

June 3, 2003

Glen Drew
Office for Human Research Protections
Office of Public Health and Science
c/o Dockets Management Branch (HFA-305)
Docket Number 02N-0475
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

Re: "Financial Relationships and Interests in Research Involving Human Subjects: Guidance for Human Subject Protection." (68 Federal Register, 15456, March 31, 2003)

Dear Mr. Drew:

The Federation of American Societies for Experimental Biology (FASEB) appreciates the opportunity to comment on the March 31, 2003 Draft "Financial Relationships and Interests in Research Involving Human Subjects: Guidance for Human Subject Protection." FASEB is comprised of 22 societies with more than 60,000 members, making it the largest coalition of biomedical research associations in the United States. The mission of FASEB is to enhance the ability of biomedical and life scientists to improve, through their research, the health, well-being and productivity of all people. The investigators represented by our member organizations manage and conduct a substantial share of the nation's publicly supported biomedical research and are stewards for the safe and responsible conduct of this research. We strongly believe that financial interests should never compromise human subject protections.

The March 31, 2003 draft guidance supersedes a January 10, 2001 draft interim guidance document to which FASEB noted objections and recommended withdrawal. Our comments noted that the draft was overly proscriptive and did not consider the ongoing initiatives of institutions and professional associations in addressing financial relationships and human subject protections. The new draft guidance satisfies these concerns to a great extent.

We are appreciative that the Guidance recognizes the concerted efforts of non-governmental organizations, including the Association of American Universities (AAU) and the Association of American Medical Colleges (AAMC), and accrediting bodies for human subject protections, including the Association for the Accreditation of Human Research Protection Programs (AAHRPP), in laying the groundwork for this accountability. FASEB is one of AAHRPP's seven founding organizations and we respect the hard work and commitment of both the AAU and AAMC in this arena.

We are pleased with the Office of Public Health and Science's (OPHS) explication that the new document is intended to provide guidance and not to dictate. It is clearly a thoughtful and useful tool to be used in the analysis and management of financial conflicts. The document provides some excellent points of consideration, yet invites the individual analysis of issues rather than a proscriptive and formalistic application of criteria. Case-by-case analysis can best support continuous quality improvement.

The Guidance sensibly places the responsibility for considering when specific financial interests in research studies might potentially or actually affect the rights and welfare of subjects on the *collective* shoulders of Institutional Review Boards (IRBs), institutions engaged in research and investigators. The Guidance implies that an IRB responsible for protecting the rights and welfare of human subjects could determine that an established institutional Conflict of Interest Committee (COIC) is adequate to examine conflicts of interest that might impact human subjects, including those conflicts of individual investigators. This is important because IRBs are frequently overburdened and do not have the expertise that is required to carefully evaluate potential financial conflicts of interest. Accordingly, the Guidance should make this point explicit within **Section C. 3. Specific Issues for Consideration Regarding...IRB review** by including a recommendation that IRBs determine whether COIC methods used for considering and managing financial interests of parties involved in the research adequately protect the rights and welfare of human subjects.

FASEB agrees that long-lasting improvements to the oversight of financial conflicts of interest can be achieved only through the collaborative efforts of all those involved in human subject research. Core accountability can best assure that the analysis of conflicts is deliberative and not merely a regulatory compliance exercise. OPHS's new draft Guidance sensibly reflects this approach.

Sincerely yours,

Steven L. Teitelbaum, M.D.
FASEB President