together, our judgment is that from an effectiveness standpoint, all drugs in the whole class are roughly comparable.

The effectiveness of fenfluramine in reducing weight is roughly comparable to any other drug in the class.

Senator NELSON. Do these studies show any indication of addictiveness of the fenfluramine?

Dr. CROUT. Fenfluramine went on the market for the first time at that time so the studies we have relating to abuse potential for fenfluramine were animal studies only at that time.

Senator NELSON. Did the animals help to self-ingest themselves?

Dr. CROUT. I believe they did not with fenfluramine. The pharmacology of fenfluramine is more like that of a depressant than a stimulant drug.

Now, an important question right now is whether in street use, after 3 years of experience, fenfluramine is turning out to be abused, for whatever reason.

Senator NELSON. Is there any indication that it is?

Dr. CROUT. I would have to defer to DEA on that.

The prominent safety issue with these drugs relates to their abuse. The intent of the Federal Food, Drug, and Cosmetic Act has predominantly been considered historically to protect the individual receiving drugs. The intent of the Controlled Substance Act is to control the abuse problem. What we are trying to say at this point is that the Controlled Substances Act is not totally successful in controlling the abuse problem, certainly with amphetamines, and perhaps with others in this class. Therefore, we should now go back under the Federal Food, Drug, and Cosmetic Act and consider abuse to society as part of the benefit-risk equation.

Now, that is a proper use of these two laws in our judgment. But if abuse per se is a reason for taking drugs off the market, you do not need a Controlled Substances Act.

The Controlled Substances Act is for the purpose of controlling the abuse of useful drugs, and while you may consider this usefulness to be minimal, they are useful in the treatment of obesity.

Senator NELSON. What is the tool under the act for enforcing the law respecting abuse of legally marketed drugs?

Mr. MERRILL. Under the statute?

Mr. GORDON. Yes.

Mr. MERRILL. The statute permits FDA to change the labeling to omit an indication. The other remedy the statute provides is to remove the drug from the channels of commerce.

We do not now have a useful mechanism for restricting availability of marketed drugs.

Mr. GORDON. Nor any mechanism for proceeding against somebody who is using the drug for nonindicated use?

Mr. MERRILL. We, generally speaking, have said the Federal Food, and Drug Act does not prohibit an individual physician from prescribing a drug for an unapproved use.

We have one case now pending in which we are proceeding against a clinic in the South that has ordered the shipment, for unapproved uses, of a series of drugs for a continuing kind of therapy. We have taken a position in court—it has not yet been adjudicated—that that kind of trafficking in unapproved use of the drug is tantamount to