Public Citizen

December 14, 1978

Commissioner Donald Kennedy
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20852

Dear Commissioner Kennedy:

These comments on your agency's proposed regulations on investigational device exemptions (IDEs) will serve to introduce you to full-time consumer oversight of your agency's regulation of medical devices. I have recently begun work for Public Citizen Health Research Group, headed by Dr. Sidney Wolfe, as the staff attorney specializing in medical devices and technology.

Your subordinates in the Bureau of Medical Devices and the General Counsel's office have issued, after a delay of over two years beyond the statutory deadline, a set of "tentative final regulations" concerning IDEs. 43 Fed. Reg. 20746-57 (May 12, 1978). These "tentative final regulations" would seriously undermine the protection to be accorded human beings upon whom experimental medical devices will be tested. The proposal flatly contravenes the Medical Device Amendments of 1976 in several respects. And the Director of the Bureau of Medical Devices, David Link, is reported to be moving toward weakening the regulations even more.

Section 520(g) of the Food, Drug and Cosmetic Act, as amended in 1976, outlines procedures and conditions under which experimental medical devices could be tested on human beings without meeting the statute's requirements concerning performance standards, premarket approval, etc. The IDE regulations, once final, will specify what those procedures and conditions for human experiments will be.

Your predecessor promulgated in August 1976 a set of proposed rules on IDEs. 41 Fed. Reg. 35299-313 (August 20, 1976). They were subjected to a barrage of criticism from industry and private practitioners. Unfortunately your subordinates have bent over backwards, during the two-year interim, to accommodate the industry's hue and cry about "over-regulation." The enclosed document, commenting on the May 1978 proposal, sets out in detail our concerns about the abdication of your agency's review responsibilities and the weakening of protections for human subjects of medical device experiments. To summarize:

1. The May 1978 proposal would force FDA to review, under an "express" notification procedure, proposed experiments posing a "substantial risk" of harm to human subjects and other experiments involving life-supporting or "vital" devices, without sufficient data to make an independent judgment on the issues of safety and validity of research design. See pp.3-4 of our comments.

2. The proposal would deny FDA any chance at all to review proposed experiments involving certain life-supporting diagnostic devices. See pp. 5-6 of our comments.

3. The proposal would exempt from all FDA scrutiny certain "custom devices," i.e. non-commercial devices used by individual health professionals only in the course of their own practices. The regulation as written presents insurmountable logical and practical problems and contravenes the statute in important respects. The regulation would amount in many cases to a license for practitioners to experiment on their patients free from supervision or review. See pp. 6-9.

4. The proposal's provision concerning export of devices creates a double standard for device testing: human subjects would be afforded considerable (though insufficient) protections if they are Americans, but only minimal and perfunctory protections if they are not. This change from the August 1976 proposal was slipped into the May 1978 proposal without comment or explanation. See pp. 9-10.

5. The May 1978 proposal would permit waiver of review of experiments by institutional review boards (IRBs) in many situations unauthorized by the statute. The IRB waiver provision is not only illegal; it is also directly contrary to the recommendations of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. See pp. 11-12.

6. The May 1978 proposal should require a fuller flow of information about the progress of an experiment from the experiment's sponsor to the institutional review boards involved. See pp. 13-14.

The enclosed comments also raise our concerns about several other less critical aspects of the May 1978 proposal.

Dr. Wolfe and I would be happy to discuss the problems in the IDE proposal with you at your convenience.

Sincerely,

Robert B Leflar
Staff Attorney

cc: Richard Cooper
Senator Edward Kennedy