Debate: The Commercialization of the Academy

by Patricia Hausman

Amid growing concern about the lack of clear guidelines on conflicts of interest in research, Emory University convened a conference last month on the Commercialization of the Academy. The event was hosted by the university's Sam Nunn Policy Forum**.** Each year, the Forum sponsors a meeting of high-ranking representatives of government, industry, and academic to address a pressing issue of public policy.

Although the stated goal of the conference was to produce "a set of values and guidelines that can be used by university administrators and faculty members in their strategic planning," speakers appeared deeply divided as to whether a serious problem exists—and how to solve it. But conferees did agree on one point: the genesis of the controversy. Few, if any, doubted that today's situation is largely, though not exclusively, a consequence of the Bayh-Dole Act of 1980. The Act amended patent and trademark laws to facilitate the transfer of technologies developed in universities and government to the private sector.

One of the first speakers, University of Arkansas professor Mary Good, addressed the history of Bayh-Dole and its impact. Good, who is also managing member of a venture capital firm that supports emerging technologies, cited estimates that Bayh-Dole has yielded more than 30 billion in economic activity; 280,000 jobs; and rates of patenting by universities that are without precedent. University of Pennsylvania law professor Arti Rai echoed Good's description of the rise in patenting activity by universities. According to Rai, private sector patenting increased only three to four-fold since 1980, while the number of patents issued to universities increased from less than 250 a year prior to Bayh-Dole to more than three thousand two decades later.

Good cautioned, however, that collaboration between industry and academia is not nearly as new as many believe. The more prestigious research universities, she said, fail to appreciate the extent to which other institutions—particularly their departments of engineering—have long provided expertise to help local industries solve technical problems. Nor, she said, is Bayh-Dole the only factor that has contributed to the current controversy. Changes in national research priorities resulting from the end of the Cold War factors have also played a role. One of these is an increased emphasis on biomedical research—an area of particular concern to critics of technology transfer.

Karen Holbrook, provost and senior vice president for academic affairs at the University of Georgia, echoed the theme of a changing research agenda—one to which she said institutions must adapt in order to survive. These shifting priorities, she said, reflect a clear conviction on the part of legislatures that technology transfer is valuable—a view that several speakers described as in tune with public opinion. Holbrook was confident that collaborations between industry and university need not compromise traditional academic values of open inquiry, peer review, and shared results. By contrast, she described current tenure and promotion policies as an unappreciated but significant obstacle to technology transfer.

Holbrook presented results of a survey of 23 research institutions about the importance that tenure and promotion guidelines assign to entrepreneurial activity. Responses showed very little recognition given to such activities relative to the more traditional criteria of research productivity, intellectual stature, teaching, and service. Hobrook expressed concern that failure to modify

these standards will not only impede mandates to the university set forth by legislatures, but also interfere with their ability to attract top-flight faculty.

Few speakers offered much in the way of specifics for managing real or potential conflicts while maintaining a strong commitment to technology transfer. Michael Johns, Emory's executive vice president for health affairs and a professor of surgery at its medical school, did outline the basic tenets of Emory's approach. These include a requirement that all financial interests be disclosed, a belief that even the appearance of conflict of interest be avoided, and a presumption that any financial interest in the outcome of research is likely to be a disqualifying factor.

Johns also discussed a policy adopted by Johns Hopkins University, where he formerly worked, to address both conflict of interest concerns and the problem of collaborating with start-up companies that were equity-rich but cash-poor. Under the policy, both the school and individuals were permitted to accept equity in these companies. However, such equity had to be held in escrow for at least two years after FDA approval of any product developed by the collaboration. This approach was adopted to allow time for problems not detected during clinical trials to emerge.

Critics of Bayh-Dole and the changing research environment presented a number of complaints. Concern with the impact on academic values was perhaps the most common, with some speakers likening the situation to the corruption of scholarly standards created by pressures to recruit and retain student athletes. Others expressed concern about removing basic research platforms from the public domain. The most pointed critics took issue with the concept that disclosure is the key to preventing conflicts of interest. "Disclosure is not the antidote," said Sheldon Krimsky, professor of urban planning at Tufts University. "It doesn't get to the root of the problem." He argued that new ethical guidelines are required instead.

Like their colleagues who were supportive of industry-academic collaborations, most critics provided few specifics about what guidelines they would put in place. Marcia Angell, former editor of the New England Journal of Medicine, offered what was arguably the most radical approach. Echoing comments she made several years ago at a conference sponsored by the Department of Health and Human Services, Angell sharply criticized drug companies, accusing them of imposing major opportunity costs on science by involving academic medical centers in trials of "me-too" drugs. She argued that universities should accept only "studies of scientific merit," a category that would exclude not only "me-too" drugs, but also trials that compare new drugs to a placebo. Such studies, she said, do not answer the "real question:" whether a new drug is superior to an existing treatment.

Emory professor Donald Stein organized and moderated the conference. A partial webcast is available on-line.

Editor's Note. *The Chronicle of Higher Education recently published an article describing technology transfer initiatives in state legislatures. CHE subscribers can access the article, entitled "States Push States Push Public Universities to Commercialize Research" at the* Chronicle website.