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Fostering innovation without compromising integrity

■ ABSTRACT

Industry's interaction with academia has created vast opportunity for innovation but also the potential for undue financial influence. Potential conflicts of interest can occur at the level of the individual researcher or the institution. Implementing guidelines and policies on conflicts of interest can help maintain appropriate separation between academic medicine and industry while permitting medical innovation to proceed. In an effort to retain public trust, Stanford University School of Medicine has enacted policies to identify and manage potential conflicts among its faculty, to divest of holdings in companies conducting studies involving Stanford investigators, and to ban all industry marketing and gifts from Stanford facilities.

The past 40 to 50 years have witnessed extraordinary improvements in our ability to diagnose, treat, and prevent a spectrum of diseases. This improvement has occurred, in part, because of parallel developments in academic medical centers and industry. Many of these developments have centered on innovation and discovery among and between these entities, which often is productive, but sometimes is not. I will share here some thoughts about how these processes are evolving and where we are today, as well as some relevant policies recently adopted by my institution, Stanford University.

■ THE CHANGING NATURE OF BIOMEDICAL FUNDING

Academic medical centers in the United States have tripartite missions in education, research, and patient care. These missions have grown over the past 30 to 40 years, largely for two reasons: (1) the funding that has emanated from the National Institutes of Health (NIH) and (2) the burgeoning of academic medical centers and clinical faculties in the wake of the Medi-

care program's creation in 1965.

At the same time, it is important to recognize the variations and undulations in these patterns of growth and the sources of its support. Witness the past 20 years, during which managed care has cut into the clinical profit margins of academic medical centers. These profit margins had been used to subsidize missions in education and research. Also consider that changes in NIH funding can alter the patterns of success within our academic enterprises, often turning the education and research missions into cost centers rather than profit centers. In the process, the support flowing into the clinical side of the equation has decreased. These developments have led many academic medical centers to look at alternatives to supplement their ability to carry out these missions.

Industry fills a vacuum

The pharmaceutical, biotechnology, and medical device industries have grown in parallel with the growth of academic medical centers, in some cases because of their underlying research and development aspects. Changes in these industries' interactions with academia have also occurred, some of which have been productive and positive and some of which have not. For instance, many of the interactions that broke down the traditional walls that separated academia from industry involved biotechnology and genetic engineering, which created vast opportunities. Significant degrees of intellectual property and patent royalties often resulted, leading to the process of technology transfer and establishment of offices for technology development at academic centers, thereby promoting innovation and discovery.

Unintended consequences

Over time, however, some of these interactions have become more challenged as some academic institutions, such as Harvard University, Washington University, and the University of California at Berkeley, have set up exclusive research arrangements with pharmaceutical or biotechnology companies. In

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other cases, interactions with industry have led academic institutions to begin thinking of ways to direct their research to maximize the degree of intellectual property associated with it, which can in some ways abrogate the process of discovery and innovation.

■ A NEED FOR GUIDEPOSTS

The question that confronts us is this: How do we create an environment that fosters innovation and discovery yet maintains a degree of separateness that does not allow financial concerns to influence the success of our enterprise?

Conflict can be personal or institutional

In medicine, conflict of interest usually means that personal interest comes into conflict with an individual's role at a university or academic medical center. These conflicts can involve any of a number of aspects of personal interest, such as career development, academic development, or financial interests.

In addition to faculty or individual conflicts, there are also institutional conflicts of interest. For example, these may include situations in which an academic medical center has an equity holding in a product or device that is used in patients being treated at the center.

Understanding and managing both types of conflicts is important.

Apply guidelines to all, even if needed only by some

An idealist may argue that many physicians and academicians need no guidelines to manage conflicts because they are always going to do the right thing. For most of us, however, guideposts can serve as a boundary to help define what we cannot and perhaps should not do. Despite any regulation, there will always be a handful of individuals who will knowingly or unknowingly violate the rules and cause difficulty for themselves or their institutions.

■ WHAT STANFORD HAS DONE

At Stanford University School of Medicine, our policy with regard to conflicts starts with the recognition that we know they are going to occur. We want our faculty to be open with us, and we want to help them manage conflict so that they do not cause embarrassment or damage to themselves or to our institution. We also want the process of innovation and entrepreneurial activity to proceed successfully.

Faculty disclosure policy

We ask our faculty to do both an annual disclosure and a transactional disclosure for any activity that they have with industry. We insist upon disclosure of any financial component associated with the activity, of

any dollar amount. If a faculty member receives more than \$10,000 annually, more than 0.5% of equity in a publicly traded company, or any equity in a privately held company, a conflict-of-interest review is always triggered. We have a committee on hand that will help faculty to manage those conflicts to limit the potential for difficulty, either personally or to the institution.

Institutional divestiture policy

We also want to be clear with regard to our institutional responsibilities. We have decided that our institution will divest any equity that it holds in a company that is conducting a clinical trial in which Stanford is a participating center.

These simple formulations have helped us to accomplish our major goal, which is to manage these interactions with at least a reasonable degree of success, consistent with our overarching plan of allowing discoveries to move forward.

Ban on industry marketing and gifts

In addition, we have taken a firm stand against marketing and advertising by drug and device companies at Stanford facilities. Industry's practice of providing gifts and free meals at educational activities over the past few decades has created an uncomfortably close intermingling between industry and academia. This form of advertising has become almost a tradition at many academic medical centers, which I believe represents a violation that erodes public trust. As a result, we have instituted a policy effective October 1, 2006, that bans all of these interactions from taking place at Stanford and its medical centers and hospitals. The ban prohibits detailing by drug representatives, distribution of drug samples, provision of meals or refreshments, distribution of pens and other small gifts, the presence of industry booths and industry literature at educational talks, and all similar advertising and marketing activities.

Ultimate objectives

Stanford's goal moving forward is to accomplish two things simultaneously. The first is to foster an environment that promotes innovation and discovery by creating appropriate degrees of connectedness between academia and industry. The second is to end the marketing by industry that contaminates how faculty think about their relationships with industry, in order to ensure public confidence in Stanford as an academic medical center focused on innovation and discovery for the public interest.

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