

Senator NELSON. And then the drugs were classed as effective, probably effective, possibly effective, not effective; is that correct?

Dr. CROUT. That is correct.

Senator NELSON. And for those that were classified less than effective, you were required to produce evidence of effectiveness; is that correct?

Dr. CROUT. The manufacturer was required to provide evidence of effectiveness; yes.

Senator NELSON. Yes.

And then if they could not prove evidence of effectiveness, they removed it from the market, which was the consequences of all fixed combinations of anti-infectives?

Dr. CROUT. Yes.

Mr. MERRILL. As you know, it took some time, because the manufacturers disputed whether or not the evidence they submitted satisfied the statutory standard.

Senator NELSON. How does this situation differ? Certainly you could not make a finding of effectiveness based upon the studies. It is seriously questionable by the experts we have heard testify that you could say probably effective.

The best you could say is possibly effective, it would seem to me anyway.

Dr. CROUT. That is not correct.

The anorectic review of 1972 reevaluated these drugs, and they are all effective and on the market at the present time, fully evaluated by that process.

Senator NELSON. Well, the language in that report was that the effect was "clinically trivial," so when you proceed under the 1938 act for proof of safety, and under the 1962 act for efficacy, are you saying you really think the evidence supports the conclusion that they would rank higher than "possibly effective"?

Dr. CROUT. That they are "possibly effective" was the judgment of the panels.

Senator NELSON. Possibly?

Dr. CROUT. Possibly. We have been through the process of evaluating the National Academy's reports, however.

That is what was done in 1972, and the committee report you read from in your opening testimony, your opening statement, referred to the process that occurred at that time.

We followed the advisory group's recommendations and our own anorectic review in upgrading all of those drugs to a classification of effectiveness.

They do beat a placebo in causing increased weight loss in patients who are on a diet, and this has been demonstrated for each drug for a period of approximately 3 months in controlled trials. That was the standard of effectiveness adopted at that time and the standard of effectiveness that is currently described in the labeling for those drugs.

Senator NELSON. But you do conclude now in your own statement today that you have got a whole lot more knowledge about the question of abuse and safety than you had in 1972?

Dr. CROUT. Yes; there is now new information to lead us to reappraise the issue of safety.