whether rightly or wrongly, the Agency's experts concluded on the basis of the data then in hand that it was indeed effective. Not greatly so perhaps, but nonetheless effective, so the agency is now on record as stating the firm effectiveness of these drugs, as Dr. Crout suggested, is there, but the issue we are now concerned about is whether or not that small effectiveness is substantially outweighed by the kind of abuse and safety problems we are seeing.

Senator NELSON. Well, there are two questions about safety: One is the widespread abuse of the drug by the users who have no weight problem, and did not get it prescribed for a weight problem; the other is the risks to the individual for whom it is prescribed, who then becomes dependent upon it. There is no supporting evidence that it has any long-term effect at all.

Consider this question: If a new drug application were filed with the FDA, under the safety requirements of the 1938 act and the efficacy requirements of the 1962 act, would you approve these drugs for marketing? Would you not be asking for the effect of their use on obesity over a long term, a year or two at least? Would not you demand of the proposed marketer that he give you controlled studies to show the long-term effect as to obesity, to say nothing now of the possible side effects from the ingestion of the drug?

Dr. CROUT. Let us set aside the drug abuse issue. The answer to your question regarding long-term effectiveness is that that issue was debated in the 1971–72 era, and we reached the conclusion that the effectiveness of this class of drugs should not be evaluated in terms of long-term effectiveness.

The reason for that is that obesity can be considered, if I can make an analogy, as one of several illnesses where dietary therapy is paramount, and the use of a drug is adjunctive.

That is true for the management of ulcer disease, that is true for obesity, that is true for the dietary management of diabetes in patients who are not insulin-dependent. We have not required that drugs for these various conditions have a perfectly demonstrated effect, a completely unequivocal demonstrated effect, on the natural history of those diseases.

They should be considered as an adjunctive therapy to diet for the management of those diseases.

Now, one can argue with that standard. All I can say is that the prevailing practice of medicine has been to support that standard and the prevailing opinion of experts has been to support that standard. In some respects we have to face up to the fact that, while these adjunctive drugs may be clinically trivial over the long term, on the average they may also be useful, even dramatically useful, in some patients. In a sense they are also the only game in town. I think if you have a long-term problem, and dietary management is the key to it, drugs that are of consistent help in any way are welcome to patients and the medical profession, providing there is not an overriding safety issue involved.

Now, our view is today, as you well know, that the above issue may well have become an overriding safety problem for the amphetamines.

We will look at whether it is an overriding problem for the nonamphetamine anorectics also, but I suspect that a strong safety case