You might be interested to know that one of the members of the Dripps Committee did come into the Food and Drug Administration to bring to our attention what he considered a problem with the approval of a particular drug. We invited him to review the data with us, and, after reviewing all the data and so forth, he was surprised at the poor quality of the evidence. He agreed with our judgment that it could not be approved until the deficiences had been corrected.

Another member of that committee was protesting because he thought we were going to remove another drug from the market. That drug actually was not going to be removed from the market. We were carrying out the efficacy study, and requiring further study, and until it was proven effective, the drug would be left on the market.

This kind of misinformation is what we face so very, very frequently. We would like to alleviate this as much as possible.

Mr. GORDON. Dr. Simmons, is the continuing marketing of new drugs necessarily a boon to the physicians or to the patient?

Dr. SIMMONS. Mr. Gordon, let's put it this way. Any useful drug should be available to the American people. Now, that doesn't always mean that the drug is better. We realize that, and maybe the man who put it into perspective, best of all, was Dr. Modell when he was testifying back in the early days of the Kefauver bill. Let me read specifically from his statement. He was asked the same question, and he stated officially, "Occasionally, molecular manipulation does bring about a significant advance, but usually a far more substantial change is needed for a real improvement. But simply because a drug is new, it is not necessarily better than those already available, safer or even just as good. Often, it is even less effective and sometimes more hazardous than the parent drug. But they also do harm by their very existence in the drug market. I take the stand that as a general principle everything that adds to the difficulty in dealing with and understanding drugs also makes drugs more dangerous. Thus, the excessive number of needless drugs constitutes a present danger. We can make the useful drugs both less dangerous and more efficient by weeding out the useless, the ineffective and the duplicates, and by so doing, make it possible for the physician to learn in depth about the potent drugs he will prescribe for his patients. We must add only those new drugs that really add something more than their mere presence."

As an example of that, we have about 100 new tranquilizers under development in this country, and at least 22 tranquilizers are on the market at present.

Senator NELSON. Twenty-two?

Dr. SIMMONS. Twenty-two; yes, sir.

Senator NELSON. You said you have 22 tranquilizers on the market?

Dr. SIMMONS. Approximately.

Senator NELSON. And about 100 pending NDA's?

Dr. SIMMONS. Under study.

Senator NELSON. Under study. Of that 22, how many are different compounds?

Dr. SIMMONS. There are a number of different chemicals represented.

Senator NELSON. Under the law, even though they aren't as effective as those already in use, and even though they might have more side effects, they still can be marketed as long as they are more effective than a placebo. Isn't that correct?