

(generic name for Parke Davis's brand Chloromycetin) was similar to that of the thalidomide victims, the only difference being that the victims of aplastic anemia were dead and their plight could not speak for them. The vote was a little more than 97 percent against the proposal. It was a vote of the stockholders and the proposal was specifically that the labeling should be the same abroad as in the United States which brought in other issues than the fundamental one of pharmaceutical companies providing objective, scientific, and complete information on proper use of their products in whatever country they are sold so that, as Mr. Squibb speculated, perhaps the question was not well put. Nevertheless, information on the fundamental issue of what inadequate misleading labeling can mean at least of one drug, Chloromycetin, in terms of human life has been brought to the attention of the company.

As a consumer whose daughter had recently died of aplastic anemia and whose letters to the Parke Davis Company were unanswered, I spoke after the end of the business meeting during the question and answer period and was only allowed to read from a one-page statement but was not allowed to read the Spanish label for Chloromycetin that I had brought with me which contradicted the chairman's, Warner-Lambert's chief executive officer's, statement that warnings of possible fatal aplastic anemia were indeed included.

After the meeting Mr. Weiringa, then President of Parke Davis and now, I believe, president of Warner-Lambert, said that he had not seen the letter addressed to him and that he would arrange an interview for me with him or preferably the medical director, Dr. Robert Hodges, Vice President for Research, as being more knowledgeable of medical aspects. At my request, he also said I could bring a physician with me and that he would give me the Chloromycetin labels for the countries abroad in which Parke Davis sold its products which, it seemed to me, were just elementary basic information needed to consider the issue intelligently by anyone—me, the President, the Board, the stockholders. Shortly thereafter, however, Mr. Weiringa rescinded his offer, saying supplying such information was "against the policy of the company".

This meant that we had to go through the time-consuming process of trying to collect Chloromycetin labels from abroad on our own travels and those of our friends for in many countries, since Chloromycetin is sold over-the-counter, to anyone and without a prescription, the labels are readily available. These labels varied greatly from those more similar to ours in the United States, such as in England, to many with no warnings at all and as many as 45 listed indications for use, many of them trivial. The Parke Davis Chloromycetin United States label has very strong, repeated, and explained warnings of possible fatal aplastic anemia and other warnings and states that it must not be used for minor illnesses, only for very serious illnesses susceptible to its action that cannot be treated with any less hazardous medicine.

Dr. Ronald Bishop and I met with Dr. Hodges for a long and cordial interview. Dr. Hodges described his own personal views of the product and explained the company's position regarding why labels were different abroad. (I have a file of notes of all my conversations and copies of letters and other statements of Parke Davis officials giving their views and will send them to include in the testimony if the Subcommittee so desires.) Dr. Hodges asked to see the Spanish label and when I inquired who was responsible for the labeling of Parke Davis products abroad, he replied that he was not but did not say who was responsible. It seemed strange to me that someone in his position would have to ask me to see the label when the Chloromycetin foreign labels were almost sure to be brought up at the annual meeting.

We then sent the Spanish label first, then later Chloromycetin labels from other countries to Mr. Weiringa, the President. Within a few months Mr. Weiringa called to say that the company had revised its Chloromycetin Monograph which is the company's basic information on the drug, is sent to all their international locations, and is used as the basis—along with each country's regulatory system's input—for labels in that country. Mr. Weiringa said that the new Monograph was essentially the same as the United States label but would not give us a copy since it was again "against company policy". Nor could an American physician obtain a copy, only a practicing physician in a foreign country in which Chloromycetin was sold. Upon inquiry, Dr. Hodges said the Monograph was basically the same as the United States label except that indications would vary in different countries and he was very definite that the company would not give us a copy or any information of this type. So again many months—about eight, I think—were spent in our finally successful efforts to obtain the Monograph from abroad.