Senator NELSON. In the earlier testimony as part of the panel, you have recommended that at the least the obesity indication be removed and put on schedule II.

Do you or do you not believe that it would meet the standards of efficacy in terms of the current statutory meaning that proof of efficacy must be based on well-controlled clinical trials by qualified investigators and considering the safety question? Do you think that if the application were now pending, and on the basis of what we know, would you approve these drugs for the treatment of obesity?

Dr. PROUT. I think it would not now qualify, and I would recommend that obesity be withdrawn as an indication for its use.

Mr. GORDON. I have a couple of questions.

This is a quotation, an excerpt from an FDA document which we have, and I will read it.

"Larger questions of long-standing remain unanswered such as the long-term effect on morbidity and mortality of the use of anorectics. These questions are of basic importance, since the usefulness of the drugs depends in large part upon the assumption that they somehow help prevent the adverse effects of obesity."

This document also states:

"In addition to evidence of abuse of amphetamines, evidence also exists in fair quantity for abuse of phenmetrazine—Preludin—and diethylpropion—Tenuate. For other anorectics evidence of abuse is scanty or lacking. Experience with other abusable drugs has shown, however, that documentation of abuse lags markedly behind abuse, and, when it appears, is only the tip of the iceberg."

Do you agree that it is desirable to use pharmacologic and chemical data to predict abuse before it occurs?

Dr. PROUT. I think this is the basis of our declaring that a drug has abuse potential. We were able to look at a large number of animal experiments in which the central nervous system stimulatory effect of a drug was easily documented. From that point of view, one could predict, since this is the effect that it was sought in the street, that as one group of drugs becomes more difficult to procure, the others will be tried and selected on the basis of their abuse usefulness. I think it is important not to wait until abuse is shown in the street, but to predict that *possibility* on the basis of *abuse potential*, and it is the reason why the FDA Committee drew the line right there.

Dr. GRINSPOON. I would agree; it seems to me ridiculous to wait until a drug is abused on the street.

There is no question we can predict which drugs will be abused, and certainly the people who argue that a drug has certain characteristics such that it will not be abused. The burden of proof should be on them.

In India about 10 years ago methaqualone was sold, and there was a lot of experience in Britain, and it was brought to the United States and sold here about 4 years ago. It was very clear at that time that it could be abused, and it is being abused on the street now, it was something absolutely predictable.

Dr. NORA. I would be in agreement with the others.

Dr. YAFFE. Yes.

Mr. GORDON. One more question.

In view of the "trivial," this is the word used by the Food and Drug Administration, benefits to a few individuals, and the danger to both