The question raised today relates to continuing abuse, even in spite of control of the amphetamines as scheduled.

Senator NELSON. How would you compare your judgment on amphetamines used for treatment of obesity, against your judgment in removing a drug from the market, as the drug which was a combination of tetracycline and novobiocin, which would be called effective in the sense that tetracycline was effective against the target organism properly prescribed. Your conclusion was that in combination the two drugs were antagonistic, not additive, so you removed that combination from the market.

There was no question, I believe, about the fact that that combination would affect the appropriate target organism.

The problem was the side effects as a consequence of using novobiocin and tetracycline in combination, which exposed the patient to the side effects of the two drugs, but only tetracycline was needed.

You, as a doctor, would concede that if you were in some remote part of the world, and if Panalba would affect the target organism, even though the patient might get some side effects, you would use the drug? What argument is there for leaving the amphetamines in the market for the treatment of obesity, when there are other ways to do it, and when the results are clinically trivial?

That is what puzzles me.

Dr. CROUT. The issues in the two cases are slightly different.

In the Panalba situation, the lack of safety applied to the patient for whom it was prescribed.

That particular patient would get a safer drug and just as effective if he took the tetracycline component of Panalba, rather than if he took the combined agents, so that decision involved was a straight benefit-risk judgment about Panalba under the Federal Food, Drug, and Cosmetic Act, where one is thinking of effectiveness versus the safety to the patient.

Now, when we originally determined in 1972 that amphetamines were effective under the Federal Food, Drug, and Cosmetic Act, that same benefit-risk approach taking into account what was said by the experts, led to the conclusion that amphetamines, when used as labeled and as directed over the short term and in the proper dose, met appropriate standards of safety to the particular patient taking the drug.

A new issue arises, however, when patients begin to take amphetamines in excess, or they divert it to drug abusers. Now there is no longer a safety-effectiveness tradeoff in the individual patient. Rather, it is a tradeoff in relation to societal abuse of a drug which would not be considered unsafe if it were, in fact, used only as labeled under the Federal Food, Drug, and Cosmetic Act.

It is this latter question that we have to address at this time.

Mr. MERRILL. There is one other matter relating to the question, and that is what is our legal posture.

That difference is that with Panalba, we had a recommendation from an expert panel that there were not the kind of studies to show the effectiveness that the law required, and we initiated action to remove that drug at that time.

With amphetamines, we had a recommendation in 1970; the agency asked for additional data; some 200 studies were submitted; and,