

Senator NELSON. Well, the statistics in the California report would be 10 more cases out of two hundred and some thousand and you've doubled the incidents.

Dr. LEY. That is correct, sir.

Senator NELSON. Please go ahead.

Dr. LEY. Cautionary information is included regarding use of the antibiotic in pregnancy and lactation. Leukemia is listed as an additional adverse reaction.

On May 7, 1968, following approval of the new labeling, we sent a "Dear Doctor" letter to every physician in the country calling attention to the proper indications for use and the strengthened warning about the hazards of this drug. The letter was also sent to all hospital administrators. The revised labeling was included with the letters, along with a facsimile of our Drug Experience Report form. Physicians were requested to report any adverse reactions associated with the use of chloramphenicol. I'd like to submit for the record a copy of this letter and the enclosures.

Senator NELSON. Thank you. Those will be included in the record.
(The information follows:)