

Accordingly, I suggest a blue ribbon panel, tapping men of good will and expertise from the various involved sectors, engaging in a 2-year commission or, preferably, by the National Academy of Sciences. Such a group would have to commission studies which could document clearly the variety of ways by which new drugs are developed with actual case histories. The Commission should explore: the imbalance between our almost infinite capacity to synthesize molecules and our restricted means of testing them.

Senator NELSON. What are you referring to as to the restricted means for testing them?

Dr. FREEDMAN. Two things. One is, there simply are not enough clinical investigators to take molecules that might be interesting or important and study them in man. It is the whole question of how you develop a drug before you get it to man. But behind that is the more important question to which I don't know the answer. If we can synthesize any number of molecules, it is insane to believe that we could or should test them all. The question is which ones do you test.

Senator NELSON. Why synthesize any if you don't test them?

Dr. FREEDMAN. First of all, you could test them in animals, or you could follow a hypothesis and say, this molecule looks interesting, it has certain effects in a biological system. Now, if we changed it and made it look something like a related molecule that had other effects and we linked them together, would this do something? If you are lucky and you know that this molecule affects a specific enzyme system, you think that enzyme system is related to disease, or you know it is, then you have a rational way of devising molecules aimed at a sequence of enzymes that might lead to change what happens in diseases. You test this in a variety of infrahuman biological systems.

Some of them may be toxic. And some won't get absorbed into the organ you want them to go into. So you have this capacity to make more potential drugs than you could possibly test in man. And, in between, you have to have the judgment of what drugs are worth testing, and on what basis. And I am saying case histories of what would be useful.

Senator NELSON. When you say testing, you are talking about drug testing?

Dr. FREEDMAN. Eventually you have to test them in man.

Senator NELSON. You are referring to that kind of testing, not some kind of laboratory testing?

Dr. FREEDMAN. Both. I am talking about the many steps before bringing the drug finally to man. And I have always been puzzled as to how people decide when to and why to.

Senator NELSON. Of course, that aspect of the drug industry which involves the company is one thing. NIH may be doing a test for one reason, and a scientist in his own university may be doing it for another reason, may he not?

Dr. FREEDMAN. Correct.

Senator NELSON. What about the present method of testing drugs by the companies? The issue of the adequacy of the present method of drug testing has been raised here many times—the fact that all testing presently rests with the control or management of the company seeking to market the drug. As a matter of fact, we are today introducing legis-