taking a placebo. While it would obviously be of value to know with certainty the effect of the drug on the natural history of the disease, we have considered this to be a public health question which an individual drug firm cannot reasonably be expected to answer in the context of evaluating its particular product.

The approach taken in conducting the anorectic review was discussed by Dr. Henry E. Simmons, the former Director of the Bureau of Drugs, in his testimony before this Subcommittee on December 13, 1972, and I would like to restate his description of its magnitude.

"The scope of the program was ambitious, and involved over 1,100 volumes of data concerned with twelve single entities. The drug products in which these entities were present, either alone or in combination, were marketed by 40 firms. Over 200 double-blind and controlled studies of efficacy which had been carried out on almost 10,000 subjects were included in the review.

Individual patient data sheets were coded and key punched to facilitate computer analysis. This produced over 70,000 computer cards, representing over 70,000 patient visits of the 10,000 subjects. Each card included certain patient characteristics as well as changes in weight, blood pressure, pulse, and other possible adverse effects from visit to visit. The cards contained over 4 million units of information. Programs were then written to permit automatic statistical analysis in order to determine what effect the active drug had when compared with the placebo under 'double-blind' controlled conditions."