Under the definitions of the American Law Institute in the Restatement of Torts and the case law, as we analyzed it, this type of data, and it is a very narrow category, would represent a trade secret because no competitor in the market can have the same drug approved without duplicating the data. This is unlike the situation where a drug becomes an old drug or becomes subject to an abbreviated New Drug Application. It is unlike an antibiotic drug which, instead of private licenses, have public regulations in the form of a monograph so once the drug is approved anyone can make the drug.

Mr. GORDON. Well, are you going to require proof that they spent $6 million and that it actually did cost the companies this $6 million? Are you going to require proof of that cost?

Mr. HUTT. No, we would not. It would make no difference in our cost whether it cost $6 million or $1 million or $16 million or $200,000.

Mr. GORDON. Doesn't the patent give sufficient protection for 17 years? Then once it expires, why shouldn't that information be available to the public in order to bring about competition?

Mr. HUTT. Mr. Gordon, we are, of course, limited in what we can do by the laws passed by the Congress of the United States. Congress has said in several statutes that trade secrets and commercial information may not be released by the Food and Drug Administration. Since 1955, every Commissioner has raised this issue in hearings before Congress, requesting that the Congress investigate the confidentiality of new drug information on safety and effectiveness and to provide us with guidance that permits us a different interpretation that I have already set out to you.

Thus far, the Congress has not changed the law or given any new guidance than is what we have followed since 1938. Therefore, it has been our conclusion to retain that policy in the way in which it was set out, somewhat more limited—and I believe it has been somewhat more limited. It has now been made more precise than it has been in the past.

For example, in the past, we had across-the-board rules that everything in a New Drug Application is automatically confidential. We have now substantially withdrawn from that position, to state that, for example, the raw data that lies behind public studies will be made available. The protocols will be made available unless there is a justification for failing to do so. We have said an assay method may be available under certain circumstances.

Mr. GORDON. If, as you say, the raw data will be available and the protocols will be available, what actually will not be available?

Mr. HUTT. Perhaps I should have made it clear that the protocols will be made available without the result. The raw data will be available or the study itself, once the study has been published.

Mr. GORDON. Are most of the studies, the results of the studies, in the NDA concerning safety and efficacy published?

Mr. HUTT. A great many are, and some are not.

Dr. SIMMONS. What the proposal also spells out is that the summary and basis for the judgment of safety and effectiveness will be prepared by the drug sponsor and modified appropriately by the FDA, and ultimately become a public document, so any interested person, lay or professional, will be able to know why the judgment was made.