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Presentation to the FDA Science Board
Enhancing Regulatory Science Animal Research

A. My qualifications

I am a Past President of the FDA Sigma Xi Chapter and I am a member of the Chapter now. In 1995, I retired as a research physicist from CDRH/OST and since then I have regularly taught, as Adjunct Associate Professor, Biomedical Engineering Department, Catholic University of America, a course in neural stimulation in rehabilitation. I am presently a nonaffiliate member of the CDRH/IACUC and I want to emphasize that my statement below is strictly my own. I am mentioning the membership in this committee to explain how I developed an interest in the regulatory science issue of enhanced animal research.

B. Rationale

The unjustified death of a volunteer at Johns Hopkins Medical Center and previously the unjustified death of a volunteers at the University of Pennsylvania Medical Center are of great concern to me. Unfortunately other fatalities in human trials have occurred as indicated in an article in the August 6, 2001 Newsweek issue on page 36-42. These are the reasons that I like to propose here that possibly enhancing the role of regulatory science animal research might result in minimizing these types of fatalities.

Before I become more specific, I would like to first refer to the FDA 2001 Science Forum that was concerned with establishing linkages between various scientific disciplines. I believe that here is another opportunity to establish new linkages between animal and human research and by doing this possibly increasing the safety of volunteers in clinical trials. Based on my own research in global-local thinking and the information explosion, I applaud the program of the 2001 Science Forum on "Science Across Boundaries".

C. Enhancement Considerations

Since I do not have specific data available pertaining to results in regulatory science animal research, all I can do is to ask a few intuitive questions and then hope that the Board will have time to respond to them.

1. IRB's
Could IRB's enhance their awareness of considering animal research in terms of trying to minimize fatalities in clinical trials?
2. FDA Reviews
Could the awareness of FDA reviewers be enhanced in terms of assessing whether animal research is needed before human trials are approved?
3. In-house Animal Research
Could the FDA focus on doing animal research in support of clinical trials be enhanced?

D. Final Comments

In support of my proposal of enhancing regulatory science animal research, I would like to refer to the statement of Dr. Schwetz in his introduction to the 2001 Forum: "As we continue to enhance the science foundation of FDA, the effective training and retraining of our scientific and our medical personnel is among our highest priorities." Accordingly, it might be useful to have a session on enhancing regulatory science animal research at the 2002 FDA Science Forum if possible or instead later on at the 2003 Forum.