

is there a reason why some different set of standards should apply where local law does not call for standards like those of the FDA?

Mr. SQUIBB. I do not believe I follow your question.

Senator JAVITS. In other words, if we assume local law permits standards other than those set by the FDA for domestic sales and promotion, do you think that there should be different standards abroad by pharmaceutical companies from those which the FDA requires them to apply here, or should they be the same everywhere?

Mr. SQUIBB. I do not necessarily accept the fact that the FDA standards for all products are the correct ones, but you do not have to accept that for it is not so much a question of legality as a question of the ethical, the proper, true, fair and complete explanation of the use and nature of the product that is under question. Whether it is law or not, in my opinion, makes no difference; the law will require you to do certain things, but your ethical approach should be the same everywhere.

Senator JAVITS. Well, I think that to me is the key.

If there is no reason why uniform standards cannot be applied everywhere, then I see no reason why you should not strive toward that as an objective. If means are not available, let us say there are no doctors in an area—and that is true in much of the world—then you may have to omit some element of the standards; but as far as they can be applied, let us put it that way, you feel that whatever is done here ought to be done everywhere as far as it can be done?

Mr. SQUIBB. If it is the correct and proper way from what we hear then, it is the correct and proper approach to the individual problem.

Senator JAVITS. Well, Mr. Squibb, thank you very much. It seems to me that is the key point that I wish to bring out under questioning.

Mr. Ledogar, did you have a comment you wish to make on this?

Mr. LEDOGAR. If I may, very briefly.

I do not think the issue is really universal standards.

The Business and Industry Advisory Committee which represents U.S. multinational firms raised that issue when commenting on the report of the United Nations group of eminent persons of which you were a member.

The issue is disclosure. Apparently, there is a resistance within industry to even disclose to host governments the FDA requirements with regard to health and safety on drugs.

I do not believe that there can be universal standards because the needs vary greatly from one country to another, but we can at least let everyone know around the world what the FDA requires and that will go a long way toward enabling governments to judge for themselves what the specific dangers of a drug are and to apply that information to the conditions in their country.

Senator JAVITS. Well, Mr. Ledogar, I see nothing inconsistent between what you have said and what Mr. Squibb and I have been saying because the FDA requires the very publicity and information which you have just mentioned. It is an element. I see no difference.

What is the difference?

Mr. LEDOGAR. But the FDA cannot require it overseas.

Senator JAVITS. I understand that but what we are trying to find out is if there is any way we can. That is what we are here for.

Mr. LEDOGAR. Yes, and I believe it should be done.