

Well, I did add in my meager remarks that I thought that the question of whether we should develop unprofitable compounds ought to be approached; what is the cost of that to society? And I think that any documentations and studies coming out of this blue ribbon commission should involve persons who had authentic knowledge and responsibility for the various steps along the line from drug development to patient care if we really wish to be informed rather than preached at. And by that I mean I really want to know from real experts. I have seen cases where a statement was not permitted, say, in a drug advertisement for a patient suffering from psoriasis. But the doctor who passed on that, the official of the FDA who passed on that, had never treated psoriasis—he had read it, but he didn't know really what happens to such a patient.

So to adjudicate these matters we want people—and they are easily available—who know something in the way of personal responsibility, personal experience, personal competence, and the areas that they are involved in. If we hear from drug houses—I would like to hear from very good researchers in drug houses who have been there for a while and have seen a lot happen.

Senator NELSON. Doesn't the experience of the NAS-NRC indicate a formula for bringing this kind of expertise to bear on the question of efficacy and relative efficacy and on the question of IND's?

Dr. FREEDMAN. Yes. I will tell you, somebody remarked that they didn't see any explicit statement in the psychiatric drug panel. My reason for not doing that is that I wanted to enlarge the community of people participating in that; that is, I wanted to see more experts that could have been tapped for that particular study, take a look at this problem. And through the American College of Neuropsychopharmacology that is being done. And I think that is a useful education for all of us too, to spread the network of involved people.

Senator NELSON. You were chairman of the NAS-NRC panel. What was the title of the panel?

Dr. FREEDMAN. "Psychiatric Drugs."

Senator NELSON. And your panel hasn't reported?

Dr. FREEDMAN. Oh, we reported. We simply made no general public statement as yet, because I would like to see more people participate in that.

Senator NELSON. So you haven't completed your recommendations yet?

Dr. FREEDMAN. Oh, yes. Each drug has been recommended. And we ourselves, for the FDA, have spoken to certain characteristic problems. We haven't published it as a white paper as yet.

Senator NELSON. So it has not been made public as of this date, is that what you are saying?

Dr. FREEDMAN. Any comments that we made to the FDA have not been extracted and put together as a paper. This is being done by many members of that panel now in collaboration with others who were not on the panel. So I think by November or December you will see something.

Senator NELSON. When the 1962 law was passed and it was decided that they would use the NAS-NRC to do the efficacy evaluations, what