system, and only one machine would be needed. "I'm thrilled that you are considering our device, Dr. Bayes," said Mr. Clements enthusiastically. "The VitreSure offers state-of-the-art surgical support, and we are excited to be introducing it to surgeons in training in the United States. In fact, because we are confident that young surgeons who have the opportunity to use the VitreSure system in training will choose our equipment once they graduate, we are willing to donate it to your institution."

Dr. Bayes hesitated. His trainees had access to an existing surgical system, but it was getting older and a new machine was warranted. He wanted his trainees to have access to as many types of technology as possible and he believed that the VitreSure was a fine system to use and become acquainted with, but VitreSure's donation of the equipment as an investment in the trainees' future gave him pause.

Commentary

The unsettling feeling that Dr. Bayes has about accepting an expensive but useful piece of surgical equipment stems from the understanding that the goal of the donation is to generate a favorable bias among his trainees toward the equipment and the company donating it. Is Dr. Bayes right to be skeptical?

The donation of new surgical equipment to the department stands to benefit trainees as well as patients, but how should this be balanced against the introduction of bias by the company? Dr. Bayes essentially has three options: (1) accept the donation of the system

and the bias toward the company and its products that might be generated because of it, (2) decline the donation and raise money for the purchase of the VitreSure or another manufacturer's device, or (3) decline the donation and continue using the department's current equipment.

Dr. Bayes's dilemma is clear: if the offered equipment is better than what the academic program currently has, but not what it would buy if it had its choice and money were not an object, he might feel disposed to accept the donation—and ethically unsure about that course of action.

Think of the Patients

One might argue that, because patients benefit from newer surgical equipment, the donation of a system is analogous to pharmaceutical companies' donating "free samples" for patient care. Many academic medical institutions now ban the [donation of free samples](#) for patient care because the sample medications are often more expensive than other alternatives, including generics, and patients can develop brand loyalty on the basis of the sample and may be reluctant to switch away from a medication that they feel benefits them [1]. This brand loyalty can lead to escalation of costs for the patient in the long term. Furthermore, both young and established physicians have a tendency to develop a "pattern of prescription," meaning that they tend to prescribe certain medications more than others. Samples can introduce expensive prescription habits that affect patients who might not even receive the samples themselves [2, 3]. In the same way that some people may always feel more comfortable driving the brand of car they learned to drive originally, surgeons may, over the course of their careers, prefer the brand of surgical equipment they trained on and be uncomfortable switching to new systems. And in surgical subspecialties, the bias towards one device can impact thousands of lives.

In the United States, drugs and medical devices are regulated by distinct divisions of the US Food and Drug Administration (FDA). While both drugs and medical devices are used in the diagnosis, treatment, and prevention of disease and must comply with federal regulations regarding labeling, advertising, production, and postmarketing surveillance, there are differences in the FDA premarket review and approval processes for the two types of products [4]. In FDA regulation, the level of premarket scrutiny is related not only to the level of clinical evidence available, but also to standards for quality of the product. FDA regulation of devices is different than regulation of drugs: the clearance of a device does not necessarily mean that safety and efficacy have been shown for the product, or even that clinical trials have been conducted [5]. Because oversight of medical devices may be less robust, the consequences to patients of bias generated toward surgical devices may be greater than those of bias in prescribing drugs. The possible effect of bias on patients argues against Dr. Bayes's accepting the donation unless it is the device he would choose to buy if the program had funds to buy the "best."

When it comes to donations of free samples, educational seminars and materials, and [gadgets such as pens](#) from pharmaceutical companies, the American College of Physicians has published statements to guide us [1]. This guidance indicates that, although industry information fills an important need, studies suggest that [it is often biased](#) [6-8]. Since providers of graduate and continuing medical education are obligated to present objective and balanced information to their participants, they should not accept any funds that are contingent on a sponsor's ability to shape programming. Medical educators need to evaluate and control the planning, content, and delivery of education and should disclose industry sponsorship to students and faculty. Where pharmaceuticals are concerned, medical educators have largely adopted explicit organizational policies about acceptable and unacceptable interactions with industry in the interest of promoting independent judgment and professionalism.

There is, however, a paucity of guidance about donations of larger medical devices. Surgical equipment donation isn't featured in the general press as often as pharmaceutical donations, but there are professional guidelines on accepting gifts. The *AMA Code of Medical Ethics'* opinion 8.061 [9] states that "gifts to physicians from industry create conditions that carry the risk of subtly biasing—or being perceived to bias—professional judgment in the care of patients." The opinion further states that physicians should decline any gifts for which reciprocity is expected or implied.

Take the Long Road

Is the department obligated to expose trainees to multiple surgical systems? No. In fact, most subspecialties use only one system with good reason. Multiple systems can make teaching and learning more difficult—it is generally easier to choose one system that works for the group. One of Dr. Bayes's options is to delay acquisition of a surgical system until the department can afford one. There are two consequences of this action: (1) current trainees and patients will have to work with older equipment until newer equipment can be purchased, and (2) since only one surgical device is needed, indeed, preferable for training, all those in the fellowship program will be influenced in favor of the existing device.

Thus, Dr. Bayes's thinking should be along these lines: if the device offered is the one the program would purchase if it had funds to buy the best, there is stronger ethical justification for accepting the donation. If it is not the device the program would purchase if it had funds to buy the best, justifying acceptance of the donation is a greater ethical challenge.

It seems, then, that Dr. Bayes may have good reasons for "going with his gut" and declining the donation of the VitreSure surgical system. The more rigorous FDA approval and marketing process for drugs than medical devices and the long-term consequences

for patients and trainees of a capital investment in surgical equipment are both key to thinking critically about the potential for bias generated by the surgical device industry's donations.

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