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Introduction to Special Issue of Accountability in Research *on Conflict of Interest in Science*

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Prior to 1980 one rarely heard the term "conflict of interest" and "science" spoken in the same breath. But as the decade got underway, academic research in the life sciences and medicine became heavily commercialized. In the aftermath of the discovery of recombinant DNA molecule technology in 1973 there was a "gold rush" atmosphere among molecular geneticists to cash in on the commercial value of gene transplantation research. New federal policies and court decisions provided incentives for university-industry partnerships that stoked the flames of entrepreneurship within academia. The Bayh-Dole Act (1980) gave all the intellectual property derived from federal grants to the grantee, their institution, and any commercial partners willing to invest in the discovery. Other enactments and executive orders during the decade helped to forge the ties between universities and for-profit companies under the rubric of technology transfer and global competitiveness.

The Supreme Court decision (*Diamond v. Chakrabarty*, 1980) affirming a patent for a microorganism developed to degrade the specific hydrocarbons in crude oil set a precedent that eventually led the U.S. Patent and Trademark Office to issue patents on genes, bioengineered animals, and genetically modified seeds. Every gene sequencer became a potential player in the competition to gain intellectual property rights over new biotechnology products and segments of the human genome itself.

By the mid-1980s some medical journals began requiring disclosures from authors on their real or potential conflicts of interest. In 1995 the National Science Foundation and the U.S. Department of Health and Human Services issued identical standards for the management of conflict of interest from their respective grantees (Department of Health and Human Services, 1995). According to the rules of the National Science Founda-

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tion (NSF) and National Institutes of Health (NIH), each institution must designate a conflict-of-interest officer who is given responsibility for balancing the autonomy of scientists and the incentives for technology transfer with protecting the integrity of science. Those guidelines postponed addressing institutional conflicts of interest.

Little was known about how the new culture and ethos of entrepreneurial science was functioning and how the federal guidelines and the journal disclosure policies were working until new research initiatives, which had begun in the late 1980s and intensified by the mid-1990s, investigated these issues. Currently, scientific conflict of interest has become a widely accepted term that describes scientists who have extra-academic financial involvements in the subject matter of their research, whether as equity partners in a venture capital company, as members of a company's scientific advisory board, or as patent holders.

A few studies have tried to quantify the extent of university-industry collaborations and the commercial interests of academic scientists. One study of fourteen leading science and medical journals found that 34 percent of the published articles had at least one lead author with a financial interest in the subject matter of the publication (Krimsky et al., 1998). A survey of 1,849 biomedical scientists indicated that 35 percent were engaged in commercial activities (Campbell et al., 2002). Another survey of life sciences companies reported that 92 percent sponsored academic research (Blumenthal et al., 1996). And the Association of University Technology Managers reported that 124 of its 183 member institutions held equity in businesses that fund research performed at the same institution (Pressman, 2000).

The four papers in this special issue of *Accountability in Research* make important contributions to a growing body of work that examines the ethical considerations, impacts, benefits, and liabilities of entrepreneurial academic science, including medicine. Two of the papers provide primary data from surveys and in-depth interviews. The second two papers offer analytical discussions of ethical and legal issues involving conflicts of interest.

Lipton et al. report on the results of a large-scale cross-sectional survey of research faculty in the nine campuses of the University of California (UC) on their understanding of conflict of interest and their attitudes of conflict of interest (COI) policies. The state of California has one of the most transparent systems for reporting faculty earnings and commercial involvements beyond their academic appointment. Each campus within the UC system has an appointed committee that advises the Vice Chancellor of Research on whether to accept, decline, or manage a conflict of interest. This nine campus survey of faculty in the UC system yielding nearly 800 responses provides unique insights into the attitudes of scientists toward COI policies.

Campbell et al. chose four geographically diverse major research institutions, two heavily focused on clinical research and two dedicated to basic science, to undertake in-depth interviews with senior administers in order to gain information about the nature of their own and their institution's industry relationships. The research team protected the anonymity of the institutions and their interviewees in exchange for full disclosure and frankness.

Solyom explores the idea of moral accountability for clinical researchers through a concept of "internal morality of medicine." In proposing a scaffolding of primary, secondary, and tertiary interests, Solyom gives clinical investigators a moral framework from which to navigate through a minefield of conflicting interests, while balancing their autonomy and their moral responsibility.

Finally, Resnik tackles the problem of managing conflicts of interest in clinical trials. Does the clinical investigator bear a responsibility, within the informed consent doctrine, to disclose financial interests he or she may have in the outcome of the trial?

Resnik applies a form of virtue ethics to reach his conclusion about the responsibility to inform.

Once insulated from the skepticism and mistrust that accompanies commercial affairs, life scientists and clinical investigators have increasingly been put under the microscope and questioned about their potentially conflicting roles as generators of knowledge and as participants in the commercial applications of discovery. The new entrepreneurial sciences have broken the innocence of the academic community and raised questions about objectivity and integrity of biomedical research. The papers in this volume reveal the new attitudes, challenges, and ethical reasoning that accompanies the changes faced by contemporary life scientists.

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