Control of Medicines in Spain

14. Control of medicines in Spain asperceived by Mr. and Mrs. Zander after personal interviews in Spain with two physicians and two officials.

CONTROL OF MEDICINES IN SPAIN

Our Parke-Davis Company in defending its product information on Chloromycetin when it is sold abroad always stresses that the company follows the rules of the health regulatory agency of the country in which it is selling its product, explaining, however, that "regulations on sales are less strict in some countries and some even limit the labeling", implying that in such countries the health regulatory agency, not Parke-Davis, is responsible for lack of adequate warnings on their labels. They also advised us to talk to physicians abroad to get their views of Parke-Davis labels for use of Chloromycetin in their own country. At the end of September 1973 we spoke to doctors and health regulatory officials in Spain on the subject. We chose Spain because Parke-Davis chloramphenicol labeling in Spain in the past has been lacking in warnings of fatal aplastic anemia and has encouraged unnecessary use in comparison with the company's U.S. Chloromycetin label and, since it now has the new Parke-Davis Chloromycetin Monograph of basic product information and a new label, a substantial improvement but still inadequately strong in warnings and use restrictions. Also, we have the most documented materials from Spain since it was there that our daughter may have been given chloramphenicol for tonsilitis that may have been the cause of her death from aplastic anemia.

Our belief that the Parke-Davis Chloromycetin labels most lacking in warnings and encouraging in unnecessary use were precisely in those countries with the weakest health regulatory agencies as exemplified in our collection of labels from various countries, was corroborated in the case of Spain by our talks with physicians and health regulatory officials. In the past, at least, if Parke-Davis had pushed to include strong warnings of fatal aplastic anemia and to restrict unnecessary use, especially for relatively trivial illnesses, when it was required to do so in the U.S., we are convinced that it could have done so in Spain.

We first had lengthy conversations with two physicians in Spain who felt so strongly and were so outspoken to us on the past weakness of their country's health regulatory agency and the power of strong pharmaceutical companies to do as they wished in pushing the sale of their product and also the consequent ignorance of Spanish doctors in general in prescribing medicines that, considering the present political climate in Spain, we do not think it wise to identify them other than to say they are well-trained and experienced in the medical disciplines required to make such judgments. We will identify them privately but have a real concern for their safety because they are so impassioned in their criticism of their country in this respect. Attached are some notes on these conversations written immediately afterwards with identifying items hopefully removed. These physicians had detailed documentation of the inadequacy - and worse - of the information on use of their products given to the medical profession by the pharmaceutical companies.

Then we had a cordial interview with the Director of the Division of Antibiotics and the Director of the Division of Chemical Analysis of the Spanish Centro Nacional de Farmacobiologia (Control of Medicines). They also said that in the past the problem of control of medicines in Spain had been severe due to lack of funding and manpower so that powerful pharmaceutical companies did more or less as they wished and acknowledged that chloramphenicol had been too widely used in Spain. However, right now they were very excited and hopeful with the appointment of well-qualified Directors of Health and of CNDF which was being thoroughly reorganized, given more funding, and a four or five-fold increase in staff. Indications of the change are seen in their new chloramphenicol basic information that is much more restrictive of use, the requirements for all companies producing it to comply with these basic ideas in their labels (not sure they are able to carry this out fully), their beginning to use the World Health Organizations Adverse Reactions reporting system, the beginning of a drop in use of chloramphenical. However, they still do not have the manpower and are powerless to control advertising and promotional materials of the pharmaceutical companies including their Spanish publications comparable to our Physicians Desk Reference, and to recall old-labeled medicines when the label is changed (five years for chloramphenicol). Attached are notes on the conversation with these official.

Both the physicians and health regulatory officials to whom we talked in Spain gave us the distinct impression that in the past at least, there has been very little effective regulating of the pharmaceutical companies and hence we believe that it was Parke-Davis itself that was responsible for the many years of inadequate labeling in Spain.