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FDA Draft Guidance on Financial Disclosures by Clinical Investigators

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COGR

an organization of research universities

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July 22, 2011

Marsha Melvin
Office of Good Clinical Practice
Food and Drug Administration
Division of Dockets Management (HFA-305)
5630 Fishers Lane, Room 1061
Rockville MD 20852

SUBJECT: Docket No. FDA-1999-D-0742 (formerly Docket No. 1999-D-4396):
Draft Guidance: Financial Disclosure By Clinical Investigators

Dear Ms. Melvin:

The Council on Governmental Relations (COGR) is an association of 184 research universities and their affiliated academic medical centers and research institutes. COGR concerns itself with the influence of federal regulations, policies and practices on the performance of research conducted by its member institutions. We welcome the creation of guidance by agencies to assist the government's partners in meeting their responsibilities in the conduct of research.

As we have noted before in responding to requests for comment on Food and Drug Administration (FDA) draft guidance and/or regulatory changes, we believe that guidance or regulations that have a direct effect on institutional employees should acknowledge or describe a role for the institution in managing compliance activities. We recognize that the FDA's primary involvement with clinical research activities in support of marketing applications occurs when those applications are presented for consideration. At this point in the drug or device development process, FDA is working with the marketing applicant and/or the sponsor of the drug or device and the role of the clinical investigator's employing institution is not directly relevant to the FDA's review.

Nonetheless, we believe that the FDA can and, where appropriate, should provide avenues for engagement by a clinical investigator's home institution in the compliance process. Research institutions including their affiliated academic medical centers have multiple roles in assuring compliance by their employees with federal regulations. Key to those roles and related responsibilities is ensuring that all research conducted either for an external sponsor or as a sponsor itself under an investigational new drug or device exemption application meets the highest standards of quality and compliance with related regulations and policies. We recognize that the FDA does not prescribe a specific process for meeting the financial disclosure requirements under the guidance proposed here. Unfortunately, in the absence of direction, many sponsors require investigators to disclose directly to the sponsor and/or applicant.

With regard to the draft Guidance for Clinical Investigators, Industry, and FDA Staff: Financial Disclosure by Clinical Investigators (May 2011), we would note that all research institutions and academic medical centers have policies and procedures in place for the disclosure, review and management of

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the financial interests and relationships of their employees (including their spouse and dependent children) that meet or exceed the disclosure requirements of the FDA. When these employees participant in a clinical trial that is a part of a covered clinical study, the marketing applicant and/or sponsor should be able to accept a certification from the employing institution that financial interests and relationships have been disclosed to the employing institution and are being managed as required by FDA regulations.

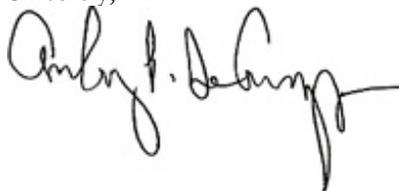
By accepting certification from an employing institution as meeting the requirement of the FORM FDA 3454 in the marketing application process when the employing institution is not the sponsor, FDA helps ensure that the employing institution is aware of and a partner in the management of financial arrangements or interests that have the potential to bias a clinical study. This participation assists the investigator in disclosing all significant payments of other sorts, as appropriate. Relying on the employing institution helps to streamline the disclosure process and reduce the administrative burden on the investigators as well as the sponsor. Investigators will be able to complete one disclosure that serves multiple purposes and the marketing applicant/sponsor can be assured that other relationship that may appear to affect the covered study have been reviewed and will be managed as appropriate according to the FDA regulation.

As a part of the draft Guidance, FDA requests comments whether and, if so, how to publicly disclose the financial arrangements of clinical investigators as they are related to covered studies. We are discouraged that FDA proposes another avenue for disclosing information that is not likely to be consistent with information voluntarily disclosed by some pharmaceutical companies, required to be publicly disclosed by certain drug/device manufacturers under the Patient Protection and Affordable Care Act (PL 111-148; Title VI, Section 6002), and proposed to be publicly disclosed under the Public Health Service revisions of the Responsibility of Applicants for Promoting Objectivity in Research (42 CFR Part 50 Subpart F).

The FDA proposes to add yet another list of financial arrangements that uses a different set of definitions for disclosing financial interests and arrangements with different thresholds and different reporting time frames. Another list will simply add to the confusion and misunderstanding by the public of the nature of the interests and relationships of a single investigator and/or their home institution. If the FDA believes such communications will truly enhance the public's knowledge and understanding, we believe that FDA should provide only a summary discussion of the interests and relationships of all affected investigators in the aggregate in the documentation released upon product approval. A summary, aggregate discussion affords FDA the opportunity to describe its consideration and conclusions concerning financial arrangements as a part of the approval process. If an individual seeks additional information, the individual can request that information through the standard FDA Freedom of Information processes. In that way, FDA can protect, as appropriate, an investigator's privacy rights.

We appreciate the opportunity to offer comment on the draft Guidance on Financial Disclosure by Clinical Investigators.

Sincerely,

A handwritten signature in black ink, appearing to read "Anthony P. DeCrappeo". The signature is fluid and cursive, with a long horizontal stroke at the end.

Anthony P. DeCrappeo
President