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May 30, 2003

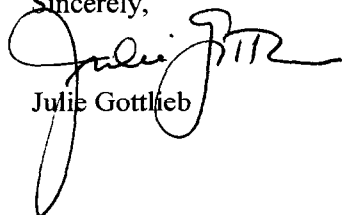
Dockets Management Branch  
Food and Drug Administration  
5630 Fishers Lane  
Room 1061, HFA-305  
Rockville, MD 20852

**Re: Docket No. 02M-0475: Draft "Financial Relationships and Interests in Research Involving Human Subjects: Guidance for Human Subject Protection"**

Dear Sir/Madam:

Enclosed please find a copy of a letter concerning the above-referenced docket that was submitted to Secretary Thompson via e-mail today. Should you have any questions, please do not hesitate to contact me.

Sincerely,

  
Julie Gottlieb

**02N-0475**

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May 30, 2003

Tommy Thompson, Secretary  
Department of Health and Human Services  
Dockets Management Branch (HFA-305)  
Docket Number 02N-0475  
Food and Drug Administration  
5630 Fishers Lane  
Room 1061  
Rockville, MD 20852

Re: Docket No. 02M-0475: Draft "Financial Relationships and Interest in Research Involving Human Subjects: Guidance for Human Subject Protection"

Dear Secretary Thompson:

Thank you for the opportunity to submit comments on the draft document titled "Financial Relationships and Interests in Research Involving Human Subjects: Guidance for Human Subject Protection." We are submitting these comments as individuals whose professional responsibilities include implementation of institutional and regulatory policies on conflict of interest as well as management of compliance with these policies. While our institutional affiliations are included below for identification purposes, our comments reflect our views as professionals working at the nexus of policy making and policy implementation in the field of conflict of interest management and not necessarily those of our institutions.

Given our responsibilities, we believe that a robust process for identifying and reviewing potential conflicts of interest is central to the protection of human research subjects. We recognize that careful management of potential conflicts of interest is critical for maintaining public trust and confidence, protecting research subjects, and preserving the objectivity of research.

We commend the Department for recognizing the complexity of conflict of interest management by issuing "guidelines," rather than proscriptive rules. Experience in administering conflict of interest policies has taught us that each arrangement involving a financial interest poses unique concerns. In taking the approach represented by the proposed Guidance, the Department appropriately acknowledges that some arrangements among government, academia, and industry involve legitimate financial relationships that create neither the potential for harm to human subjects nor risks to objectivity in research. Likewise, there are arrangements that give rise to such risks and must be managed. Accordingly, we support guidance that allows institutions to adopt policies involving case-by-case review.

We applaud DHHS for issuing Guidance that, within a framework of case-by-case review, advises investigators, institutions, and IRBs to ask key questions not only about the magnitude and nature of financial interests, but also about how particular interests will impact the subjects in specific research projects. In particular, the Guidance allows institutions themselves to develop a system for assessing the impact of financial interests in specific situations and determining which conflict of interest management tools will be most effective given the circumstances of each case and the governance structures of their institutions.

The Guidance provides a useful framework for the consideration of institutional financial interests and their potential impact on human research subjects. This issue is particularly

complex. Here, as in other areas, the Guidance sets forth important points for consideration in establishing and implementing policies on institutional conflicts of interest. We are pursuing active dialog with one another in an effort to identify best practices.

Along with recent contributions from the research community itself, the draft Guidance represents a valuable tool for evaluating and enhancing our institutions' conflict of interest management programs. Our work will benefit from the framework set forth in the document. We strongly urge the Department to maintain this programmatic approach and flexibility in the final Guidance document, as well as in related future initiatives.

Finally, as the Guidance acknowledges, conflict of interest policies differ from institution to institution. Yet institutions and investigators around the country confront similar issues. We strive to learn from one another and are participating in informal networks of professionals in the fields of conflict of interest and compliance. We appreciate the opportunity to partner in the development of HHS policy on conflicts of interest and urge the Department to actively continue this dialog with us.

Sincerely,

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