is your view of this approach to this particular problem? In other words, is there a better way, or is this a good way?

Dr. FREEDMAN. It is an incomplete way. What is now needed—and I think there is a movement afoot—if we are concerned about efficacy, is further work on the criteria by which you establish efficacy. And once we do that, there will be an impact. Somebody out there is making drugs and needs to test them. Do they have the appropriate guidelines of what they need to do, from cost accounting to specialized personnel, to safeguards for clinical testing, the whole gamut—do they know how to proceed? Do the Government officials in FDA know precisely what to require, now that we have begun to look at criteria for efficacy?

Senator NELSON. You are talking about——

Dr. FREEDMAN. The consequences of beginning to make that a legal requirement.

Senator NELSON. Do I correctly understand that the requirement that was laid down with respect to the various panels of NAS–NRC was that there had to be presented well-controlled scientific studies that supported the claim for the drug?

Dr. FREEDMAN. Each claim, exactly.

Senator NELSON. Then in addition to that, do I understand correctly that the individual understanding, expertise and experience of the panel members was brought to bear on the question also?

Dr. FREEDMAN. Exactly. And they could call on any consultants outside the room that they wanted to represent either that or any other kind of expertise, correct.

Senator NELSON. And if a drug was not supported by an adequately controlled scientific test, it failed at that point forthwith, didn't it?

Dr. FREEDMAN. It certainly did.

Senator NELSON. Have you been raising the question as to whether or not the so-called well-controlled scientific tests are themselves adequate.

Dr. FREEDMAN. Yes. They have to be developed. In some areas they are adequate, they will be improved. In others we need improvement. You run into some problems that you don't know how to adjudicate in terms of objective tests. You run into the problem that there are in fact different modes of practice and you finally run into the business of regulating it. I think we did a good job; it was an awful job to have to do, because it is very hard to be the official person saying that this is veritably the truth. You can't program drug use, is what I am trying to say. So occasionally you will come into differences of opinion. And that was accommodated for in the study; you have a minority report and a majority report. I don't think our panel ran into that—we almost did once or twice, but we came to agreement. But you worry about being the arbiters of medical practice and patterns of medical practice. You don't know how the FDA is going to use your material.

Nor do we know if what we say is going to have standing in court. And all of this is what I mean by the health network. What statements of public bodies do indeed have adjudicative validity and will be used—or misused—as such in individual instances, such as malpractice suits or other kinds of instances? One should be very, very careful, as to the burden of an objective scrutiny of the data and assertions