against the nonamphetamine anorectics cannot be made at the present time.

Senator NELSON. When you say non-amphetamine anorectics, are you referring to the so-called congeners?

Dr. CROUT. Yes. The ones that are in schedules III and IV today.

Senator NELSON. I think the testimony of some of our expert witnesses is that a number of those are also addictive, highly stimulative, and subject to abuse too.

Dr. CROUT. But I think, as we will see from the graphs here, the evidence is that their degree of abuse is much less than with the drugs in schedule II.

Senator NELSON. Well, all right.

On that point, let me say there is nothing in the statute that I know of that is specific about the long-term, short-term, trivial, clinically trivial, and so forth, so one could come to the conclusion as a result of what we know, it is clinically trivial.

As a matter of fact, it seems to me more logical that it is clinically trivial. It is obviously subject to abuse, and it would be logical for the FDA to tell the producer of that drug to come in and show the long-term effect, not only from the standpoint of the safety to the individual, but the proof of its efficacy in reducing obesity.

Dr. CROUT. Again, I simply have to go back to the analogy with many other drugs. I think your comment applies to many agents that are intermediate between truly symptomatic remedies and those that are truly known to be effective in the cure of diseases.

We have got a lot of remedies in the drug area that are useful on occasion, in individual patients for purposes of helping them alter their own dietary habits, for purposes of treating transient problems. I think that the lack of evidence of long-term effectiveness does not mean we should draw the conclusion they are known to be ineffective over the long term.

It simply means a lack of knowledge.

Senator NELSON. That is not what the law says.

The law says you have to have substantial evidence based upon well-controlled studies, and to say that there is no proof——

Dr. CROUT. Such proof is there for the short term.

There is no requirement in the law that a drug must alter the natural history of disease over the long term.

Now, that can be put in the law and drastically alter the number of drugs we have, but I think one should discuss at length the ramifications—I think first we should consider the consequences of such a change. We must recognize that the bulk of drugs are adjunctive to the natural processes of healing.

Senator NELSON. Well, yes, but we are here dealing with a particular class of drugs—for obesity. What other drugs is there on the marketplace that is addictive, widely abused, in which its effect may be very specialized in individual cases, or short term—what other ones?

Dr. CROUT. Set aside the drug-abuse problem, and——

Senator NELSON. Well, no, you have to include that, because the fact it is addictive and widely abused increases the risk factor, making the benefit-to-risk ratio unfavorable.

Dr. CROUT. I agree with that, and our testimony is that we are prepared to take action assuming a well-documented case for the abuse