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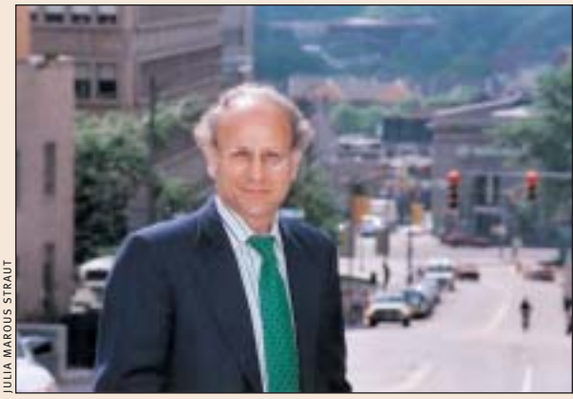
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JULIA MAROUS STRAUT

In September 1999, 18-year-old Jessie Gelsinger died while taking part in a gene-therapy trial at the University of Pennsylvania. On March 28 this year, largely as a response to his death, the Bush Administration proposed guidelines that would let research institutes decide whether to restrict scientists' financial interests in studies involving human subjects and whether such interests should be reported to the research volunteers. (The director of the Gelsinger clinical trial owned stock in the company that financed the trial.) This guidance represents the next step, short of a mandated and specific nationwide standard, in the response being made by many academic organizations, and now the government, to this and other such trials. The concern: Where outcomes of certain trials actually had the potential to pad researchers' bank accounts—might that factor have clouded objectivity? And might it have influenced the well-being of patients and normal volunteers? The potential for reward influencing the way research is pursued has always been with us—the historic reward being promotion, tenure, or honors. However, it is science itself that has added to the potential for wealth in this milieu. The possibility of very substantial financial gain from human subjects research is rather recent, emerging as biology has evolved from a purely descriptive to an experimental science, with a yield of drugs that have made many researchers wealthy. Furthermore, the Bayh-Dole Act of 1980 encouraged commercialization of academic discoveries and, in fact, mandated the transfer of these technologies to the commercial sector if federal dollars supported the discovery. Thus both science and the law have set the stage for this "duality of interests." It's important to note that not only may an investigator be conflicted, perhaps unconsciously, but an institution may be conflicted—especially in economic times when institutions are grateful for the royalties accruing to them as research leads to marketable discoveries.

St. Augustine once uttered, "O Lord, help me to be pure, but not yet." About 25 percent of all biomedical scientists now have financial affiliations with industry, and 70 percent of academic institutions have equity in start-up companies arising from intellectual property. Entrepreneurship has become the "fourth mission" of many academic medical centers, given the extraordinary financial constraints under which most such centers now labor. Nonetheless, economic partnerships between the academy, government, and industry have time and again accelerated research and promoted medical advances. Thus the challenge is to manage conflict when it cannot be avoided. How? Institutions can separate responsibility for financial and research decisions; establish committees to verify the absence of financial interest; verify that IRB members have no conflicts of interest regarding the protocols they consider; assure that an independent third party explains clinical research studies to subjects and obtains consent; provide subjects with information on the source of research funding; and make the same information available in every relevant research grant application and publication.

Biomedical research is sustained by public support and trust, and we must never permit conflict of interest to threaten scientific integrity and the safety of human subjects. Transparency is necessary but not sufficient. Good judgment and rigorous oversight are critical. Entrepreneurship needn't be at the expense of trust, and we certainly do not want its management to become a witch-hunt. If forced to choose between riches and integrity, however, there is no choice.

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