set forth in the advertisement. The omitted warning information related to information that the physician needed to know, namely, that the drug should be used with caution in individuals with anorexia, psychopathic personality, history of homocidal or suicidal tendencies, and emotionally unstable individuals known to be susceptible to drug abuse.

With respect to the new drug charge on the Oby-Rex capsules and tablets we stated that such drug was a potent amphetamine mixture with well recognized hazards, which had not been shown or recognized to be safe in the 30 mg. dosage for which the drug was intended. To place such unproved dosage on the market in utter disregard of the new drug procedure was, we believed, a substantial violation of the law.

The Department of Justice replied to our letter of protest and stated that it remained of the opinion that prosecution was not feasible.

Name of Defendant or Product: Syntex Labs.
F.D.C. No.: 53222.
Date Referred to Dept. of Justice: 3–16–67.
Judicial District: New Jersey.

Problem: We had recommended prosecution on the basis that the labeling for Norinyl, an oral contraceptive drug, failed to bear adequate directions for use, and that the advertisements for such drug did not bear information relating to the side effects and contraindications of the drug as required by law. The Department of Justice in Washington declined prosecution with respect to the advertisements on the ground that the information omitted did not relate to side effects and contraindications as we alleged but instead to matters which were not so categorized in the approved New Drug Application labeling.

We protested this decision on the basis that Congress intended that the advertising provision of the law should apply to all matters relating to side effects and contraindications and not be restricted to fixed artificial categories of information under those headings.

The Department of Justice affirmed its decision on the advertising charges but did approve prosecution on charges of inadequate directions in the labeling of the drug, and forwarded the case to the U.S. Attorney for prosecution on this basis.

The U.S. Attorney declined prosecution because it appeared doubtful to him that we could prove that the labeling of the drug consisting of the Physician's Desk Reference monograph was substantially different from the approved New Drug Application labeling, and thereby establish that the drug failed to comply with the conditions for exemption from the requirement of adequate directions for use.

We protested this decision on the basis that some of the most vital safety information in the approved labeling had been omitted from the PDR monograph. The United States Attorney subsequently affirmed his decision against prosecution.

Name of Defendant or Product: Merck & Co.
F.D.C. No.: 54763.
Date Referred to Dept. of Justice: 3–21–68.
Judicial District: E. Pa.

Problem: We recommended prosecution based on defendant's failure to immediately report to FDA the defendant's findings with respect to the drug MK–665. We considered such findings to be "alarming" within the meaning of the NDA regulation and therefore findings which should be immediately reported because they disclosed the development of cancer in animals which had been tested with the drug.

The Department of Justice declined prosecution because it did not agree with our interpretation of the NDA regulation relating to immediate reports on "alarming findings."

Name of Defendant or Product: Warner-Lambert Pharm. Co.
F.D.C. No.: 53548.
Date Referred to Dept. of Justice: 2–15–68.
Judicial District: New Jersey.

Problem: We recommended prosecution on the basis that the labeling of the drug Peritrate was false and misleading and failed to bear adequate directions