bronchoscope associated with chloramphenicol at any time in the history of this drug?

Dr. LEY. This is difficult to say. In the 1950's perhaps this might have been a very reasonable correlation, bronchoscopy, severe pulmonary infection, lung abcess, and chloramphenicol. We have very carefully looked at this and the similar cystoscope ad, and although the text is absolutely word-for-word as stated in the package insert, we feel at this point in time that that type of visual display with that copy is inappropriate.

Senator NELSON. The drug has never been indicated, has it, for any upper respiratory diseases?

Dr. LEY. No, sir. It is not so indicated now. However, in the very early days in antibiotic therapy, chloramphenicol, tetracycline, and so forth, were widely used for many infections. That was in the late 1940's and early 1950's. Times have changed.

Senator NELSON. It is well known in the scientific community that if the ad were ever justified, it was many, many years ago, is that correct?

Dr. LEY. We believe that statement is correct.

Senator NELSON. And this ad was run on February 5, 1968?

Dr. LEY. I'm aware of that. It has since terminated.

Senator NELSON. So this ad was run many years after any conceivable claim could have been made for this kind of indication?

Dr. LEY. I would agree.

Senator NELSON. Fine.

Dr. LEY. The same orientation, I might add, will be used for other antibiotics as labeling is revised to carry out efficacy recommendations of the National Academy. The rational choice of an antibiotic should be predicated on the judgment of the prescribing physician as to the causative organism. It also should take into consideration the possible adverse effects of an antibiotic as well as its established efficacy. The current package insert for chloramphenicol, as I indicated a moment ago, illustrates this approach. The indications section is basically oriented to causative organisms and the labeling also highlights the serious adverse effects of the drug.

I know that the committee is specifically interested in the overall use of this antibiotic. After the hearing before this committee last February, the issuance of the FDA "Dear Doctor" letter, and the discontinuance of "reminder" advertising for the drug, the quantities of chloramphenicol certified dropped materially. In calendar year 1968, we certified for all dosage forms for systemic use slightly less than half as much as in 1967.

This is still, in our opinion, more than is needed for all of the approved uses of the drug and we are exploring further measures that may be in order.

Senator NELSON. Yesterday, Doctor Wehrle—I hope my memory is correct—in making some judgment about the use of chloramphenicol and using the statistics from his hospital and extrapolations from there, concluded that of the 30 million hospitalized patients annually, if the same standards for use were applied as were established for his hospital, about 2 million grams a year would be used on hospitalized patients. I am sure you are aware this was formerly Los Angeles Gen-