But it apparently does not help. And I do not think it will change if you say "dangerous drug," I am sorry to say. But I am willing to consider that. Senator, you yourself said 18 years have gone by with this kind of information.

Senator NELSON. And that sure shocks me.

Dr. GODDARD. Yes, sir. And I say when you cut aside all the verbiage, it comes down to the fact that somebody has to make a decision. Are you going to have in this country a system that provides control, very tight control, on a drug or all drugs in a different fashion than we have ever had before. I am sorry—I am not trying to be obstreperous. I am simply trying to point out it gets down to that kind of fundamental issue.

Senator NELSON. I think it does.

Thank you very much. You have been a very gracious and pleasant witness.

(The complete prepared statement of Dr. Goddard follows:)

STATEMENT OF DR. JAMES L. GODDARD, COMMISSIONER OF THE FOOD AND DRUG ADMINISTRATION, U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Mr. Chairman, I appreciate the opportunity of appearing before your Committee today to discuss the Food and Drug Administration's action and intentions in regulating the interstate distribution on the antibiotic drug, chloramphenicol.

The Nation has watched with great interest the testimony unfolding before this Committee in the past weeks. The Committee's hearings have brought renewed attention to important questions that concern us all: Is this a drug too dangerous to remain on the market? Should its use be restricted in some way? Are the FDA, the medical profession, and the manufacturer of the drug taking all necessary steps to assure the safest possible use of the drug?

Before discussing these questions and alternatives, however, it may be useful to outline what has been done in the past. Chloramphenicol was first isolated in 1947 from a soil sample collected in Venezuela. It was found that liquid cultures of the organism, *Sterptomyces venezuelae*, possessed marked effectiveness against several Gram negative bacteria and also exhibited antirickettsial and antiviral activity. Shortly there after the chemical structural formula was determined and the antibiotic was prepared synthetically. And, as you know, it was later patented by Parke-Davis and Company.

In 1948, chloramphenicol was produced in amounts sufficient for clinical trials and general clinical use. It was found to be of value in the therapy of a variety of infections, including epidemic typhus in Bolivia and scrub typhus and typhoid fever in the Malay Peninsula. On January 12, 1949, the Parke-Davis New Drug Application for Chloromycetin, that company's brand of chloramphenicol, was allowed by FDA to become effective. In the summer of 1949, as the result of new legislation, Chloromycetin was classified as a "certifiable antibiotic," subject to the bacth certification provisions of the Food, Drug, and Cosmetic Act.

When chloramphenicol was first introduced in 1949, it was widely heralded as a "broad spectrum antibiotic" effective against an impressive range of microorganisms. It was also considered to be largely nontoxic. There was no indication at that time that the drug had any serious side effects.

Early in 1950, however, a few published reports drew attention to the possibility that chloramphenicol might cause serious and fatal blood dyscrasias. The 1951 edition of *New and Non-official Remedies* warned that "changes in the peripherial blood or blood forming organisms have been reported during the use of chloramphenicol." An editorial in *The Journal of American Medical Association*, June 28, 1952, referred to additional reports of blood disorders. It went on to say:

"A second and more serious type of reaction that has been encountered is production of a true aplastic anemia. In the experience of one group this anemia has occurred in patients who have previously received one or more courses of chloramphenicol without untoward effect. When the drug was subsequently administered, even in small doses, a severe blood abnormality has appeared. Even deaths have been reported."