them to paying attention to things. This is exactly what is happening here in advertising. My point is that I think medical educators, scientists, industry, bureaucrats, legal and economic people, ought to get together and look at our health system as it is related to drugs. They ought to be encouraged to.

The other way to do it is to legislate components—and if you do that I don't know that you will always anticipate the consequences—like the consequences of the Kefauver Act certainly are that we are going to have to work together to develop guidelines as to what are the criteria for developing a drug. And if there were an expert that you could turn to and say, this man has been doing guidelines for 800 years (the pharmaceutical old man in the cave), and he could really tell you how to do it, fine. But that is not the name of the game.

Mr. GORDON. To be more specific, can you tell us how you came out with respect to the efficacy problem of the NAS-NRC report? Did you find many drugs that are inefficacious and shouldn't be on the market?

Dr. FREEDMAN. We found a good number. Most of them we found ineffective weren't marketed or aren't selling any more. These were drugs that came out since 1938. You see, you had various ratings from "effective," to "possibly effective," which puts the burden on the drug house. They now at some point are going to have to make that "possible," a "probable," or "effective." But in order to do that they have to do studies. I don't know that anybody has told them how costly it will be and how many drug trials they will have to do. If a number of "me-too" drugs fell into that category you would think a smart drug house would drop them.

Mr. GORDON. The statute calls for substantial evidence of efficacy, not "probable" or "possible" efficacy.

Dr. FREEDMAN. They have to be rated. And then it is up to FDA as to what they want to say to the drug companies as to what to do about that rating. Some very good drugs would need very little in the way of objective data to make them absolutely clean for the cleaned up claims we said they could claim.

Mr. GORDON. But you did find quite a few that were not effective?

Dr. FREEDMAN. We found quite a few that weren't in the "effective" category, quite a few that were "probably effective," and a large number that were "possibly."

Senator NELSON. Your ratings were "effective," "probably effective," and "possible effective"; is that correct?

Dr. FREEDMAN. The ratings were "effective," the second rating was "effective but." The drug is effective but; if the manufacturer's claim would remove this adjective, then it would be a clean statement. A third would be "probably effective." The bulk of evidence so far, so far as you can tell, certainly from the bulk of clinical practice, means that this is probably effective, but there are deficiencies in terms of objective studies.

Senator NELSON. When you reach the probably effective category, the FDA will make the judgment as to whether they will be required to submit additional controlled studies to prove effectiveness?

Dr. FREEDMAN. Right. But how all those things are going to be adjudicated I don't know. But, however it is done, there absolutely will be consequences for the whole health community.