about the state of the art as it is, if it has that kind of official stamp.

But that aside, the real issue of the 1962 act was, what guidelines do you need if you are going to develop a drug.

For drug efficacy, we have arrived at some notion of what the situation is at the moment for testing, for objective data, and for claims. But if somebody is developing a drug, what is it that they have to do? And this we haven't said. Criteria will and should shift with new knowledge.

And so it is in limbo. The drug house has to guess, or should have passionate people there that want to know all the facts or know how to develop them. But they had better have understanding when they come to FDA. And FDA has to be protected. That is, the people there may make an error. If they have so to function that they must never make an error, they may never make a ruling.

Senator NELSON. That happens in some bureaucracies.

Dr. FREEDMAN. Yes, sir.

Mr. DUFFY. Doctor, if I may interrupt you just a moment, I am curious and would like to explore a little bit into your comments, about the use of these NAS–NRC studies and your concern as to how they may effect future court actions, and so on. Are you in essence saying that perhaps regulation may interfere with the practice of one's profession and the ability to innovate in that practice?

Dr. FREEDMAN. You have said it. I tried to indicate what medical practice intrinsically was, without giving you a boring professional lecture on how in fact the physician operates with flexibility and innovation with certain drugs and with certain therapies. This was always a question during the drug efficacy review. Nobody knew whether this would be interfered with or not. And some of us asked that the FDA be sure to take our work as advisory. The burden was on them; here is the best we could come up with. And I assure you that we were highly critical. But we wanted to know what use will others make of what we say.

Mr. GORDON. Doctor, may I interrupt you. You are not saying, are you, that there is no such thing as a concept of good medical practice or bad medical practice?

Dr. FREEDMAN. In fact I am saying just that. There is a good medical practice. But you cannot arbitrarily legislate in good medical practice—I have seen revered teachers argue about the appropriate treatment of diabetes. The argument was instructive.

Mr. GORDON. Instructive?

Dr. FREEDMAN. Instructive. But you cannot program—you cannot make rules without reason—reasoning is more important than rule. I don't want to be the doctor telling people how they must use psychotropic drugs. I will tell them why I think they must use it in this way. And I would like to join an argument and a good scientific debate and see what we can learn. That is what good medical practice is all about.

But it means that there is a limit on the extent to which you can program what has to be done. Science works by improved consent among peers—not by fiat.

Now, if you have flaccid medical control and flaccid medical constraints and lack of initiative by isolated medical bodies on any one of these issues that you have looked at, then somebody has got to push