

its shoulder, and something else throughout Latin America. But we find it a little more difficult to accept when it is obvious that what a company says about its product in Mexico City is not the same as what it says in Guatemala City or in San Jose de Costa Rica, which in turn is different from what it says in Colombia or Ecuador or Rio de Janeiro.

And, finally, there is the statement: "Each of our foreign subsidiaries is managed by a citizen of the country. He knows the laws and regulations, and he abides by them. We are not breaking any laws."

This defense has apparently been impenetrable. The hearings of this committee, Mr. Chairman, were effectively blocked from further investigation on Chloromycetin. One of the reasons is now clear. It is not easy to obtain copies of Latin American drug laws in this country. Fortunately, it became possible for us to work on the spot in a number of Latin American countries to acquire up-to-date copies of the laws, and to analyze them with the aid of Latin American attorneys and drug specialists, both governmental and private.

The legal situation may be summarized as follows:

In a number of countries, when the companies say they are not breaking any laws, they are telling the truth. They are not breaking any laws because there are no laws requiring disclosure of hazards. Each company can follow its own conscience and its own ethical standards, and that is the end of it.

In a few countries, there is a kind of a grey zone; the picture is not so clear. Governmental officials believe they probably have the legal authority to require full disclosure, but the authority has never been spelled out in adequate detail, and the laws have not been enforced.

But in some countries—notably Colombia—there is no lack of clarity. The laws are on the books. They require full disclosure of all hazards to all physicians. And these laws are now being flaunted. If the companies say they are not breaking the laws in Colombia, they are lying.

Let me, if I may, Mr. Chairman, recite a portion of the Colombian laws. In one section, the National Health Code says, "In the labels of the products there must be included the name of the product, the number of the license, the dosage, the manner of use, the contraindications, the name of the producing laboratory and the sales price to the public." And even more potent and completely clear is this regulation passed in 1963:

In the text of propaganda, whatever the medium used, in the literature to the medical profession, in the labels, in the package, and in the literature or package inserts accompanying the drugs, there should always appear the contraindications, secondary effects, and precautions for use.

Senator BEALL. Doctor?

Dr. SILVERMAN. Yes, sir.

Senator BEALL. Now, you are saying in the case of Colombia, the law is on the books and you are saying that the people are breaking the law. Why does not Colombia enforce the law?

Dr. SILVERMAN. That is a matter for the Colombian Government to determine.

Senator BEALL. I know; but what bothers me about our discussion here is what can we do about that? If a country has a law that says that it is illegal to do something, and a U.S. company is making some-