

Mr. CUTLER. These are the leading medical authorities of the country in the National Academy of Sciences.

Senator NELSON. Go ahead.

Dr. LUECK. The National Academy of Sciences is recognized as the highest ranking scientific body in the United States.

It might be of interest, Mr. Chairman, to note that it operates under Government funds.

Now, the National Research Council has responded, as I said, on two occasions to inquiries from the Food and Drug Administration as to the place of Chloromycetin in the therapeutic armamentarium of physicians.

I might quote, on January 11, 1961, the Chairman of the Division of Medical Sciences of the National Research Council replied by letter and among other things, he commented as follows:

Chloramphenicol is considered to be a valuable drug that should remain on the market. In fact in certain infections, it is a drug of choice. The newer antibiotics that have appeared on the market since chloramphenicol was last evaluated by the National Academy of Science's National Research Council in 1952 can't replace satisfactorily in all cases.

Point 2, and I quote further:

A restriction of the usage of chloramphenicol to hospitalized patients is not deemed to be indicated. * * *

3. A knowledge of the untoward side effects that may occur with this drug should be adequately known to all prescribers. The information should be disseminated as a warning on the drug label and elaborated in an enclosure in the drug package. Beyond this, there is need for the continuing education of the physician through the media of medical meetings and the medical literature. This, of course, is a responsibility of the leaders of medicine and not of the FDA.

Point 6. Almost, if not all, potent therapeutic agents cause some undesirable side effects. Therefore, it should be pointed out that chloramphenicol is not the only antibiotic that may cause unfavorable reactions of a serious and sometimes fatal nature.

In addition to the National Research Council review, the Food and Drug Administration in 1957 published comparative data of side effects comparing various antibiotics.

Now, Mr. Chairman, let us look at this article in this publication, and let us look at the potential dangers of chloramphenicol in true perspective; in other words, comparing it to other anti-infective agents or other antibiotics. Let us take a look at disabling and death-dealing reactions that may occur with the other antibiotics. The last significant and overall review of severe reactions to antibiotics was communicated to the medical literature by personnel of the FDA in 1957. Now, it consisted of a nationwide study, including more than 800 hospitals and interviews with 1,600 physicians, and uncovered 1,070 severe antibiotic reactions that were life-threatening.

Senator NELSON. Any deaths in that list?

Dr. LUECK. Yes. In a paper published in Antibiotic Medicine and Clinical Therapeutics, 1957, these authors brought out the fact that