

concentrations, and price. The countries that we selected are those that have books comparable to PDR.

Essentially, we conducted a comparison of what each company said about its product to physicians in the United States through PDR, and what it said about its identical product to Latin American physicians in somewhat comparable—but not entirely comparable—Latin American reference volumes.

Two points are important here.

In the first place, I personally am in no position either to support or to condemn the policies and the decisions of FDA as these are reflected in PDR. But PDR, I think, may be viewed as a rather useful standard for comparison. It has the virtual blessings of an important governmental agency; it is based in large part on the advice of distinguished governmental and nongovernmental experts; it is widely distributed to physicians, and frequently used by them. And the drug industry in this country, although it may continue to dispute certain FDA decisions, has learned to live with them and to live with them without substantial financial trauma.

In the second place, it must be understood that PDR and the Latin American books are not exactly the same. In PDR, the statements presumably have governmental approval. The promotional statements in the Latin American books, however, do not have approval from any governmental agency; they say what the company wants to say.

Among the books that we have looked at is one known as the "Diccionario de Especialidades Farmaceuticas," which is published in one edition for Mexico—published in Spanish—another edition for Central America, and still a third edition for Ecuador and Colombia. Another, published in Portuguese, is the "Index Terapeutico Moderno," in Brazil, and another which I brought along with me is the Argentine "Therapia Vademecum," which also is somewhat different. In the case of the other Latin American books, the company says what it wants, and this is generally published without any formal or informal governmental approval or blessing.

For the Argentine book, the material is written not by the companies but by the board of editors and, accordingly, the company has no responsibility for what is published. We have included it in our study if only to indicate to our readers what kinds of information are presented to physicians in Argentina.

A second fact came out very quickly.

In the United States, the list of the contraindications, and warnings, and potential adverse reactions is lengthy and detailed. Virtually every unhappy, serious, or possible lethal side effect to which a physician should be alert is included.

But in striking contrast, the potential hazards published in the Latin American volumes are usually minimized or glossed over or totally ignored. In some instances, the company may disclose that the drug may perhaps cause stuffiness of the nose, but neglects to mention that the drug can kill you. In some cases, not a single danger is disclosed.

Let me cite a few examples.