From: Lee, Bonnie on behalf of GC-GCP Questions
Sent: Monday, November 21, 2005 11:48 AM
To: [people]
Subject: RE: FDA and Foreign Clinical Trials

Dear [people],

- On June 10, 2004, FDA published a proposed rule to revise its regulations, "Human Subject Protection; Foreign Clinical Studies Not Conducted Under an Investigational New Drug Application," 21 CFR 312.120. The proposed revision reflects FDA's efforts over the past decade to harmonize and achieve "Good Clinical Practice" regardless of where in the world a clinical trial is conducted. By requiring that studies be conducted in accordance with GCP, including review and approval by an independent ethics committee (IEC), the proposal more clearly articulates FDA's expectations for both the protection of human subjects and the quality of scientific data in foreign studies. Specifically (and in keeping with Office of Inspector General's recommendation), FDA is recommending that documentation about the conduct of the studies submitted to the agency as part of an application include attestations by clinical investigators that the studies were conducted in compliance with GCP. I cannot predict when the final rule will be published (I hope soon). However, the preamble to the proposal should be helpful to you. It is available on the internet at: http://www.fda.gov/OHRMS/DOCKETS/98fr/04-1583.htm. (The preamble is the section, in the Federal Register document, that precedes the codified section.)
- FDA has coordinated efforts by the World Health Organization, the Pan American Health Organization, CIOMS, and other international organizations to develop and harmonize guidance for Good Clinical Practice. For example, FDA has contributed to WHO's, pilot-state "Surveying and Evaluating Ethical Review Practices" (published February 2002) and to the CIOMS International Ethics Guidelines for Biomedical Research Involving Human Subjects (published November 2002). FDA is also contributing to the WHO Handbook of Good Clinical Practices: Resources for Health and Biomedical Research, which aims to strengthen research investigators by centralizing relevant information to support the conduct of studies, data gathering and reporting, and provide advice to researchers on the application of GCP under varying and novel conditions.
- FDA has proposed and begun implementation of an initiative to develop better communication with the European Agency for the Evaluation of Medicinal Products (EMEA) and improve coordination and harmonization of our respective inspection programs for clinical trials. Better communication channels would allow FDA and EMEA to share information about inspections of clinical study sites and to leverage resources, by providing both agencies with more information than either authority would obtain from its own inspection program. Such inspectional information would improve the agencies' knowledge base both with respect to the reliability of data and compliance with human subject protection requirements.

Sharing program information will also facilitate a more harmonized approach to our respective oversight programs. By harmonizing inspection procedures and policies, the agencies may eliminate duplicative or divergent approaches to clinical trial oversight and, in turn, reduce the regulatory burden for multi-national companies conducting global clinical trials. Reduction of unnecessary regulatory burden would also enhance the efficiency of the clinical trial process with respect to data quality, subject safety, and time to approval for promising new therapies.

FDA has assisted other countries with capacity building activities for international GCP inspectorates. For example, FDA provided training for a new inspectorate at the Health Sciences Authority - Singapore (January 2004) and lectured on GCP inspections for Therapeutic Goods Administration (TGA) Australia (July 2004). FDA plans to address GCP at the Asia-Pacific Economic Council (APEC) Regulators meeting in Korea (November 2004). FDA has also begun concept planning for training on a GCP inspectorate in Jordan (late 2005).

I suspect that skepticism about FDA's ability to regulate clinical trials conducted outside the United States stems from some parties misunderstanding of FDA's authorities. The information there on the acceptance of foreign clinical studies describes our requirements; see the second sheet at: http://www.fda.gov/cder/ebridge/ebridge.htm.

If you haven't looked at it, you might also want to review the GAO report on the Globalization of Clinical Trials at: http://cog.hhs.gov/ser/reports/ser-01-08-00190.pdf. Although (if memory serves me right) I believe the GAO misunderstood certain items, it does describe the controversy you mentioned.

I hope that this is helpful to you. Some of the "bullets" above, could probably be updated; but if I did that, you'd have to wait longer. Happy Thanksgiving.

Sincerely,

Bonnie

Bonnie M. Lee
Consumer Liaison for Human Subject Protection Policy
Good Clinical Practice Program, FDA
This communication does not constitute a written advisory opinion under 21 CFR 10.85, but rather is an informal communication under 21 CFR 10.85(j) which represents the best judgment of the employee providing it. This information does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed.

-----Original Message-----
From: [people]
Sent: Monday, November 14, 2005 11:21 AM
To: [people]
Subject: FDA and Foreign Clinical Trials

Hello.
I am looking into the area of the FDA's role in regulating clinical trials conducted outside the US with regards to drugs destined for the US market. Throughout the CFR it appears that the FDA has the necessary jurisdiction and the congressional mandate to insure that these trials are carried out under sound scientific practices, specifically within the realm of human subject protection.

Yet, numerous law review articles suggest the FDA is lacking in this area. Is it a matter of political will, i.e. funding?

Any suggestions on helping me better understand this area of controversy? Who I could speak with or where I could turn?

I cheerly thank you in advance for any suggestions and guidance.

Sincerely,
[people]