

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,