law, on animals and humans, and substantial experimentation to demonstrate that they have gone through all the steps to prove the safety and efficacy of the drug.

Then the New Drug Application is approved.

Am I correct thus far?

Mr. STETLER. Senator, you are absolutely right on the first New Drug Application. But somebody else can come along later, file another New Drug Application for the same drug, and on the second, third, or fourth time around, a New Drug Application can be approved with less than all of the data you have described. Animal toxicology, animal testing, clinical investigation to the same extent may not be required the second time or third time around.

The first one has met all these requirements. The latter ones may or may not have, and probably have not.

Senator NELSON. If I recall the law correctly, this matter is in the discretion of FDA. In other words, X may be granted a New Drug Application after he submits all the extensive tests. Then this drug is in the marketplace and extensively used by the clinicians, and they have not developed any contraindications or bad side effects, and find that it is effective and valuable. Thus, you have developed a whole body of medical knowledge about the drug.

At the stage that the FDA is satisfied that the tests that were submitted in fact prove that a drug is effective and valuable they have the discretion to say, "A, B, C may now market this drug without further clinical proof of safety and efficacy provided that their product meets the chemical standard."

Is that correct?

Mr. STETLER. That is correct. And as a matter of fact, the example that we are going to talk to you about, that Dr. Lueck is going to talk about, is a specific situation where for the first brand of Chloramphenacol, Chloromycetin, a New Drug Application, or the comparable form for an antibiotic, was processed by Parke, Davis. Later, the three other products that are discussed in this comparative testing were approved by FDA. But the FDA did not require clinical investigation. Now, this was a discretionary matter, and they said "No." Now, as we look at these products on the market available from the drugstore, we find that in performance they lack the ncessary ability to get into the bloodstream and to perform effectively. With an antibiotic of this type, that is a very serious proposition. But it did represent an exercise of discretion.

But our case will show that unless you do require clinical proof from every manufacturer, you have a problem, or at least a potential problem, with that drug.

Senator NELSON. Well, this gets at the question I am interested in.

The New Drug Application is approved after extensive investigation and testing. And nobody else can go to the market with that drug, except the one who got the New Drug Application.

However, the firm whose application was approved can, under the law, turn around and license other manufacturers; can he not?

Mr. STETLER. No, sir. His only authority to license is with respect to his patent rights.

Senator NELSON. He cannot license the new drug?

Mr. STETLER. No, sir.