They said the CNDF does require the same warnings and use restrictions on all forms of a medicine marketed by a company when the basic label is changed as in the case with the Parke-Davis Chloromycetin label change this past year although we bought Parke-Davis chloramphenicol products of different forms of presentation while we were in Spain whose labels varied considerably. They explained this as due to old-labeled products still being available which were still within the five-year duration of effectiveness. In otherwords, they do not require the companies to recall their old-labeled madicines. They explained even now they still just do not have the manpower to enforce such a regulation.

The CNDF is also still unable to control advertising and promotional materials of of pharmaceutical companies for the same reason, lack of manpower. They agreed the Parke-Davis promotional materials we showed them were bad, especially the Chlorostrep ad and letter to doctors although I believe they were trying to say Chlorostrep is not nearly as potent as Chloromycetin since only 20% is absorbed . (However, the irreversible fatal aplastic anemia is not dose-related and can be triggered by very small doses as well as large doses.) They said the pharmaceutical companies just put out such promotional materials without CNDF's knowledge and they do not have the manpower to monitor it.

The CNDF officials also said that the Vademecum Daimon, comparable in Spain to our Physicians Desk Reference , widely used by physicians and put out by the pharmaceutical companies, isn't at all like our PDR nor up to it at all. But they said no other country has anything like the quality of the United States PDR and asked so how could Spain be expected to have something comparable? The gross inadequacy in warnings and use instructions of the product information in the Vademecum Daimon has been fully documented by a Spanish doctor.

They flatly stated that they do require all other companies to have the same warnings and use restrictions on all forms of their product as are on the original medicine that was changed, such as Parke-Davis's Chloromycetin. In the past, at least, we are not sure this was so as there is quite a variation in the chloramphenicol labels of other Spanish companies. At least checking our labels, we are sure it was not and is not required verbatim as in the U.S. labels for chloramphenicol products but apparently they do believe in the principle. Whether it is adhered to and they can enforce it is another question which we did not ask.

Dr. Martinez Arroyo and Dr. Ferrandiz were very cordial and friendly, interested in any information we had as well as freely answering our questions even though the manner in which their health regulatory agency in the past handled the labeling of medicines by the pharmaceutical companies could have been embarrassing. They were so happy and hopeful of the change in the fortunes of their agency that they looked confidently toward a better future in this respect in their country. This optimism, though, was not shared by the physicians that we talked to earlier who felt that however good the new men are, that they will not be able to buck the powerful monied interests in the end. They did say, though, that there is some hope if a rumor that they had heard is true; that is, that the larger pharmaceutical companies in Spain were beginning to demand stricter labels (I presume Parke-Davis would be one of them) and that they had hopes this may have a good effect even though they felt the reason for the demand was to drive the smaller competitors out of business.