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Assistant Corporate Counsel
Legal Division

June 27, 2000

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, rm. 1061
Rockville, MD 20852

**Re: Draft Guidance for Institutional Review Boards, Clinical Investigators, and Sponsors: Exception from Informed Consent Requirements for Emergency Research
Docket No. 00D-0805, 65 Fed. Reg. 16923 (3/30/2000)**

Dear Dockets Management:

Pfizer Inc. submits these comments on the *Draft Guidance for Institutional Review Boards, Clinical Investigators, and Sponsors: Exception from Informed Consent Requirements for Emergency Research* published in the *Federal Register* on March 30, 2000.

1. The draft guidance states FDA's expectation that sponsors will bear the costs for community consultation and public disclosure activities. It is not clear why FDA is commenting on the question of costs, which in this context are outside the Agency's regulatory authority. We suggest that statements regarding costs be removed from the draft guidance.
2. In the section "Type and Frequency of Community Consultation," the draft guidance states that "low attendance at meetings should not be construed as meaning that there is no interest in or objection to the research by the community(ies)," and goes on to suggest that additional outreach must be made in such situations. We disagree that an IRB cannot infer lack of community interest/objection from the community's silence on an issue. If proper notification to the community has been made, a lack of expressed interest is a strong and reliable indication that the community has no objections to the study. Sponsors should not be required to engage in pointless importunings to arouse interest where there is none. We thus suggest inserting the word "necessarily" before the phrase "be construed" in the passage quoted, to remove the suggestion that community silence is inherently unreliable.

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3. In Section B 1, under "Content," the draft states, "the clinical investigator and IRB must disclose the study plans to the public." Due to the proprietary information contained in study protocols and investigator's brochures, we believe that the sponsor, in addition to the IRB and clinical investigator, should determine the appropriate information for disclosure.

Thank you for your consideration.

Sincerely yours,

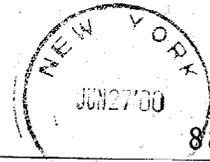
A handwritten signature in black ink, appearing to read "Jeffrey B. Chasnow", with a long, sweeping horizontal stroke extending to the right.

Jeffrey B. Chasnow

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