Dr. LEY. All right.

Mr. GORDON. How were the smaller companies treated?

Dr. LEY. There is only one other firm besides Parke, Davis which is marketing succinate at this point in time. That firm's application for approval of the product was submitted—do you remember the exact date that came in?

Dr. MINCHEW. It was in, I think, late 1967.

Dr. LEY. Approximately late 1967—and approved following the receipt of the Academy recommendations on the succinate product. All labeling for that product is the new labeling revised along the lines of the Academy recommendations.

Senator NELSON. Please proceed, Doctor.

Dr. LEY. As a part of the overall review of drug efficacy being conducted for FDA by experts selected by the NAS–NRC, the Panel on Anti-Infective Drugs has been studying the various dosage forms of chloramphenicol. On August 9, 1968, we received reports from the Academy giving the results of this study. I submit copies for the record.[1] These reports showed that the Panel on Anti-Infective Drugs:

(1) Endorsed the warnings that FDA required in the labeling of chloramphenicol.

(2) Emphasized the toxicity of the antibiotic.

(3) Recommended the use of less hazardous agents where they could be expected to accomplish the desired therapeutic effect.

FDA reviewed the Academy reports and agreed with them.

We also reviewed, in the light of these reports, the labeling we had developed in May for the various chloramphenicol preparations and concluded that:

(1) The labeling of chloramphenicol capsules was consistent with the Academy's recommendations.

(2) The labeling of chloramphenicol palmitate oral suspension was consistent with the recommendations.

(3) The labeling for parenteral forms of chloramphenicol required further revision. The panel had noted the higher and preferable blood levels obtained by intravenous use, compared with intramuscular administration. It also recommended a change to the oral chloramphenicol as soon as possible since these gave better blood levels. The new labeling reflecting these recommendations, was approved on September 3, 1968. I submit a copy of the revised labeling for the record.[1]

The Academy reports also discussed the effectiveness, or probable or possible effectiveness, of chloramphenicol in treating a variety of specific conditions for which it had been promoted—such as various surgical infections, respiratory tract infections, and urinary tract infections—but none of these are listed specifically in the drug's current labeling, which is oriented to causative organisms rather than sites of infection.

Senator NELSON. Do I understand, then, that this kind of ad, which shows a bronchoscope, is now prohibited?

Dr. LEY. That ad is no longer running. We would not look with favor upon such an ad.

Senator NELSON. Was there any valid medical reason for using the

[1] See information, pp. 4407–4476.