CASES CLOSED BY DECLINATION OR UNSATISFACTORY SETTLEMENT

Name of defendants or products: Wyeth Labs.
F.D.C. No.: 52677.
Date Referred to Dept. of Justice: 12–5–66.
Judicial District: E. Pa.
Problem: Dept. of Justice in Washington, D.C. declined prosecution on false and misleading advertising charges relating to the drug Serax because seizure resulted in correction and because FDA intended to publish new advertising regulation.
We recommended prosecution for the following reasons:
1. The defendant had been warned by a notice of hearing under 21 U.S.C. 335, which issued about six months prior to the publication of the ads involved in Count 2, against the use of false and misleading ads such as were involved in Count 2.
2. The ads involved in this prosecution were false and misleading as follows:
(a) the ads referred to a study, in support of a claim of effectiveness in geriatric patients, in which no proper controls were exercised, only a small portion (14%) of which were geriatric patients, and the dosage administered exceeded the dosage permitted by the approved New Drug Application labeling;
(b) the ads falsely claimed that the drug was over 90% effective;
(c) the ads recommended the drug for use in anxiety-linked depression, which use was not set forth in the approved New Drug Application Labeling;
(d) the ads failed to emphasize that the drug should be used cautiously by elderly patients because of the possibility of serious hypotensive reactions.
As a result of such false and misleading ads, physicians who relied on them could be led into an error of medical judgment in prescribing Serax for their patients.

Name of defendants or products: American Cyanamid Co.
F.D.C. No.: 53050.
Date Referred to Dept. of Justice: 11–7–66.
Judicial District: S. N.Y.
Problem: U.S. Attorney declined prosecution on advertising charges relating to aristocort tablets and Pathibamate tablets because law and regulations were vague and emissions of side effect and contraindication information in the ads were not sufficiently grave.
A letter of protest was sent by us on 11–6–68 explaining that the law and regulations were not vague and that the warning information omitted from the advertisements for the drugs was important for the physician to know in order to provide safe patient care. The ad relating to the aristocort tablets did not state that such tablets may produce such potentially serious side effects as acne, spontaneous fractures, aggravation of infection, psychotic disturbances, thromboembolism, gastrointestinal hemorrhage. The ad relating to the Pathibamate tablets did not state that hypotensive crisis, anuria, anaphylaxis and proctitis are possible side effects and that the tablets are contraindicated in cases of known hypersensitivity to meprobamate.
We did state in our protest letter that in view of the age of the case we would have to agree that it was unlikely that pressing this case to prosecution would improve the advertising practices of the defendant and of the industry.

Name of Defendant or Product: Rexar Pharmacal Co.
F.D.C. No.: 53053.
Date Referred to Dept. of Justice: 1–17–67.
Judicial District: E. N.Y.
Problem: Dept. of Justice in Washington, D.C. declined prosecution on advertising charges relating to Obetral tablets since the side effects we charged to be omitted were not believed to be required by the law but were only "precautions"; prosecution also declined on new drug charges against Oby-Rex capsules because of age of offenses and because factual situation was unattractive for criminal case.
A letter of protest was sent by us on 4–18–68 stating that the warning information omitted from the Obetrol advertisement and which was described as "Precautions" in the full disclosure labeling of the Obetrol tablets was in fact "side effect" information which was required by the law and regulations to be