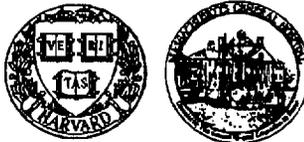


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Dockets Management Branch
Food and Drug Administration
Room 1061, HFA-305
5600 Fishers Lane
Rockville, MD 20857

RE: Docket No. 98N-0339

This letter is to express my strong opinion that it is critically important for the FDA to maintain an excellent capacity for basic science research in order to foster its ability to perform its regulatory duties.

I have been a member of the Biologics Response Modifiers Advisory Committee for the past several years. I have been a Chairman of a Site Visit to the FDA. I have also discussed the problems of regulation and basic science with numerous members of the Food and Drug Administration. There is no question in my mind that the public safety is protected best when regulators of the Food and Drug Administration have personal experience with the basic research issues involved in their fields. In addition, I believe it is to the advantage of corporate sponsors that they have experienced and knowledgeable reviewers evaluating their applications. Regulators without personal research knowledge in the field are more apt to ask numerous questions and to miss the critical features of any new proposal.

It is my strong sense that support for research at the Food and Drug Administration has diminished considerably. Many of the regulators I have talked to who are attempting to perform basic science research have mentioned the reduction in support personnel and in funding for post-doctoral fellows. The sense that performing research at the Food and Drug Administration in the future may well become impossible has led many individuals to suggest that employment elsewhere would soon be required.

One important step that could potentially improve the outlook for investigators at the FDA would be to ensure that they have access to research funding from agencies such as the National Institutes of Health, which have traditionally denied funding to employees of the Food and Drug Administration. In addition, the in-house research budgets should be maintained at the FDA to the highest extent possible. I believe this is a major priority for the organization in its effort to serve the public well.

Sincerely,


Hugh Auchincloss, Jr., M.D. /cms
(Dictated but not signed in absence.)

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