EDUCATIONAL AND PROFESSIONAL EXPERIENCE

A.B.—Emory University 1953.
M.D.—Emory University School of Medicine 1957.
Intern—University of Arkansas Medical Center 1957–1958.
USPHS–CDC–EIS (Epidemic Intelligence Service) Fellowship in the Division of Allergy and Infectious Diseases, Johns Hopkins Hospital 1958–1960.
Residency in Internal Medicine—University of Washington 1960–1962.
Private Practitioner, Internal Medicine 1962–1963.
Medical Officer, Food and Drug Administration, Bureau of Medicine, Division of Antibiotic Drugs June 1963–February 1965.
Medical Officer, Division of New Drugs, Investigational Drug Branch February 1965–July 1966.
Deputy to the Assistant for Drug Coordination, Bureau of Medicine, May 1965—July 1966.
Acting Deputy Director, Bureau of Medicine, July 1966—September 1966.
Assistant to the Director for Professional Development, September 1966—January 1967.
Deputy Director, Bureau of Medicine, January 1967—Present.
Director, Antibiotic Task Force, Bureau of Medicine 1966.
Clinical Instructor in Medicine, Georgetown University Medical School.
Physician, Group Health Association, 1964—present.

SOCIETIES

American Association for the Advancement of Science of Washington, D.C.
Academy of Medicine of Washington, D.C.
The American Public Health Association, Inc.

Dr. MINCHEW. The application for approval for marketing of Vibramycin (called a form 5 application for antibiotics) was submitted by Chas. Pfizer & Co. on June 22, 1966.

It was reviewed by the Office of New Drugs and by the Division of Antibiotics and Insulin Certification.

The original submission was inadequate and additional data were required. On October 13, 1966, we received further analytical data and on the next day, October 14, additional clinical reports were submitted.

By January 11, 1967, the preclinical studies in pharmacology had been reviewed. Our conclusions were that liver toxicity was shown in the dog, gastrointestinal toxicity was exhibited in the dog and the monkey, and thyroid changes were found in the monkey, the rat, and the dog. Nonetheless, the pharmacologist felt that the animal data did not preclude approval, so long as the package insert described the toxicity noted to alert the physician to the possibility of comparable effects in man in clinical use. A final review in May of a longer rat study confirmed these conclusions.

Senator NELSON. Confirmed what conclusions?

Dr. MINCHEW. The conclusions of the animal toxicity that had been seen on the shorter term studies.

By February 15, 1967, the chemical controls review had been completed. Manufacturing controls were considered adequate.

The medical review was concluded the same day. The evaluation was that the drug was another tetracycline similar in safety and effectiveness to the previously approved tetracyclines. Its distinguishing characteristics were more rapid absorption and a longer half life, permitting the drug to be given once or twice a day (rather than the usual four times), in smaller doses, to achieve similar clinical results as those seen in higher and more frequent doses of the older tetracyclines.

Mr. GORDON. Doctor, you talk about toxicity studies in animals. Do