

the somewhat less familiar terms of drug abuse. Here is a problem from which we cannot divorce our thinking in favor of medical considerations.

Throughout FDA's records there can be found a depreciation of the usefulness of these drugs for antiobesity purposes:

The degree of extra weight loss was small—a few tenths of a pound a week in many cases—and variations were great.

Larger questions of long standing remain unanswered, such as the long-term effect on morbidity and mortality of the use of anorectics. These questions are of basic importance, since the usefulness of the drugs depends in large part upon the assumption that they somehow help prevent the adverse effects of obesity.

The objective of these hearings, therefore, is to ascertain the present views of the Food and Drug Administration on the safety, efficacy, patterns of use and abuse, and the future of these drugs.

We are particularly interested in hearing:

One. Why the first recommendation of FDA's advisory committee that all these drugs be placed in schedule II was not accepted. This is especially puzzling in view of FDA's testimony before this subcommittee in 1972 that:

Evidence presented for newer anorectic congeners of the amphetamine family and nonamphetamine drugs do not set them apart as having higher benefit or lower risks than older available drugs. (Hearings: Advertising of Proprietary Medicines, pt. 3.)

Two. Why some combination antiobesity drugs are still on the market. On February 12, 1973, the FDA took steps to remove Eskatrol from the market, but the drug is still being sold—\$5.4 million worth at manufacturer's prices.

The sales of another combination, Dexamyl, for 1975 amounted to \$2.6 million. In other words, the sales of these two Smith Kline & French drugs, which should have been removed from the market years ago, amounted to \$8 million in 1975.

The February 12, 1973 Federal Register also noted that the FDA is aware of a study conducted for Smith Kline & French relating to abuse potential of Eskatrol and which was not submitted to the FDA as required by law.

What action was taken by FDA against this violation of the law?

In the March 30, 1973 Federal Register it was announced that Smith Kline & French had requested a hearing with respect to Eskatrol. The FDA allowed the drug to continue to be marketed pending a ruling on the request for a hearing.

It is now 3½ years later, and the hearing has not been yet held. Why?

We would like to have an explanation of why it was not.

The principal problem, however, is justifying the continued existence of these drugs on the market.

Given a utility which is "clinically trivial," to use FDA's own term, and given the very extensive list of serious risks to individuals and society including the potential and actual abuse, questions have been raised whether their availability for antiobesity purposes constitute a hazard to the public.

Dr. Thaddeus Prout, Chairman of FDA's advisory panel on these drugs, told our committee last Tuesday that he now favors that in addition to placing all these drugs in schedule II, obesity be withdrawn as an indication for the therapeutic use of these drugs.