physician determining the applicability of the particular drug to a particular case.

Second, there is the basic doubt as to a universal and automatic competence of the FDA or any other governmental agency in all matters it touches. Rigid acceptance of FDA controls, with appeal or review difficult and very expensive, makes for an unsatisfactory system. Political pressures are significant in drug control regulation when they should not be, and there is sometimes too much shortsighted action taken just to get rid of an immediate problem. This results in an ever-increasing body of industry rules which tend to develop into a rigid formula for establishing black and white, without any regard for the vast grey area which exists in medical procedures.

It would seem that one of the best ways that is now available to evaluate a new product, or a new use of an old one, is to try it in a market where there is some latitude permitted in promotion efforts. This is not to justify in any way exploitation of a product for indications known to be wrong, or without warning of possible side effects that have been established by previous use elsewhere. Full disclosure is always essential. Absence of conscious deception is always essential. Acknowledgment of different opinion is always essential. After that, if there is still room for use of the product with advantage to the patient, it is clear there should be opportunity to do so.

Mr. GORDON. In your prepared statement you said: " * * * that one of the best ways that is now available to evaluate a new product, or a new use of an old one, is to try it in a market with some latitude permitted in the promotional efforts." You are not implying this takes place, are you?

Mr. SQUIBB. Certainly not.

Mr. GORDON. You agree that opinions are not sufficient, but we need "adequate and well-controlled studies."

Mr. SQUIBB. I mean sound medical opinions.

Mr. GORDON. Resulting from adequate and well-controlled studies.

Mr. SQUIBB. Resulting from medical studies. It could be all types of studies, or course, made in different geographic situations and for different conditions of living in different parts of the world.

For honest men of good will, the problem is exquisitely difficult. Such scientists do not accept the automatic infallibility of Government regulators, nor do they accept the limitations placed by arbitrary controls on their own conclusions.

Dishonest men who deliberately exploit ignorance to their own advantage by offering hope of cure without concern for anything except the monetary return to themselves are the object of our efforts here today. Just where and how to separate the two groups should be easy, but in fact gets more and more difficult as medicine increases in its potency and complexity.

As far as the established companies of the American pharmaceutical industry are concerned, and it seems that all too often they are the ones that are concerned with the problem under discussion here, the solution ought to be found right in their own internal operations.

The industry constantly claims for itself high standards of ethics and close attention to its admitted unique high degree of social responsibility, yet all too often it seems to fail in this regard in promotional matters. It would seem that as a matter of policy, if the question