16. Notes on interview with Chief of Antibiotic Division and Director of Division of Chemical Analysis of the Centro Nacional de Farmacobiologia (Control of Medicines), Madrid, September 1973.

Interview with Dr. Martinez Arroyo, Chief of the Antibiotics Division of the Centro Nacional de Farmacobiologia and Dr. Garcia Ferrandiz, Director of Division of Chemical Analysis of theCentro Nacional de Farmacobiologia: on September 28, 1973:

The interview withDr. Martinez Arroyo andDr. Ferrandiz was very cordial and conducted in English which may have occasioned some slight difficulties in understanding since it was not their mother tongue. The basic impression they left with us was that in the past in Spain the problem of control of medicines has been very severe. The Centro Nacional de Farmacobiologia (Control of Medicines) has been very weak, headed by political appointees with inadequate backgrounds, underfunded, understaffed. In this situation the powerful pharmaceutical companies did more or less as they wished and the physicians prescribed more or less as they wished. The CNDF just did not have themanpower and funding to control the situation.

However, " at this moment" everything is changing: the new Director of Health, Dr. Federico Bravo Morate and the new Director of the CNDF, Dr. Jose Manuel Reol Tejada are very well- trained people, apparently for the first time. The staff of CNDF has been increased four or five-fold and there has been a total reorganization and they are moving to a much larger building. They sound very excited and hopeful of the future, readily admitting that though they have many improvements in the works at present, there are many things that they still cannot do all at once.

We were given a copy of the World Health Organisations Circular of the United States FDA-required Chloromycetin label and two brief statements of the CNDF's new basic position on use of chloramphenicol which, we believe, are used as a basis for the new chloramphenicol labels of all pharmaceutical companies. They are surprisingly restricted in the indications for use, much like our label, "surprisingly"considering past chloramphenicol labeling in Spain,but they do not have strong and full enough warnings of fatal aplastic anemia (perhaps because the Spanish officials themselves think that the Spanish people are not subject to this reaction, though in the past they have not kept records. They believe the fatal type is genetic and northern European peoples, especially Anglo-Saxons, are more subject to it. (yet they have 32,000,000 tourists each year, mainly from northern Europe). However, they have just begun with WHO record keeping of adverse reactions to medicines so that eventually there may be evidence to support or discredit their belief that Spaniards are not as subject to chloramphenicol-related aplastic anemia.

They readily agreed that chloramphenicol has been too widely used in Spain with much unnecessary use but said that use is beginning to go down, especially with the new medicines coming along, like ampicillin. They estimated that 80% of chloramphenicol in Spain is prescribed by physicians in the National Health Service with the other 20% private and sold over-the-counter with no prescription.

About our own Parke-Davis Company, they said that it is one of the smaller companies in Spain in selling its own product but said that Parke-Davis manufactures "tons" of chloramphenicol to sell to other Spanish pharmaceutical companies to market in Spain. They agreed that Parke-Davis Chloromycetin is a good quality medicine. They said the new Parke-Davis Monograph and label is , of course, not the same as the U.S. FDA-required label and indicated that they personally would like an even stronger label. They also said that they would not want United States companies to be required by the U.S. government to have the same labels in Spain as in the U.S. (the proposal the Project for Corporate Responsibility tried unsuccessfully to have adopted by the five major U.S. exporting pharmaceutical firms) but would want to require including fatal warnings etc. themselves. Parke-Davis has stressed that labels should be different in undeveloped and developing countries than in the United States but we had not thought Spain was in this category with countries like Columbia which Parke-Davis officials cited as an example. However, these Spanish health regulatory officials said that Spain healthwise actually was a developing county and implied it still is to a certain degree today while they are in this process of change. However, they did not go on to say that this justified past labeling of chloramphenicol, rather that it explained the poor labeling in the past in terms of the weakness of the health regulatory agency.