

UNIVERSITY OF MINNESOTA

February 19, 2007

Office of the Vice President for Research

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Division of Dockets Management (HFA-305)
Food and Drug Administration
Room 1061
Rockville, MD 20852

To Whom It May Concern:

Re: Docket No. 2006N-0061
RIN number 0910-AF13

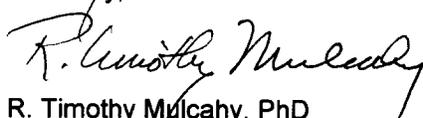
Clinical research involving prescription drugs is a major activity in most university academic health centers. At the University of Minnesota there are about 60 investigator-held IND studies in progress at any one time. Of these 60 studies, approximately 75% involve lawfully marketed drugs. In half of these studies the costs of these drugs are covered by their manufacturer or by external funding. The remaining studies have no means of recovering the cost of the drugs. In all but 2 of these cases, the studies have not yet begun or have been abandoned. There are other instances where the investigator has decided not to pursue the research when an IND is needed because of the response from FDA denying authorization to charge for the investigational drug that is otherwise lawfully marketed.

Most investigator-initiated IND research involves small- or intermediate-size patient populations, usually less than 200. The research projects are intended to acquire generalizable knowledge to be shared with the medical community through peer-reviewed publications and presentations. This research is often not supported by the manufacturer of the drug. It is not the intent of our researchers to commercialize the results of the studies. Therefore, there is no mechanism by which the cost of the study drugs can ever be recouped by the researcher.

The University of Minnesota supports the FDA's proposed rule to revise the current charging regulation to clarify the circumstances for which charging for an investigational drug in a clinical trial is appropriate. In particular, the University of Minnesota supports clarification and changes to the regulations as they pertain to requests to charge for approved drugs used in studies by sponsor-investigators that are intended to evaluate the approved drug for a new use. The University of Minnesota believes that requests to charge for investigational drugs in these situations are appropriate.

In conclusion, the University of Minnesota supports these proposed rules.

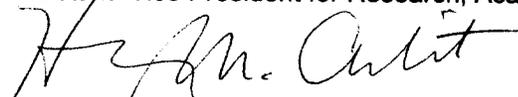
Sincerely,



R. Timothy Mulcahy, PhD
Vice President for Research



Mark S. Paller, MD, MS
Assistant Vice President for Research, Academic Health Center



Harvey Arbit, PharmD, MBA
Director, IND/IDE Assistance Program

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