formation are available for public disclosure when the Food and Drug Administration withdraws approval of the NDA or determines that the drug is not a new drug or may be marketed pursuant to an abbreviated NDA unless extraordinary circumstances are shown.

(e) A protocol for a test or study is available for public disclosure unless an adequate showing is made that it constitutes a trade secret or confidential information because it is unique, has not previously been disclosed in an authorized manner to anyone other than a company employee or a paid consultant, has been developed at significant cost, and provides a competitive advantage.

Now, isn't it correct that most drugs on the market today are considered new drugs?

Mr. HUTT. Are you talking about new prescription drugs?

Mr. GORDON. Yes, sir.

Mr. HUTT. I am not certain that that is true.

Dr. SIMMONS. Most are qualified as new drugs.

Mr. GORDON. This characterization is applicable, no matter how long a drug has been on the market. Is that right?

Dr. SIMMONS. Well, that is generally true now, but I think it will be less true in the future.

Mr. HUTT. There is an increasing number, for example, that are subject to abbreviated New Drug Applications. My understanding is that today there are only roughly 2,000 to 2,500 active New Drug Applications and I am uncertain whether that includes abbreviated New Drug Applications or not.

Mr. GORDON. Do you have any idea how many old drugs there are on the market?

Dr. SIMMONS. I would——

Mr. GORDON. How many drugs are on the market today that are considered old drugs?

Mr. HUTT. Well, there have been a number that have been marketed without New Drug Applications. We do not have a list and will not have one until the Drug Listing Act is enacted, which will provide us with that information. I have been told there is a substantial number of prescription drugs marketed without an NDA, that still remain on the market.

Mr. GORDON. Why are drugs considered new drugs indefinitely?

Mr. HUTT. Some are not, and some have been subjected to abbreviated New Drug Applications. If I recall correctly, there have been approximately 17,500 New Drug Applications since 1938. I am informed that roughly 15,000 of those are now obsolete or inactive. Either the drug has become an old drug or has gone off the market completely.

Mr. GORDON. Now, what is the justification for keeping data on safety and efficacy from the public, as provided by those sections in the *Federal Register* which I read.

Mr. HUTT. This was probably, Mr. Gordon, the most difficult area which we had had to face in formulating this proposal. I would first emphasize that it is a proposal. If we receive comment which would help in changing this in any respect, we will do so.

With regard specifically to this issue, it was our conclusion that the safety and efficacy developed for a New Drug Application, which may cost literally millions of dollars, $6 million to $15 million in terms of economic investment by the company, it represents the type of confidential and trade secret information that Congress requires us to keep confidential because it does provide a very important competitive advantage over another corporation that does not have the data.