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Perhaps the title of my talk should, more accurately, have been, "The Commercialization of Biomedical Research: A Rambling Discourse in Spotting Legal Issues."

As you know, just a few weeks ago, the Massachusetts General Hospital announced a long-term pact with a German pharmaceutical firm, Hoechst, A.G., to pursue basic research in molecular biology.<sup>1</sup> Earlier, Harvard and Monsanto, and Exxon and MIT had entered into agreements for sponsored research.<sup>2</sup> Other institutions will no doubt follow suit. Indeed, the new links being established between industry and academia have recently been heralded as one of the major scientific developments of the '80's.<sup>3</sup>

As with all areas in a state of flux, it is not possible to make categorical statements about how the law is apt to influence the developing relationships between academia and industry. This is especially true with regard to governmental regulation of industry-sponsored biomedical research. Next week a Congressional subcommittee is holding hearings into the whole issue of the commercialization of biomedical research.<sup>4</sup> Various legislation is being considered or has already been enacted on the state level.<sup>5</sup> And even some cities have adopted regulations purporting to restrict the conduct of DNA research.<sup>6</sup> These laws and regulations, if adopted, will have a significant impact on privately-funded research; but, for the time being, we will have to abide the event. Accordingly, the most I can hope to do is provide a brief overview of the more significant developments in the area, and point out some of the legal ramifications of the present trend toward a greater commercial presence on campus. Then, if time permits, I will touch upon a few recent regulatory developments affecting research in the groves of academia.

The first point I should like to make is that it is all but inevitable that industry sponsorship of research, in one form or another, will play an increasingly important role in funding university research activities. Since World War II, the great bulk of biomedical research in this country has been carried out in university medical and dental schools and related research institutes, and has been funded principally by the Federal Government. While the Federal spigot has not been turned off, it probably has topped out, at least in real dollar terms, in funding basic research. Federal grants and contracts at one leading university have shrunk from a peak of nearly 40% of departmental operating income in the "hey days" of the Great Society to a present level of about 25%.<sup>7</sup> As inflation continues, and operating expenses continue to rise, universities will have to turn to new sources of funding in order to maintain quality and to be able to compete with private industry for the services of top faculty. The most likely source of such additional funding is private capital.

Dr. Bernard Davis, a Harvard professor, recently noted in the *New England Journal of Medicine* that, "[t]here are surely risks in developing industrial connections, but they must be balanced against increasing financial insecurity of universities today and against a monolithic dependence on an often unsympathetic government."<sup>8</sup> There are unquestioned advantages for the university as well as private indus-

try in industry funding of research. First, such funding provides an invaluable counterbalance to the universities' present near-total dependence on Federal Government funding. Second, it is flexible. The variety of the arrangements possible between corporations and academic institutions is limited only by the imagination of the contracting parties. Third, such research should be comparatively free of the red tape and the mountains of paperwork that increasingly bog down Federally-funded projects. Richard Muller, a Professor of Physics at the University of California at Berkeley, colorfully described this burden in an article entitled, "Innovative and Scientific Funding" in the August, 1980, issue of *Science* magazine:<sup>9</sup>

"When I began research in 1965, our research group often received more than the minimum support necessary for our projects. . . by 1972 our proposals were scrutinized to ensure that we received no more than the necessary minimum. . . by 1976 few of our proposals received enough money even to sustain a project, and we had to obtain support from more than one agency. Much of the time we had devoted to thinking about new projects was now spent writing and polishing proposals. . . the most fundamental mistake made by funding agencies is in assuming that the ability to write good proposals is equivalent to the ability to accomplish good research."

Private sponsorship of research—according to Adam Smith, at any rate—should turn that equation around and place the emphasis back where it belongs—on good research.

Finally, whatever the problems that arise from the injection of the profit motive into university laboratories, they are not likely to be avoided simply by a university's abstention from privately-sponsored research projects. Faculty members at a number of universities are already involved as investors in, or employees of, private corporations engaged in research-for-profit. Microbiologist Jonathan Beckwith was recently quoted in *Time* as saying that, "I already know of several. . . universities where people within the same department won't communicate with one another because they are directors of competing companies outside the university."<sup>10</sup> The possibilities of conflicts of interest and the dis-incentives to free exchange of information that arise when professors are acting as officers of private corporations (while at the same time continuing to teach) cannot be ignored. Moreover, the association of a professor turned entrepreneur with a prestigious university no doubt adds luster to his new business, which often translates into additional dollars for the professor. The university, however, gets nothing—except, perhaps, a blow to its good name if the new business proves a flop.

Therefore, it is clear that universities have no choice but to deal with these conflict problems. And one common-sense way to do it is for the university itself to articulate a policy and actively promote industry-sponsored research on campus, while at the same time placing some restrictions on faculty use of the university name in connection with private money-making ventures which are not directly sanctioned by the university.

Universities, in order to protect their own interest, may also have to adopt a get-tough policy with respect to the unauthorized commercial use of research data generated

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