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May 20, 2003

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

Re: Docket No. 02N-0475; Draft Guidance, *Financial Relationships and Interests in Research Involving Human Subjects; Guidance for Human Subject Protection,* *68 Federal Register 15456 (March 31, 2003)*

Dear Sir or Madam:

Bristol-Myers Squibb is a diversified worldwide health and personal care company with principal businesses in pharmaceuticals, consumer medicines, nutritionals and medical devices. We are a leader in the research and development of innovative therapies for cardiovascular, metabolic and infectious diseases, neurological disorders, and oncology. In 2002 alone, Bristol-Myers Squibb dedicated $2.2 billion for pharmaceutical research and development activities. The company has more than 5,000 scientists and doctors committed to discover and develop best in class therapeutic and preventive agents that extend and enhance human life. Our current pipeline comprises of approximately 50 compounds under active development.

For these reasons, we are very interested in and well qualified to comment on the proposed Financial Relationships and Interests in Research Involving Human Subjects; Guidance for Human Subject Protection.

Summary of BMS Comments on Proposal

We commend the Department of Health & Human Services for proposing points for consideration by Institutions, IRBs and Investigators in establishing and implementing methods to protect the rights and welfare of human subjects from conflicts of interest created by financial relationships between parties involved in research.

However, there are several aspects of the proposed guidance that appear contrary to HHS's stated objectives, which we have cited below.

As referenced in the draft guidance, there are a number of existing regulatory requirements

regarding potential conflicts of interest in clinical research, and additional policies and guidelines have also been developed by various nongovernmental organizations. It is unclear whether the proposed guidance will provide any further protection to subjects enrolled in clinical trials. The proposal is likely to require additional paperwork and may create confusion over conflicting requirements. To ensure the guidance does not place unnecessary burdens on clinical trials, HHS should clarify how this guidance would address specific gaps in the protection afforded human subjects by existing requirements.

Specific Comments

The guidance recommends that institutions establish conflict of interest committees (COICs) and have IRB members and staff, officials of the institution, and investigators report financial interests to the COIC. The guidance does not provide sufficient direction on how this information should be collected, communicated, assessed, or acted upon by the COICs. Without such direction, these recommendations could be open to broad differences in interpretation and implementation.. The assessment of the potential for conflict of interest of an institution's key leadership and of all IRB members is complex, and many institutions already have in place a process for review of financial considerations. The creation of new layers of review will introduce additional paperwork, costs, and potential delays in clinical research programs. The guidance does not indicate what information, if any, should be forwarded to the sponsors of clinical trials.

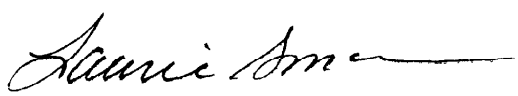
Recommendation: HHS should clarify how information about financial relationships should be collected and evaluated. Due to the various levels of potential financial relationships, it may be difficult to standardize, at best, in a meaningful way. A more favorable solution would be to increase the scope of the IRB, rather than to form an additional committee (COIC).

We agree that financial relationships should be addressed by the investigator through a statement that would be included in the informed consent document. This would inform the participant that the investigator/institution is receiving payment for the conduct of the clinical trial.

Recommendation: The guidance should clarify the intent of the additional IRB responsibility beyond what is currently specified in existing requirements.

BMS appreciates the opportunity to provide comment and respectfully requests that HHS give consideration to our recommendations. We would be pleased to provide additional pertinent information as may be requested.

Sincerely,



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