

COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY 13591

firm. It had been advised as far back as 1958 that its 30 mg. Obetrol tablets and capsules were New Drugs. Despite this warning, the firm still failed to file a New Drug Application for these drugs and continued to ship them in interstate commerce without an approved New Drug Application. Similarly, the firm was advised in early 1964 that its advertising for its Obetrol 10 and 20 mg. tablets was false and misleading and that it could only advertise the drugs through the use of claims set forth in the labeling approved in the firm's New Drug Application. While it is true the firm discontinued advertising its 10 and 20 mg. Obetrol tablets until the new labeling for these drugs was approved in the summer of 1965, the firm started to illegally advertise again as soon as the final printed labeling had been approved. This time the firm omitted the precautionary statements which relate to the side effects, contraindications, and effectiveness required to be fairly presented in the advertising by the regulations under the drug advertising section of the law. It is our opinion that prosecution of the firm and the two responsible individuals is fully warranted.

WITNESSES

The principal witnesses in this case will be the Government inspectors who collected the samples; cooperating physicians who subscribe to *Modern Medicine* and medical officers of the Food and Drug Administration's Bureau of Medicine who can testify as to the approved New-Drug applications, approved labeling, and the serious nature of the alleged medical journal advertising misbranding.

It is requested that, if the Information is amended, the United States Attorney furnish us with a copy thereof; also, that the United States Attorney keep us advised of the progress of the case and its disposition. The New York District of the Food and Drug Administration will arrange for the presence of the necessary witnesses and assist in the presentation of the case. Upon request, we shall render such further assistance as may be possible.

Very truly yours,

WILLIAM W. GOODRICH,
Assistant General Counsel,
Food and Drug Division.

UNITED STATES DEPARTMENT OF JUSTICE

Washington, D.C., April 24, 1967.

Re Rexar Pharmacal Corp., Armin Rosner, and Martin Benjamin, FDC No. 53053, Federal Food, Drug, and Cosmetic Act.

DEAR MR. GOODRICH: This is in reply to your letter to the Attorney General of January 17, 1967, in which you request the institution of criminal proceedings against the above-captioned subjects for violations of the Federal Food, Drug, and Cosmetic Act committed between April, 1964, and October, 1965.

We have carefully reviewed the statements set out in your letter concerning the subjects' activities relative to the sale of certain drug products.

As to the fifth count, we are not disposed toward the conclusion expressed in your letter that the words of the statute, also used in your regulations, requiring a statement of contraindications, side effects, and effectiveness in prescription drug advertisements are so clearly inclusive of "precautions" as to give the subjects "fair warning" that such items must be included. We have observed that in the advertisement in *Modern Medicine* in September, 1965, the subjects included, under the statutory headings, the full and exact language found under those headings in the labeling approved by the Food and Drug Administration. There is nothing in the Act or the regulations to indicate that the words therein have a larger meaning than that of the approved labeling. Accordingly, we are of the opinion that the advertisement to which reference was made in your letter is not violative of the Act. Moreover, we do not believe that the factual situation here is such that the Government would be able to prevail in the event the theory suggested in your letter were to be tried out in a criminal prosecution of Rexar and its officers. Therefore, prosecution is declined as to the charges set out in Count V of your suggested information.

Inasmuch as the violations of April 18, 1964, and March 1, 1965, were not reported to us for criminal prosecution until after the appearance of the advertisement in *Modern Medicine* in September, 1965, we are uncertain as to whether you are of the opinion that prosecution is merited on the basis of those acts