Senator JAVITS. In other words, are you against our applying of FDA standards to the extent possible overseas as well as domestically?

Mr. LEDOGAR. Yes, I think in some cases it can be an interference in the internal affairs of another government.

Senator JAVITS. And that is your reason for being against?

Mr. LEDOGAR. Also because standards cannot be the same all around the world.

Senator JAVITS. No one said they are to be the same.

All we said is insofar as it is possible, but you do not accept that? You say we would be interfering in the internal affairs of another government?

Mr. LEDOGAR. I do not believe we can unilaterally impose them.

Senator JAVITS. No one is trying to impose them, sir.

All we are saying is if we can find a way to do it that we should make FDA standards universal insofar as they can be applied in each given country.

Mr. LEDOGAR. I am simply saying a first step is disclosure.

Senator JAVITS. All right, Mr. Ledogar, thank you.

Do you have questions, Mr. Gordon?

Mr. GORDON. Mr. Squibb, on the top of page 6, you stated that: "Government regulatory bodies tend toward policies which take absolute safety and so on and so forth, and then you say while the independent scientists tend to evaluate a drug on a risk-benefit basis."

Is that not what the FDA uses as a basis for approving or rejecting a drug?

Mr. SQUIBB. I would think, for example, of the Delaney amendment.

Mr. GORDON. That does not deal with drugs. That deals with food additives.

Mr. SQUIBB. But I say Government regulatory bodies tend to look toward absolute safety, and they have to because of the publicity attendant to any accident or any fatal or harmful results of the drug.

I think that is a well-established fact and it is inevitable that they do so.

We heard some testimony yesterday from Dr. Lee that the individual physician can determine whether the illness or the condition for which he is using the drug is such as to warrant risking the chance of serious side effects from the drug.

There is no question about that possibility, whereas the regulation may say specifically it cannot be used for that indication for the reason there are a lot of serious side effects.

The risk factor that an individual physician can determine is often a major consideration as to whether that drug is properly used.

Mr. GORDON. In your prepared statement you also say: "There is the basic doubt as to a universal and automatic competence of FDA or any other governmental agency in all matters it touches."

I merely want to emphasize that at least the FDA does not have a financial interest in getting a drug on the market, whereas a company generally does.

Mr. SQUIBB. That is right. This is again the problem I point out, the difficulty and conflict between commercialism and medicine.

It is a very difficult problem, and of course, all these companies that make these remarkable drugs are commercial operations which require a profit for their stockholders on the one hand, then on the other