though the FDA does have major statutory responsibilities in this area, too.

Recommendations were forwarded to the BNDD and controls were imposed by that agency.

The results of our review, which ended in the latter half of 1972 with implementation of the decisions in early 1973, were as follows:

First, a consistent policy and set of regulatory actions for all anorectics, based on a better characterization of their limited but unequivocal superiority to nondrug therapy and including recommendations that they be used only for short-term use as adjuncts to diet.

Second, the elimination of a large number of combination drug products. Only two major combination products remain on the market, with litigation ongoing.

The position of the manufacturer of these drugs, Smith, Kline & French, appears ethically and legally weakened by their failure to report important adverse information on the abuse potential of one of their products.

Mr. GORDON. Could you elaborate on that, please?

Dr. SCOVILLE. This was pointed out in a Federal Register notice of 1973.

The decision may have to be decided in court or in a hearing of this nature. Representatives of SKF came to FDA, bearing marketing studies which they felt supported their claim that their drug has little or no abuse.

Independently, it also turned out they had in their possession a separate study carried on by contract, showing that their drug was known and shown to be sold in the street.

This was a study that they did not submit. This selective submission of evidence to the FDA seems to strike at the very basis of our current regulatory process.

Mr. GORDON. I have some more questions along those lines.

What finally happened? Is not this a violation of the law?

Dr. SCOVILLE. In my perception of the events, if they turn out to be true, it will be against the law.

Mr. GORDON. You said if it turns out to be true, you think there was a violation of the law?

Dr. SCOVILLE. Yes. If the facts are correct, yes.

Mr. GORDON. If the facts are correct—you think there was a violation of the law?

Dr. SCOVILLE. Yes.

Mr. GORDON. Has there been anything done about that as far as you know?

Dr. SCOVILLE. Well, the FDA put this statement in what is called an opportunity for hearing, a proposal to withdraw approval of new drug applications.

Mr. GORDON. That was in 1973?

Dr. SCOVILLE. Yes, sir.

I am somewhat sympathetic with what appears to be the untimely response of the FDA, in that they are involved in large numbers of responses to notices of opportunity for hearings, for a very large number of drugs which are under the DESI review.

I am sure they have a document in preparation dealing with this issue, but it has not to my knowledge been yet published.