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1053 72 MAY 24 2002  
Dockets Management Branch  
HFA-305  
Food and Drug Administration  
5630 Fishers Lane  
Room 1061  
Rockville, MD 20857

**Subject: Docket No. 01N-0322  
Institutional Review Boards: Requiring Sponsors and Investigators to Inform  
IRBs of Any Prior IRB Reviews ANPRM**

23 May, 2002

Dear Sir/Madam:

Thank you for the opportunity to comment on the "Institutional Review Boards: Requiring Sponsors and Investigators to Inform IRBs of Any Prior IRB Reviews" ANPRM published in the Federal Register on March 6, 2002. Below are Genzyme's comments for your consideration.

1. Patient safety is of primary importance to us, and we welcome regulatory initiatives in that regard. However, we question whether mandatory disclosure of previous IRB decisions would prove to significantly increase patient protection enough to justify the tremendous administrative burden placed upon Sponsors, Investigators, and IRBs. This proposed rule would require IRBs to supply Sponsors and Investigators with detailed rationales as to why proposed research was approved or rejected, something that is not currently done. This proposal is surprising as the OIG report specifically recommended that Federal IRB requirements be recast to eliminate or lessen some of the procedural requirements directed to IRBs. We wonder if IRBs believe that the perceived value of seeing other IRB decisions outweighs the time spend to create, provide, and review incoming and outgoing documentation.
2. Currently, there is nothing to prevent IRBs from soliciting information as to whether other IRBs or regulatory authorities have raised concerns about any aspect of proposed research.
3. We are concerned that this proposed rule could potentially paralyze trials involving human subjects. While the documentation alone is a significant hurdle, we can envision a scenario where individual IRB would elect to wait until other IRBs had rendered a decision, thus creating considerable delay at multiple sites.
4. We also note that protocols are occasionally rejected because of resource constraints or an institutional lack of interest in the research topic. Surely circulating this kind of information adds little value to subsequent IRBs.

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As noted earlier, IRBs are free to gather more information, as they deem appropriate. However, if FDA decides to amend the IRB regulations, we respectfully suggest the following:

- A. If FDA decides that Sponsors are to be responsible for disclosing IRB information, we ask that this disclosure be clearly limited to substantive decisions, i.e., approvals, rejections, and supporting documentation. It is imperative that any regulations exempt the flurry of paperwork that normally accompanies an IRB application from disclosure, as the administrative burden will be crushing to all involved parties.
- B. Further, we agree that disclosing only negative responses is potentially biasing, therefore we ask that if disclosure is required, that it be balanced and include positive and negative reviews. If a negative review is received the sponsor should clearly state what actions if any were taken to overcome the objections or why it believes the IRB should have granted a positive disposition.

Genzyme appreciates the opportunity to comment on the "Institutional Review Boards: Requiring Sponsors and Investigators to Inform IRBs of Any Prior IRB Reviews" ANPRM. Please contact me at (617) 374-7275 or Juliette Shih at (617) 761-8929 should you have any questions regarding this letter.

Cordially,



Robert E. Yocher  
Vice President  
Regulatory Affairs



Juliette E. Shih  
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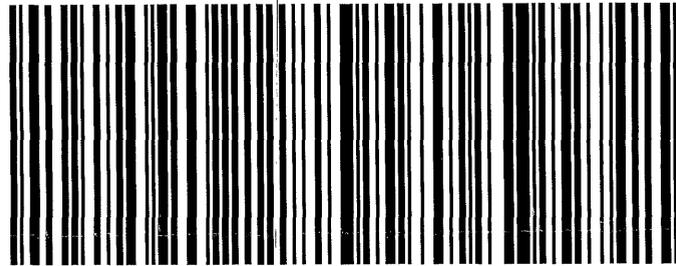
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