

lation to provide for the establishment of a national drug testing and evaluation center which would be operated and maintained as a part of the FDA. You may have read the article in the New York Times yesterday—

Dr. FREEDMAN. The Times comes to Chicago a day late. Sorry.

Senator NELSON. I would commend it to your attention. It is a very long, detailed article involving this particular matter. But in any event, I wanted to ask you what your viewpoint was about the current method of testing and producing IND's and developing the drug?

Dr. FREEDMAN. I think it is confusing to everybody. One of the problems is adequate clinical investigators, adequate staff, and adequate adjudication of what that drug needs to have before it can get an IND. I would not want to be sitting in FDA deciding that. That is why I am proposing here that we really do some case histories involving the parties involved and find out how to make this process work more efficiently and smoothly. For example, there is no question in my mind that for psychotropic drugs it is hard to get new populations of patients to try these drugs.

It is a very difficult matter to get a drug to test. I wouldn't want to see any drug tested that was a "me too" drug—I would want to see something revolutionary and new. My question is, If you had something new and you had a good hunch, what would you have to go through and what would it cost? If you are a pharmaceutical researcher—and he is supported by the marketing and other departments—you are in fact working with fellow researchers, and you think they have discovered something, and you have at great expense tested it out in chemical tests and in animals; what does it now cost also to try that in man? What does it cost in terms of redtape, what does it cost in terms of very careful and honest adjudication of the safety of putting it ahead into clinical tests, let alone who tests it. That represents, as you have shown in testimony here, a maze of problems—including the choice of who tests it. How do you underwrite its financial support, and so forth? Over the years I have run into different segments (and different views) of this whole network of the drug establishment—I now really think people have got to sit down and iron this out. I don't know if they can come up with solutions for everything. But they have got to present the problems and see—if you play the role of a regulator, and I play the role of a manufacturer, and we turned it back and forth for a while, could we come out with some sensible solutions?

As it is right now, there is a great deal of discouragement, because most of the rules have been laid down by law and have not really been generated out of the interplay of real events. And that is what I am urging upon us. I think it can be done, and I think people want to do it in all these sectors of the drug "establishment," or preferably—the "drug network."

I never knew until a few years ago, when I consulted with one or two drug houses, how substantively you do develop a drug. So in all my medical education I never had any course on the development of a drug. I knew how Fleming approached penicillin. And there are some other romances. My ignorance cannot be unique.

Senator NELSON. He developed it by accident.