medical treatment in order to alleviate or eliminate this unfortunate condition. Our antiobesity products, and those of other responsible manufacturers, remain recognized as the only effective prescription medicinal aid available in a course of antiobesity treatment.

Moreover, as we have discussed today, the manufacture and distribution of those products is closely regulated by competent Federal agencies, which have the requisite expertise to evaluate the quality of our products and the legitimacy of their use.

The regulatory processes established by the Congress, over the years, have created a framework within which the serious questions which concern this committee have long been the subject of professional concern, both within the regulatory agencies and within the pharmaceutical industry. That process affords all of its participants due process, from investigatory, scientific, and legal perspectives.

Pennwalt appreciates the opportunity to appear before this committee in order to state the bases upon which its products are manufactured and distributed. Pennwalt remains confident that it can continue its 126-year-old reputation for integrity while engaged in this part of its enterprise.

I am ready to answer any questions you may have.

Senator NELSON. Thank you very much.

Do you have any well-controlled studies of your own, or are you aware of any well-controlled studies that would produce substantial evidence to refute the conclusion of the report to the Director of the Bureau of Drugs by the panel of consultants on anorectics headed by Dr. Prout in 1972, when that panel in its conclusions stated that the natural history of obesity is measured in years, whereas the studies cited are restricted to a few weeks duration, thus the total impact of drug-induced weight loss over that of diet alone must be considered clinically trivial?

Do you have any studies, or any evidence that would refute that conclusion, that this impact is clinically trivial?

Mr. MCGRAW. I can show in the studies we submitted to the FDA, they were done over a 16-week period of time.

Senator NELSON. Were these studies submitted to the consultants on anorectic drugs?

Mr. MCGRAW. No, sir.

Senator NELSON. When were they submitted?

Mr. MCGRAW. They were submitted in 1971 to the FDA.

Senator NELSON. The report I am referring to is dated 1972.

Mr. MCGRAW. As a result of the report of NAS/NRC, these products were ruled possibly effective, and we had to submit efficacy studies to the FDA.

Senator NELSON. The NAS/NRC panel was concluded in 1972. I was wondering if your studies were well-controlled and if they produced substantial evidence to refute the conclusions of the panel that the effects of these drugs were "clinically trivial." We would like to have those.

Mr. MCGRAW. As I was saying, Senator, the studies we submitted for our efficacy studies were done over a 16-week period of time, and on a week-to-week basis, there was a fractional difference in weight loss, let us say a half a pound.

At the end of the 16 weeks, that was sometimes double as compared to a placebo, and I think that is significant as a statistical evaluation.