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February 20, 2001

Wendy Taylor, FDA Desk Officer
Office of Information and Regulatory Affairs
Office of Management and Budget (OMB)
New Executive Office Building
725 17th Street, N.W.
Washington, DC 20503

Dear Ms. Taylor,

As Chair of the Harvard Committee on Microbiological Safety, the Institutional Biosafety Committee for Harvard University and its seven affiliated hospitals, I wish to submit comments regarding the Proposed Rules on public disclosure by the FDA (Federal Register of 18 January 2001, pages 4688 through 4706).

I am in full agreement with the FDA as to the value of public disclosure of non-confidential materials submitted to the Administration in support of gene transfer and xenotransplantation studies. I also applaud the FDA's intention to provide the public with reasons behind its regulatory actions. I look forward to specific details as to the material to be disclosed.

I am, however, concerned about the lack of coordination between FDA and NIH in their disclosure requirements. For instance, both agencies accept sponsor submissions using a structure mandated by the NIH Guidelines in Appendix M. It is disturbing that this cooperation is not in evidence in the proposed rule. A cooperative effort between FDA and NIH to resolve conflicts in their regulations would have been welcome. A clear distinction must be made between the projected public roles of the FDA and NIH RAC.

Until the two agencies coordinate their reporting policies, investigators will be forced to devote needless effort to slightly different agency requirements. These duplicate efforts will in no way benefit the public. They may, perversely, lead to public confusion. Slightly different definitions will lead to reporting differences that obscure rather than illuminate.

In short, I fully support the FDA's disclosure efforts but hope that redundant reporting requirements can be minimized.

Thank you for your consideration,

Andrew B. Onderdonk, Ph.D.

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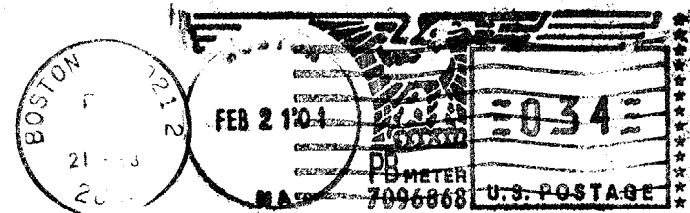
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