of a sin, rather than with the humility which would be appropriate to a condition the causes of which are poorly known and the treatment of which is difficult. As if that weren't enough, the drugs proposed for treatment almost all involve a set of moral issues of their own, those associated with drug abuse.

In preparing broad policy on the use of anorectic drugs we have been reviewing questions associated with them quite intensively since late last fall, through a project of which I have been the manager and Dr. Gardner the chief adviser, and of which I will tell you more later.

The questions underlying the discussions here are not new, and you may wonder what leads FDA to review the question of anorectics at this time. Broad national concern for drug abuse, including CNS stimulant drug abuse, lies behind many of the questions, but there are four relatively recent elements which have made more acute the need for broad policy.

The first factor was the Drug Efficacy Study. In this study the National Academy of Science/National Research Council and FDA reviewed the status of all drugs—approximately 3000—which were first marketed between 1938 and the passage of the Kefauver-Harris amendments to the Food Drug and Cosmetic Act in 1962. These 3000 drugs included all marketed anorectic agents except one (Pre-Sate or chlorphentermine). The NAS/NRC Panels expressed qualifications as to efficacy of anorectics so that the FDA publications on anorectics to date have indicated them to be less than effective, requiring more evidence in the form of clinical trials. Such evidence has been submitted, and I'll come to that later.

As a corollary of the NAS/NRC review, FDA also reviewed the status of the amphetamines and concluded that they, too, were affected. Amphetamine manufacturers responded in 1971 and 1972 to an FDA announcement to this effect with applications to continue marketing 106 amphetamine drug products.

The need to review the 106 amphetamine applications and other material submitted in the context of the Drug Efficacy Study was the first element leading to our project. A second involved applications for drugs not yet on the market. Within the last year and a half, 3 major manufacturers have requested approval for marketing of anorectic agents which they had been investigating, and of course decisions are required here consistent with any policy relevant to anorectics subject to the Drug Efficacy Study.

The third and fourth elements requiring policy towards anorectics involve drug abuse, with its many medical, social, and legislative implications. The problems of drug abuse led in October, 1970 to the passage of the Comprehensive Drug Abuse Prevention and Control Act. This Act, also known as the Controlled Substances Act, vests a number of responsibilities in the Department of Health, Education and Welfare; two are of particular concern to FDA in respect to anorectics. One is the need to determine the degree of control under the various schedules of the Act appropriate to any drugs with abuse potential or which are abused. More control has been considered necessary for oral methamphetamine, the other amphetamines, and phenmetrazine, for example, and they have now been placed under the restrictions of Schedule II. The remaining anorectics are not controlled under any schedule, and it has been proposed by some that amphetamine congeners like diethylpropion and benzphetamine have abuse potential, too, so that their use should also be restricted. The Secretary of HEW bears fundamental responsibilities in respect to scheduling drugs, and within HEW, FDA plays a leading role in advising the Secretary.

The last major element which has led to the current review of anorectic efficacy is another new responsibility stemming from the Comprehensive Drug Abuse Act. This is the Secretary of HEW's new responsibility to report to the Department of Justice on the legitimate medical and scientific needs in the U.S. for drugs controlled in Schedule II. This means specifically how much amphetamine, methamphetamine, and phenmetrazine is needed each year in the legitimate treatment of obesity. Within the Department of Justice, the Bureau of Narcotics and Dangerous Drugs relies heavily on HEW estimates of medical need in establishing quotas for the amounts of these drugs which may be manufactured each year.

So, to summarize, the efficacy review of older anorectic drugs, the review of applications to market new entities, the responsibility to determine appropriate control schedules for abusable drugs, and the responsibility to estimate medical needs for anorectics have been the four major immediate elements leading to our present work to define more clearly and consistently the place of anti-obesity drugs.