enclosed is in black and white, and the graphs do not reproduce clearly because of the contrasting colors used in the magazine. However, the printing can all be read. If this case goes to trial the FDA will obtain back copies of the magazines from the publishers for use. There are no extra copies available at this time. The ad highlights the study made by Alexander Oscharoff, M.D. and reported in the article "Pentaerythritol Tetranitrate as adjunct Therapy in the Immediate Post Infarction Period." The same ad was rerun in the February 7, 1966 issue of *JAMA*.

The advertisement for the drug which was run in the April 15, 1966 and April 22, 1966 issues of Medical World News is a two page ad which reports a study conducted by B. L. Brofman, M.D. using Peritrate SA.

On February 28, 1966 in the Eastern District of New York, a libel was filed against the shipment represented in Counts I and II and the drug was seized on the same day. The libel alleged that the drug was misbranded in the same manner as Count I does, and also alleged its shipment in violation of the new drug provisions of the Act as now alleged in Count II. Warner-Lambert Pharmaceutical Company filed a claim of ownership and on May 12, 1966 consented to the entry of a decree of condemnation without admitting the allegations of the libel. The rest was then destroyed.

Hearings pursuant to 21 U.S.C. 335

Counts I and II.—On April 18, 1966, a hearing was held in the Food and Drug Administration's offices in New York, New York, with the following people representing Warner-Lambert: Mr. Robert Clark, President, and Dr. Frank DiTraglia, Medical Director, Warner-Chilcott Laboratories, Mr. James Hoge and Mr. William F. Weigel of the law firm of Rogers, Hoge & Hills.

Mr. Weigel stated that the firm recognized the seriousness of the charges, based on the *JAMA* advertisement but denied any violation of the Food, Drug, and Cosmetic Act. He also submitted a written statement referring to the charges set forth in the Notice of Hearing.

Mr. Weigel said that the claims with respect to myocardial blood flow, increased oxygen, and collateral circulation were made prior to October 10, 1962 and were therefore in his opinion grandfathered. This would include the claim concerning collateral circulation in the mailing piece allegedly supported by study of Lumb and Hardy.

The written statement asserts that the firm never intended to make any claim for the use of the drug in the postinfarction period as found in the mailing piece but felt it was necessary to set forth in detail the manner in which the drug had been used in the Oscharoff study.

The statement continued that the Oscharoff studies, which claimed that 22 percent more patients treated with Paritrate SA at a time closely following myocardial infarction remained alive after two years than patients treated with a placebo, were used in good faith and the firm had no reason to question the results of the study. In using these results as part of their labeling and advertising, the firm maintained that it was unaware of the fact that technically it might be making a new claim for the drug. Mr. Weigel indicated that since no case law was established as yet on interpretation of the advertising provisions of the Act, it was his opinion that it should be established first in civil actions before criminal prosecution should be instituted.

Count III.—On July 22, 1966 a second hearing was held with the following people present, representing Warner Lambert Pharmaceutical Company: William F. Weigel, Esq., Attorney with Rogers, Hoge and Hills, Frank J. DiTraglia, M.D., Corporated Medical Control Director, Mr. Frank Markoe, Jr., Senior Vice President, Secretary and General Counsel, Warner Lambert Pharmaceutical Company. This was held to discuss the deficiencies of the advertisement in *Medical World News*.

Again Mr. Weigel stated that the firm admitted that the shipment had been made and that the firm issued the advertising which was the subject of the hearing, but denied any violation of the law. He emphasized that the ad offered the drug only for use in the treatment of angina pectoris, in accordance with the policy of the Food and Drug Administration that nitrate-containing drugs are considered as useful only in the management of angina pectoris. Warner Lambert denied the charges contending that Dr. Brofman's findings were clinically significant and that the manner in which the subjects were chosen, the methodology employed, and the evaluation of the results were in accordance with generally accepted procedures for such studies. Dr. DiTraglia dictated a prepared statement of his interpretation of the study substantially as follows.