

We look forward to hearing the views of today's witnesses on this subject.

Our first witness is Dr. J. Richard Crout, Director, Bureau of Drugs, of the Food and Drug Administration.

We welcome you here this morning, Dr. Crout. If you would identify your associates for the reporter, and for the record, so we will have all statements appropriately and properly printed, I would appreciate it.¹

STATEMENT OF J. RICHARD CROUT, M.D., DIRECTOR, BUREAU OF DRUGS, FOOD AND DRUG ADMINISTRATION, ACCOMPANIED BY RICHARD A. MERRILL, CHIEF COUNSEL, FDA, AND WILLIAM W. VODRA, ASSOCIATE CHIEF COUNSEL, FDA

Dr. CROUT. Thank you very much, Mr. Chairman.

On my left is Mr. Richard A. Merrill, Chief Counsel of the Food and Drug Administration, and on my right is Mr. William W. Vodra, Associate Chief Counsel for Drugs of the Food and Drug Administration.

We welcome this opportunity to appear here today to discuss the activities of the Food and Drug Administration with respect to anti-obesity drugs.

Previous actions by both the FDA and DEA have had an important impact on the availability, labeling, and use of these drugs.

In spite of this, abuse of amphetamines in particular, appears to be a continuing problem in our society. It is appropriate that additional action in regard to amphetamines be considered at this time.

The story I will emphasize in this testimony is that the available data, while preliminary and incomplete, indicate that the amphetamines remain, among the anorectic drugs, the major offenders as drugs of abuse.

This problem cannot be solved by invoking additional controls under the Controlled Substances Act since these drugs are already in schedule II, the most tightly controlled category for marketed drugs. The only meaningful next step which can be taken is to remove the indication for obesity from the labeling for amphetamines or to remove them from the market.

FDA is working with the Drug Enforcement Agency and NIDA, the Federal agencies with detailed information regarding drug abuse, to develop the necessary documentation for such a position.

Abuse of amphetamines continues to occur, with deleterious and often devastating effects on the individual who abuses or becomes dependent upon them.

We must move ahead vigorously in addressing this important problem in drug safety.

Senator NELSON. May I ask a question. I read your statement this morning rather quickly.

Do you know what additional documentation is required?

I recall from your statement, if I am wrong, please say so, I believe there is not any further necessity for large controlled, double-blind studies beyond what has already been done, am I correct?

¹ See prepared statement and appendixes of Dr. Crout beginning at p. 14640.