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

COMMENTS RE: DOCKET #2005D-0103

I am writing in support of the idea to use a centralized IRB review process for multicenter clinical trials, and respiratory clinical trials in particular.

Recently, our organization has been approached by a number of clinical investigators and IRB members regarding the use of our FDA approved drug, Provocholine® in the clinical research setting. It is our position that a centralized IRB, specializing in a particular therapeutic area would gain a much higher level of expertise and efficiency, augmenting the IRB resources of a particular institution.

Below is a summary of the reasons we feel a centralized IRB, focused on Respiratory based clinical research may improve the safety of human subjects and reduce the liability of clinical investigators, sponsors and institutions:

1. Currently, IND forms do not contain any information on diagnostic drugs being used as part of a clinical research protocol when it is not the new drug being developed and tested. Many respiratory based research protocols include methacholine challenge testing as part of the study protocol but IRB's routinely fail to ensure that the methacholine drug supply is approved for human use, and therefore also fail to include it in the patient consent form. It is our belief that a centralized IRB, specializing in Respiratory research will develop a higher level of expertise in specific issues of this type and therefore better protect human subjects in clinical research.
2. Multiple reviews by multiple IRB's can not only result in unnecessary duplication of effort, delays, and increased expenses but also may require variations that decrease standardization from site to site. A common example from our experience is when local IRB's require

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methacholine challenge protocols to be performed differently according to safety information obtained from different sources/references.

Thank you for the opportunity to submit our comments. Please feel free to contact me directly if you would like any further clarifications. I would also like to request that discussions regarding standards for specific therapeutic areas include further comments and suggestions by individuals and industry.

Sincerely,

A.M. Hayes

Anne Marie Hayes,
Sales & Marketing Manager

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