

Senator NELSON. When you say FDA discontinued the certification, did that remove it temporarily from the market?

Dr. GODDARD. No further batches of the product could be introduced into the market. It was not recalled at that time. What was in place, and was being used, was permitted to remain on the market.

Senator NELSON. Whatever was already in the marketplace could continue to be used?

Dr. GODDARD. At that time.

Senator NELSON. All the experts who have testified here on the administration of this drug, and have discussed the statistics of serious side effects, including death, were really unable to come up with anything approaching an accurate estimate of the number of deaths or serious permanent injuries which have left people ill for the rest of their lives.

Does FDA have any reasonably valid statistical information on how many people are being seriously and permanently affected adversely by the administration of this drug?

Dr. GODDARD. Senator, this is a problem, as you well know, not only with this drug, but with many other drugs. We do not have the kind of data base that would give us, with a high degree of assurance, reliable data on which to draw such conclusions.

Let me point out that the best study, in our opinion, is the one carried out by the California Medical Association. As a result of that survey, and study that they carried out, now some—

Dr. LEY. The survey was published in January 1967.

Dr. GODDARD. It was published in January 1967. We note that they find a fatality incidence of 1 in approximately 24,000 persons receiving this particular drug.

Senator NELSON. Fatal?

Dr. GODDARD. Yes, sir.

Senator NELSON. Now, how many had serious permanent side effects—what percentage?

Dr. GODDARD. I do not know that.

Dr. LEY, do you?

Dr. LEY. The chief figures in the report are aimed at fatalities. There are a number of other conditions which they mention, most of which I believe are reversible.

Senator NELSON. Well, what about instances where the drug suppresses the capacity of the bone marrow to produce blood by 20 percent, or 10 percent, which leaves the person ill the rest of his life, although he lives. Are there any statistics on that kind of result?

Dr. GODDARD. Senator, I would be happy to have our people go through the CMA report again, and provide that for the record, if I may. I do not recall it.

(The subsequent supplemental information follows:)

STATEMENT OF THE FOOD AND DRUG ADMINISTRATION REGARDING NONFATAL COMPLICATIONS REFLECTED IN CALIFORNIA MEDICAL ASSOCIATION STUDY

Our review of the California Medical Association Report does not disclose any non-fatal, drug related experiences with Chloramphenicol. The California study was based on a review of death certificates; therefore non-fatal complications of Chloramphenicol administration would not be reflected in the study.