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Chevy Chase  
MD 20815  
August 21, 2004

To: Division of Dockets Management  
5630 Fishers Lane, Rm 1061  
Rockville, MD 20857

**Re: Docket No. 2004N-0018,  
Human Subject Protection; Foreign Clinical Studies Not Conducted Under an  
Investigational New Drug Application**

As a medical epidemiologist I write to urge the Food and Drug Administration to reconsider its proposed rule for foreign clinical studies “to eliminate the reference in §312.120 to the Declaration” of Helsinki, replacing it with Good Clinical Practice (GCP) guidelines established by the International Conference on Harmonization (ICH).

Until its adoption in 1964 by the World Medical Association, there was no universal standard of ethics for physicians engaged in research involving human subjects. The Helsinki Declaration has since come to be regarded and respected worldwide as the most important standard of ethical conduct for research involving human subjects. It is not a static document and is amended periodically to reflect medical progress.

Clinical trials are often conducted in developing countries, because they are said to be cheaper there with less regulation and bureaucracy and greater availability of subjects. Populations of developing countries are very often more vulnerable by virtue of their relative poverty and lack of education and sophistication.

Eliminating reference to the Helsinki Declaration for foreign clinical trials might send a message that the agency no longer supports high standards of ethics in research involving human subjects in foreign countries, and is in effect abandoning the moral high ground. As a Federal agency FDA must be mindful of the fact that many serious ethical violations have been committed by various Federal agencies in the past. We must be careful not to undermine the trust and credibility that are the basis for human subject participation in research.

I understand the need for data standardization as proposed in the ICH GCP and would therefore urge the agency to add GCP guidelines without eliminating reference to the Helsinki Declaration. The two are not mutually exclusive.

Lois La Grenade, MD, MPH