

Senator NELSON. All right. We will leave it in the record.

We have got to win one once in a while, and so your chart shows there is a much higher abuse-potential of the amphetamines used for the same purpose?

Dr. CROUT. Yes, sir.

Senator NELSON. This is a very convincing case. If they are roughly equivalent in terms of their trivial effectiveness, then it would appear that something ought to be done about the amphetamines?

Dr. CROUT. Yes, sir.

Mr. VODRA. It also indicates, Senator, that there is, for whatever reason, a significant difference in the response of the "abuse community."

Senator NELSON. Roughly what?

Mr. VODRA. A major difference in response of abusers to the schedule II anorectics, that is amphetamines and phendimetrazine, over the other drugs. This is the point I was suggesting earlier: For some reason we have not determined, the abusers prefer amphetamines by a wide margin. They have stated this preference in the illicit market for the scheduled anorectics. Amphetamines remain the problem area.

Dr. CROUT. [Reading.]

CONCLUSIONS AND PLANNED ACTIONS

Mr. Chairman, I would like now to state our present regulatory position in regard to the anorectics and to indicate our plans for future actions regarding these drugs.

The anorectic review of 1972 demonstrated that all these currently marketed drugs meet appropriate standards of effectiveness under the Federal Food, Drug, and Cosmetic Act. On the basis of the information available at that time, FDA also determined that this class of drugs meets the safety requirements of the act and are, on a benefit-risk basis, appropriate for marketing for the indication of obesity on a short-term basis as adjunctive therapy. The most stringent controls possible under Federal law have been in place for 5 years on those drugs which demonstrate greater abuse risk than the others, and the remainder of the class of anorectic drugs has been controlled under other schedules of the CSA for 3 years.

Recent information indicates, however, that the schedule II anorectics—amphetamine, dextroamphetamine, methamphetamine, and perhaps phenmetrazine—have continued to be abused at a relatively unchanging rate over the past 3 years. While there is considerable opinion that the current rate of abuse of amphetamines is well below that of the late 1960's, there is also evidence that the regulatory measures taken in the 1971-73 period may have accomplished as much as they are going to accomplish. It also appears that the major residual problems of abuse and misuse involving anorectic drugs lie with those already in schedule II and not those in schedules III and IV.

If the information currently being developed by DEA clearly indicates, as we anticipate it will, that amphetamines remain a major cause of abuse in spite of being in schedule II of the CSA, FDA will move ahead vigorously to withdraw the indication for obesity from amphetamines. We need to be sensitive to the other indications for which these drugs are used—narcolepsy and minimal brain dysfunc-