stration offices in New York, New York, and submitted a written response dated November 30, 1965.

Mr. Lebeis said that the nature of the charges were understood and a discussion was had of the misbrandings by the journal advertisements of the Aristocort tablets and the Pathibamate tablets. Mr. Lebeis then requested, and received, additional time in which to submit a supplemental response. The supplemental written response was received on December 14, 1965. In its written response dated November 30, 1965, Lederle Laboratories stated that the Artane Elixir was put into 3800 pint bottles on June 8, 1964, that tests performed by the firm's quality control section disclosed that the bottles filled at the end of the run contained less of the labeled amounts of the active ingredients than permitted, and that these subpotent bottles were destroyed. 3,117 bottles, however, were released for sale. Lederle Laboratories believed that all the subpotent material had been rejected and that it acted in good faith in releasing the balance.

With regard to the charges that the medical journal advertising for Aristocort and Pathibamate tablets caused these drugs to be misbranded, Lederle Laboratories said that it was apparent that a medical journal advertisement is neither intended nor required to instruct the practitioner how to practice his profession or to remind him of things which are a part of the "common law" of medicine.

Lederle Laboratories then proceeded to deny the charges, contending that: (1) statements in the advertising relating to side effects, precautions and contraindications served to adequately call to the reader's attention the required warning information in the labeling; (2) the information omitted represented that which is part of a physician's overall fund of medical knowledge; and (3) the drug has one of the best records for not causing edema, and therefore there was no necessity for the warning that edema might occur in situations such as renal disease.

With regard to the charges that the advertisement for Aristocort lacked a fair balance in its presentation, Lederle Laboratories contended that the advertisement did not imply that the otherwise untreatable patient became treatable with Aristocort, but rather that the advertisement carefully pointed not to all, but to "large numbers" and to "many" in the untreatable group who were able to benefit from Aristocort therapy. Lederle Laboratories also said, that the advertisement pointed out that patients with certain diseases or conditions could not be treated with other steroids, *viz.*, overweight, with cardiac disease, with hypertension, with pulmonary fibrosis associated with congestive heart failure, and that it was for these patients that weight loss was desirable and for them alone that the drug is called to the attention of the physician.

CONCLUSIONS

We believe that the factors which have been set forth in some detail above show that the advertisements used by this firm have not met the standards required by law. The omissions and deceptive statements involved were numerous and serious. Moreover, the side effects and contraindications were already well known to the company as they were set down in the New Drug Application labeling. Advertising prescription drugs should be a very special operation—wholly unlike advertising the 1967 model automobiles or the tars and nicotines of cigarettes. It should be based on the scientific data that allowed the drug to enter the market—you need look and can look no further than the labeling accepted in the New Drug Application for the allowable claims and the required warnings. In drug advertising the law does not provide for product touting or "puffing" when it entails a compromise in the requirement of full disclosure. The advertisements involved in the charges contain half-truths designed more to boost sales than to provide a physician with the information essential to the proper and safe prescription of the drug. Busy physicians should and must be able to rely on statements concerning a product without referring back to the original source to look for inconsistencies and contraindications.

We also believe that the Artane Elixir was substantially subpotent, and such fact was known to the firm through the tests it performed on the drug. Defendant clearly acted in callous disregard of the public health by shipping a drug known to be subpotent.

The manufacturers of potent drugs, better than others, know the potential hazards of their products. We believe the prosecution is fully warranted.