

Finally, I would comment that whatever future action we in FDA might take in regard to this class of drugs, some degree of abuse may well continue. Clandestine manufacture and smuggling across international borders will remain a problem. Even if amphetamines are removed from the market, other stimulant drugs will remain available and abuse of these agents may grow. The abuse of stimulant drugs will thus remain a matter of continuing concern, and its control will require sustained vigilance from all of us. Drugs of this type are intrinsically attractive to a segment of our population and, at least for the foreseeable future, will remain so.

Control of the abuse problem in our society will require the continuing effort of many parties, as these hearings have made clear—physicians, pharmacists, the drug industry, education, and law enforcement agencies. FDA is proud of its record in the past in handling the anorectic drugs, and we look forward to maintaining that record in the future.

Thank you, Mr. Chairman; this concludes my formal statement. My staff and I would be most willing to answer any questions you may have.

Senator NELSON. Thank you very much.

What does the FDA plan to do about these drugs; whether to leave the amphetamines on the market as they are, whether to remove them entirely; or change the labeling so the indicated use may not include obesity?

Dr. CROUT. I think we will have to be imprecise on that.

The DEA is helping us, and we are dependent on that information. I think we will have to review with our advisory committees, or at least with our consultants, the two indications of narcolepsy and hyperkinesis due to minimal brain dysfunction in children, because much depends on whether amphetamines are needed for those uses. I think we can get our opinions in order on that within a number of weeks certainly. We expect it will be several weeks before we hear from DEA, and I am sure it will be a number of weeks after that before we go through an advisory committee procedure on those issues.

How soon an action can be taken would depend on the industry response and the legal processes, what hearings are required, whether there is court review, and so on.

That is simply impossible to predict.

Senator NELSON. The court review would not occur until sometime after a ruling has been made.

My question is in regard to the time when a conclusion is expected to be reached.

Dr. CROUT. I think with this, we can reach a conclusion within a matter of some weeks, as I mentioned.

I think a regulatory action is impossible to predict. Whether hearings are required or not I do not know.

Senator NELSON. Chart 3, shows the much higher incidence of drug abuse of amphetamines than the anorectic congeners. Given the conclusion which, I understand to have been reached by Dr. Crout's testimony, that they have about the same amount of effectiveness, what is the legal problem in saying that since in the marketplace there are available a number of nonamphetamine congeners which are as effective for purposes of controlling obesity, and which are not as addictive,