Administration on November 23, 1964, pertaining to the information required in a brief summary. They also stated that they were guided by other firms' advertising for similar drug products. In addition, they felt that the context of the advertisements was geared for physicians, and since the doctors themselves received other material, such as brochures, the doctors undoubtedly would have some realization of the precautionary guides to be observed. However, they admitted that they were wrong in omitting the precautionary statements, and they assured the Food and Drug Admiinstration that this error had been corrected in the current advertising for the drug.

The firm knew full well that the gravamen of the regulations was pertaining to prescription drug advertising. It had been warned in 1964 that its drug advertising for this product was false and misleading. It had discussed with the Food and Drug Administration the advertising drug regulations and how to correct its advertising. Despite this information, the firm blatently advertised this drug in the summer of 1965 without giving full information as required by the regulations. The precautionary statements, which the firm omitted, contained the most important information about the cautions to be observed in patients with anorexia, insomnia, vasomotor instability, asthenia, psychopathic personality, a history of homicidal or suicidal tendencies, and individuals who are known to be hyperactive to sympathomimetic agents or emotionally unstable individuals who are known to be susceptible to drug abuse; and that certain monoamine oxidase inhibitors may potentiate the action of Obetrol.

With respect to the interstate shipments of the Obetrol 30 mg. tablets and capsules, the firm stated that this drug was sold by the firm since 1952. Hence, the firm was under the impression that the drug fell within the scope of the "grandfather clause" and a New Drug Application was not necessary.

Unfortunately for the defendants, the "grandfather clause" (Pub. L. 87-781, Section 107) requires that the drug be generally recognized, as of October 9, 1962, as safe when used for the purposes intended. This drug was not so recognized on that date.

The second point the firm made at this Hearing was that the drugs were sold directly to physicians and not through regular commercial channels. This, it said, was an ordinary "Physician-Pharmacist" relationship, whereby the firm was simply filling a prescription for the physician. The defense fails to explain how an order involving some 3,000 tablets sold to one physician and a 1,000 tablet order to a second physician is the same as prescribing for an individual patient as is usually done in the physician's daily practice of medicine. Another objection to the defendant's defense is that, when there is a violation of 21 U.S.C. 355(a), there is no exemption for any so-called "Physician-Pharmacist" relationship. As you recall, the first four counts charge a violation of 21 U.S.C. 355(a). The firm had been previously advised that this conception of theirs was wrong during the Hearing held in early 1963.

The third point the firm made was that the 30 mg. tablets came within the limits of the 60 mg. daily dosage requirements under their New Drug Application for the firm's 10 and 20 mg. Obetrol tablets. This argument had no merit since the New Drug Application provided for the marketing of a specific formulation of the drug with specific labeling. The formulation and labeling for these 30 mg. preparations differed from that provided for by the New Drug Application, hence, these preparations were not covered by the New Drug Application.

Lastly, the respondents stated that they were currently preparing to submit a New Drug Application for their 30 mg. Obetrol tablets and capsules. This Application is still pending. The firm was well aware of our position with respect to the status of this drug. It was advised in August, 1964, that the Food and Drug Administration considered these preparations to be New Drugs without an effective New Drug Application and was told that the Food and Drug Administration could not condone the marketing of this drug in interstate commerce without an approved New Drug Application. Yet, the firm chose to continue the sale of this drug without an approved New Drug Application. It is noteworthy that, at the time of the Hearing, the firm indicated, that it had ceased distributing this drug in interstate commerce, but that it was still selling this drug in intrastate commerce.

CONCLUSIONS

Warnings at Administrative Hearings and at meetings with the Bureau of Medicine of the Food and Drug Administration have gone unheeded by this