has focused on effectiveness rather than safety, although safety sometimes is involved, we have not found a drug that represented what we could honestly say is an imminent hazard to health.

Accordingly, there are a number of drugs that remain on the market which have been found by FDA to be ineffective, for which the administrative proceedings have dragged on for some time, including some which have gone all the way to the Supreme Court in various court cases. I would say it will take several years, even after we have completely gone through the review of effectiveness, to complete the entire process of the administrative appeals.

Mr. GORDON. I am puzzled by the fact that you separate safety from efficacy. I thought that the concept of safety was a ratio of the two, since all drugs have adverse reactions. They have certain problems, risks. If there is no efficacy, then I thought that the FDA regards those as unsafe drugs.

Mr. HUTT. That is true. What I was referring to was the fact that prior to 1962, we were able to review a product only for safety, and we were not permitted to disapproval a New Drug Application on grounds of lack of effectiveness. It was in 1962, as you know, with the Kefauver-Harris drug amendments, that that was changed, and we were mandated to review all prior New Drug Applications for effectiveness. Therefore that distinction, while artificial, was written into the law prior to 1962. We are now in the process of repairing that difficulty.

Mr. GORDON. Now, a drug firm, if there is no evidence that their product is effective, can do one of two things; either supply you with substantial evidence as required by law, or they can take you to court to delay it. Is that not right?

Mr. HUTT. Yes, that is true.

Mr. GORDON. So, what is usually done is that they take you to court in lieu of giving you the substantial evidence, as required by law.

Mr. HUTT. I would not say that is usually done. It has been done where there are important drugs with significant sales that are involved. We have, I believe, to date, in excess of 200 objections and requests for hearings on situations where we have proposed to withdraw new drugs from the market. In all of those cases, the drug would remain on the market pending completion of the administrative proceedings, and possibly, if the drug company can obtain a stay from a court of appeals, also while the court review is subsequently undertaken. Again, I would, as I have on many occasions in the past, urge Congress to look very closely at the provisions of the law which allow that to happen. That is not an issue that the Food and Drug Administration can correct internally or by administrative regulations.

Mr. GORDON. What you are saying, then, is that where there is a lot of money involved, they take you to court. If there is not much money involved, and if they do not have the evidence, then they just——

Mr. HUTT. I would say, thinking back over the drugs on which the legal battles have been fought, that that is an accurate statement. There are, of course, exceptions, but by and large, that would be true.

Mr. GORDON. When do you expect that the market—well, I guess