

on which he can base the appropriate prescribing decision. It is whether or not the drug companies tell the truth and all the truth.

Again, the problem is not simply a matter of violating laws in the developing nations, as important as that may be. It is that what should be the objective presentation of knowledge is being twisted by the morals of the marketplace. That is, if it is possible and you can get by with it, it is ethical. The problem is that medical science is being prostituted.

There are, Mr. Chairman, many related aspects on which others far more competent than I may wish to comment.

There are matters of drug prices and the handsome profits that some of these global drug companies have been extracting by means of their promotional practices in Latin America. This may be blood money, indeed.

There are the matters of ethics and morality, and how drug companies view their social responsibilities and to whom they feel responsible, whether it is to their corporate officers, their stockholders, or patients here and abroad.

And there is the matter of telling the truth, all the truth, and of deciding whether the truth depends on international borders, whether what is truth in one country may be untruth in another. For example, I find great difficulty in comprehending how a company can describe one of its products as dangerous in San Diego but safe a few miles across the border in Tiajuana, or how it can promote the product as effective in only 4 conditions in Washington, D.C., in 10 in Mexico, and in 17 in Central America.

There is another aspect that I am sure has not escaped the attention of this committee. Over the years, we have all heard American drug companies individually complain bitterly in public that the present FDA laws are excessively harsh and, in fact, are totally unnecessary. The companies insist they would live up to their moral and social responsibilities, laws or no laws.

The record of their performance in Latin America, where the laws have been safely bent, or broken, or ignored, or where there are no legal restrictions on drug promotion, might, to coin an expression, make a person wonder.

Remaining for consideration is what can be done about this unpleasant affair. As I noted earlier, so far as I can determine, there is nothing that FDA can do under existing law, especially if the product is put into final dosage form and bottled outside of the United States. And even though the Congress is empowered under the Constitution to regulate foreign and domestic commerce, it is my understanding that the Congress cannot enact any laws to regulate this kind of foreign commerce. Instead, it is my belief that there are a number of things that must not be done. There are some that could be done and some that must be done.

Among the steps that must not be taken is to attempt in anyway to act as Big Brother, to try and export the policies and practices of FDA to Latin America, to export our clinical or social standards, or to tell Latin American physicians and pharmacists how they should practice their professions. We must never tell Latin American legislators what drug laws they should enact. Any such efforts on the part of this or any