Dr. CROUT. That is correct.

Senator NELSON. Then what additional documentation do you refer to?

Dr. CROUT. We would have a legal burden of making a safety case using the drug abuse data that are anticipated from our sister agencies to make the case that under the Federal Food, Drug, and Cosmetic Act, those drugs are no longer safe for their labeled use. That is a decision which is contestable, a position which is contestable in a hearing and later in court, so one has to have his legal ducks in a row, so to speak.

Furthermore, an accompanying regulatory action would be a movement of those drugs from schedule II to schedule I.

Senator NELSON. Would be what?

Dr. CROUT. An accompanying action in any removal from the market would be a change from schedule II to schedule I of the Controlled Substances Act, and that too requires appropriate documentation and can be challenged in court.

Senator NELSON. When you say removal from the market, are you saying removal from the market for any indicated uses?

Dr. CROUT. Were that to occur, yes, those drugs would be changed from schedule II to I.

Senator NELSON. How does the legal situation change if the FDA decided to remove treatment of obesity from its indicated use?

Dr. CROUT. The legal situation does not change.

We would have to go through the legal process of issuing a notice of opportunity of hearing, and perhaps having a hearing, for that indication.

Senator NELSON. Are you saying that you have the same legal question and the same problem of removing the drug from the market as you do of changing the indicated use of the drug?

Mr. MERRILL. If I can, Mr. Chairman, let me respond to that.

Because there are some proven indications of these drugs for medical treatment, if we were to take the more drastic action of taking the drugs off the market altogether, it is possible our burden would have to be higher because we might have to show that the risks of abuse in connection with the treatment of obesity outweighed any use including legitimate use of the drug.

If we simply removed obesity as an indication, we would make a case based on balance of the risks and benefits for this purpose. We would also have to decide whether that action would be sufficient, because it would mean that the dosage form was still available in the pharmacy, and still legally available for a physician to prescribe.

Dr. Crout reminds me that there is no misunderstanding, that the legal process through which we must go is precisely the same.

The amount of evidence required to sustain our case might be greater.

Senator NELSON. Let me see now.

With respect to those drugs that are under the 1962 Kefauver amendment, the Food and Drug Administration set up a procedure, and that procedure using the National Academy of Sciences, established panels of experts on each class of drug; right?

Dr. CROUT. Yes.