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## Fax Cover Sheet

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Date: Monday: August <sup>14 (real)</sup> 11, 2000

**TO: Dr. Stuart Nightingale**

**Re: NIH Conference Materials, Aug. 15-16, 2000**

**Fax Number: (202) 205-8835**

**Sender: Ronald Collins (202) 332-9110, #322 • e-mail: ronc@cspinet.org**

**Pages Faxed:** includes this cover page: four (4) pages

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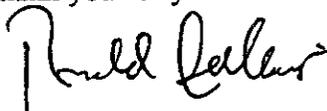
**Subject:** Background Materials for Aug. 15-16, 2000 conference

**Comments:** Dear Dr. Nightingale,

Per this fax, please find some supplementary information which we respectfully request be included in the background materials for the Aug. 15-16, 2000 conference on Human Subject Protection and Conflict of Interest.

(Also, I have tried, with no luck, to e-mail the above to you.) <sup>real</sup> ~~last~~ <sup>1</sup> week.

Thank you for your consideration.



Ronald Collins & Sheldon Krimsky

## **RECOMMENDATIONS ON MANAGING FINANCIAL CONFLICTS OF INTEREST IN SCIENTIFIC RESEARCH**

**TO:** Members of NIH Panel on Human Subject & Financial Conflicts of Interest  
**From:** Ronald Collins & Sheldon Krimsky  
**Date:** August 7, 2000

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The issue of the integrity of science and conflicts of interest, especially in the university world, continues to draw public attention and raise public concern about the soundness of scientific judgments. See, e.g., Robert O'Harrow, Jr., "Academic Research Under the Microscope: Faculty Members' Business Interests Stir Controversy," *Washington Post*, August 5, 2000, A-1; Karen W. Arenson, "Columbia Leads Academic Pack in Turning Profit From Research," *New York Times*, August 2, 2000, A-1. Equally concerned about the same general problem, the World Health Organization just released report -- prepared by Drs. Thomas Zeltner, David Kessler, Anke Martiny, and Fazel Randera -- with nine strongly-worded recommendations to strengthen WHO guidelines on conflicts of interest. (<http://www.who.int/home/whatsnew.html>) Similar recommendations were presented last May to the National Academy of Sciences by a variety of public interest groups. ([http://www.cspinet.org/new/nas\\_letter.html](http://www.cspinet.org/new/nas_letter.html))

Consistent with Secretary Shalala's call for a "national dialogue" on conflicts of interest, we respectfully offer the following observations, albeit in summarized form.

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### *The Problem*

Ethical norms notwithstanding, university science departments are increasingly becoming corporate outposts, replete with all sorts of tempting perks for enterprising faculty. For example:

- Boston University and others have entered into partnerships with drug companies to create research centers in which industry-directed research is conducted;
- the University of California and others own equity stakes in corporations that have financial research contracts with their faculty;
- Despite the myriad of conflict-of-interest problems, some universities, such as Vanderbilt University, have started their own venture-capital funds to create campus companies, this with the hope of attracting rich outside investors;
- More and more academics -- even at public universities -- are engaged in industry-sponsored research under contracts with draconian confidentiality restrictions. For example, a contract with Brown University prohibited or substantially delayed public disclosure of both the methods and results of academics' research;
- The expansion of intellectual property rights to life forms and genes has made molecular geneticists, at Berkeley and elsewhere, overnight entrepreneurs; and
- Increasingly, university events (from public conferences to published symposia to luncheons) are being bankrolled by industry -- this in addition to lavish industry

honoraria, gifts, trips, and what-have-you for professors willing to do corporate-friendly research.

In light of all of that and more, too many university presidents, college deans, science professors, and on-campus venture capitalists act as if such industry ties -- under euphemisms like "remunerative collaboration" or "partners in progress" -- do not, and could not, bias research, skew studies, or influence the outcome of research. (Empirical studies on the matter reveal otherwise.) They likewise routinely deny or ignore the real dangers associated with conflicted science -- e.g., the controversial company-sponsored gene-therapy research conducted at the University of Pennsylvania, which in 1999 resulted in the death of 18-year-old Jesse Gelsinger.

Such states of denial need not render scientists and others oblivious to the obvious, namely, that the university must always keep a cautious distance from the lures of commerce. As Dr. Marcia Angell, the outgoing editor of the *New England Journal of Medicine*, so aptly put it: "We need to remember that for-profit businesses are pledged to increase the value of their investors' stock. That is a very different goal from the mission of [the university]."

### *Some Suggestions*

So what should be done? The responsibilities for protecting the integrity of science and the public welfare from conflicts-of-interest must be shared by universities, government, and professional societies and journals. At a minimum, universities (especially professional schools and science departments) need to:

- develop uniform and rigorous rules, with enforcement measures, governing conflicts-of-interest;
- adopt policies of full and public disclosure applicable to conflicts-of-interest concerning the university, its departments, and faculty;
- prohibit secret industry-university contracts with public universities and discourage them in private universities;
- prohibit certain kinds of financial arrangements and relationships of faculty who engage in corporate-sponsored research (e.g., equity interest, management role) and carefully monitor the rest;
- formulate clear policies to protect whistle-blowers who publicize conflict-of-interest problems;
- take steps to assure that the ethics of science is an integral part of a scientific education; and
- require faculty to disclose potential conflicts-of-interest in their published articles, when human subjects are used in research, and elsewhere.

Likewise, the federal government should consider taking the following steps.

- require that all federally-funded researchers disclose financial conflicts of interest along with the source of federal funding in published papers resulting from their grants;
- develop ethical guidelines for institutional conflict of interests at universities;

- specifically include conflict of interest under the responsibilities of the Health and Human Services (HHS) Office of Research Integrity;
- require public disclosure of financial conflicts-of-interest of scientists who serve on governmental advisory boards and who testify before congressional committees; and
- require conflict of interest disclosures in informed consent forms used in human subject experiments.

Independent inquiry is one of the hallmarks of the university. It must not be sacrificed to financial self-interest. That core precept must hold center stage. For all of the above reasons, we respectfully call on Secretary Shalala, the HHS, and the Members of the Human Subject protection and Financial Conflicts of Interest panel to consider and endorse the aforementioned recommendations.

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