STATEMENT OF BARRETT SCOVILLE, M.D., OF WASHINGTON, D.C.

Dr. SCOVILLE. I formerly directed the Division of Neuropharmacological Drug Products, which is one of the six FDA drug review divisions.

Senator NELSON. Your statement will be printed in full. You may present it in whatever way you desire.

Dr. SCOVILLE. Thank you, sir.

I will read the statement.

Mr. Chairman, members of the subcommittee, I am here to provide you and the public with information on the decisions made about anorectic drugs—drugs used in treating obesity—during the time I worked in the Food and Drug Administration, and about my current personal opinions on what modifications of those decisions may be desirable, as well as on any other matters you wish to ask me about.

I have testified before this committee in the past about the FDA review of drugs used in treating obesity.

To recapitulate, in 1971 and 1972, the Food and Drug Administration was confronted with decisions on the efficacy and safety of old and new anorectic drugs, some 11 chemical entities in all, over 130 drug products.

The questions about efficacy included questions on the amount of weight loss, if any, associated with the use of anorectic drugs by obese patients, the duration of administration of the drugs, and possible differences in efficacy among the different chemical entities evaluated.

The safety questions involved chiefly the public health hazards of a special toxicity, that of the potential of these drugs for producing dependence and for being abused.

Data bearing on the efficacy questions included over 200 controlled trial involving almost 10,000 patients, trials carried out by drug manufacturers and submitted to FDA as part of various applications.

The data on safety were a more heterogeneous assemblage of different sorts of evidence—chemical, animal, and human—which might have some bearing on abuse potential and other safety questions.

The efficacy review involved an unprecedented reexamination of all individual patient data sheets, representing 70,000 patient visits, computerization of the data, and FDA reanalysis of the data, using its own computers and statisticians—who deserve much credit for the massive job.

In making the final decisions on the drugs, the FDA was advised by a consultant panel headed by Dr. Thaddeus Prout. The former Council on Drugs of the American Medical Association, headed by Dr. Harry Shirkey, also gave us its opinion on the proposed actions.

The institutional FDA decisions were embodied in a comprehensive memorandum proposing various alternatives with the pros and cons of each, the final decisions being initialed by the Commissioner of Food and Drugs.

In carrying out the decisions, the FDA itself implemented decisions with respect to marketing approval and relabeling.

Decisions on controls to be imposed because of abuse potential were and are the primary responsibility of the Bureau of Narcotics and Dangerous Drugs, now the Drug Enforcement Administration, al-