Secondly, it has been demonstrated that the amphetamines and their related compounds have such trivial indications for the treatment of obesity, that we should look at questions of whether or not obesity should be withdrawn as an indication for their use.

This is the major medical excuse for the manufacture of amphetamines, and the risk of overproduction far exceeds the benefits that might be cited through anecdote of a few patients who, in association with rigid dieting, have believed that the so-called anorectics were the causative agent in their particular weight reduction.

I would, therefore, recommend that obesity be withdrawn as an indication for the therapeutic use of these drugs.

This action has in fact been taken by Canada and other countries, and my own State of Maryland, this action was taken there, and I think it is a model law that might be indicated in Federal statute, that it be duplicated in Federal statute.

Dr. CROUT. May I comment on that?

Senator NELSON. Surely.

Dr. CROUT. Dr. Prout is the valued chairman of our indocrinology and metabolism advisory committee. He is also a personal friend. We are in touch. I have not had a chance to talk with him on the phone since that testimony, but let me assure you that his opinions will be taken into account by us.

I suspect, though, if he has changed his mind since 1972, he is changing his mind for the same reason I am testifying. It relates to the safety problems in spite of control under schedule II, and not to any change in the degree of effectiveness of these agents through the years.

Senator NELSON. Of course, effectiveness under the statute, as you are well aware, in vague situations such as this one is a judgmental factor.

There is not a very good test such as one would get with an antibiotic versus a particular target organism which could be demonstrated conclusively in the lab and in the treatment of the diseases of the particular patient.

I agree and think myself personally that the Food and Drug Administration should have asked for some more evidence of its long-term effect, because I doubt that you can justify massively dosing people with a highly stimulating central nervous system drug without some really substantial benefits, and the substantial benefits have never been proven. Are you saying that even if it is highly stimulative to the central nervous system, is addictive, and has trivial clinical results, we think it meets the standards of safety?

Dr. CROUT. I am not saying that.

Senator NELSON. That is where we are at.

Dr. CROUT. I am saying that the standard of effectiveness adopted is one relating to short-term use.

The standard of safety is that the benefits justify the risks to the individual. Were there no issue of abuse, then one would, I think, have little concern about the safety of these drugs for that use.

Today's issue is whether the degree of abuse continuing with drugs that are under schedule II of the Controlled Substances Act is reason to take away that indication, or take them off the market.

Senator NELSON. Would you not agree, though, that this is a semantic question, you cannot separate safety from efficacy?

They are together. It is one ball of wax. There is no way to separate them. The benefit-to-risk ratio is based upon safety and efficacy, and it is all one question.