Dr. EDWARDS. I think another thing, Mr. Chairman, that I would have to add is that the Food and Drug Administration is a regulatory agency having the responsibility of monitoring a multibillion dollar industry. In order to do this we have to have adequate resources which I do not think in the past we have necessarily had.

Senator NELSON. For example, the inspectors that inspect the plants are paid for by the Government?

Dr. EDWARDS. Yes.

Senator NELSON. There is no assessment.

Dr. EDWARDS. There is no assessment, although we have been looking into various financing mechanisms that could be utilized by the Food and Drug Administration. It still is not assessable to the manufacturer.

The only part of our operation that is paid for by the manufacturer is our antibiotic certification, insulin certification, and color additives are certified and paid for by the industry.

Senator NELSON. How can the objective of rational prescribing be achieved unless the question of relative efficacy is considered, especially in view of the thousands of drugs in the marketplace. Previously we were talking about the Darvon case, but there are lots of others.

How does the physician make an election as to what the best mild analgesic is unless there are some relative efficacy studies and the information is available?

Dr. EDWARDS. I think your point is well taken. I think this is an area that we have to get into much more than we have been in the past. Obviously, this indirectly influences many of our decisions today. We certainly cannot totally ignore the relative efficacy question when we are evaluating any new drug. But as you know, we do not have the authority, at least I believe I am correct, in keeping from the market any drug that is considered to be safe and efficacious, but compared to what is another question, and I think that very frankly, we are the only reliable source which the practicing physician should be able to look to to obtain some of this relative efficacy type information.

Senator NELSON. Is there any sound reason for permitting the introduction into the marketplace of a drug if there is another drug in the marketplace that is just as good and there is no proof that this one is better? Is there really any rational reason for permitting it to be marketed?

Dr. EDWARDS. I think this is probably the reason that, and some people disagree with me, is probably the reason that we have some 20,000 drugs on the market today when maybe half or fewer would be enough.

No. I do not think there is any rational justification for it. On the other hand, you know better than I, I am sure, that industry spokesmen would disagree with this position.

Mr. GORDON. Mr. Chairman, I would like to read from a statement that Dr. Walter Modell made before the Kefauver committee way back in 1961 in which he says:

Occasionally molecular manipulation does bring about a significant advance, but usually a far more substantial change is needed for a real improvement.