have saved many lives, not only in this country but in the Latin American countries. But their effective use depends on their appropriate use. Although each is demonstrably effective in one or more conditions, each has equally demonstrable hazards. Some of the side effects may be only annoying, like a stuffy nose or a rash, others may be serious or fatal. And it is only with the knowledge of both, the good and the bad, the advantages and the potential hazards, can a physician in any country select the right drug to prescribe for each patient to get the maximum benefit with the least possible risk.

In the United States physicians are given such information—the good and the bad—in the package insert or in what is known as "Physicians' Desk Reference," or PDR, with which I know some of you are quite familiar. The drug company is not obliged to publish in PDR; he may elect to do so in the form of paid advertising. This book, sometimes called the "bible for prescribers," is distributed annually at no cost to every practicing physician of this country.

Although the statements in both the package insert and PDR are prepared and paid for by the drug industry, no firm can make any statement it wants. The claims for efficacy or usefulness are restricted to those for which the company has submitted what is known as convincing scientific evidence to the Food and Drug Administration; and all potential hazards must be fully and openly disclosed. In some cases, the company is required to include a special warning which may read something to the general effect of: "Do not use for trivial conditions."

It is important to emphasize that this information, required by law, is intended only to inform the physician. The physician, if he wants, may use the drug for any indication, approved or not. He may ignore the warnings partially or entirely.

For many years, as you pointed out, it has been known that the situation in other countries is somewhat different. As this committee disclosed at its hearings almost a decade ago, the Parke-Davis brand of chloramphenicol—known as Chloromycetin—carried warnings that were very strict in the United States but far more relaxed in Great Britain. And some of us, I am sure, will recall that when this discrepancy was called to the attention of a company official, he offered the defense that full disclosure of hazards was not required by British law, and, in fact, he went on to say that in his mind, British physicians would be insulted if full disclosure of hazards were included in advertising.

That revelation before this committee was a brief but tremendously important prelude to what we can report today.

In our own studies, we investigated these 26 drugs as they were promoted in the United States, and also in Mexico, the six Central American countries—Guatemala, El Salvador, Honduras, Nicaragua, Costa Rica, and Panama, along with the Dominican Republic—and in Colombia, Ecuador, Brazil, and Argentina.

Mr. GORDON. Dr. Silverman, why did you not also include other countries like Venezuela, Bolivia, Peru, or Chile?

Dr. SILVERMAN. Because, Mr. Gordon, in these other countries, there is no such comparable volume. The drug information is included almost entirely in the form of catalogs, which gives dosage forms,