to the side effects, toxic or otherwise, of the dosage recommended. Nowhere is there any voice of industry who would argue for such courses of action, and yet here are examples of just such things happening. How can this be?

In the record of hearings of this committee are two significant explanations offered as to just how these promotional differences between countries are explained or rationalized. One approach is the one set forth by the president of a major pharmaceutical house that whatever standards, indications, or claims for a drug are approved by the in-house scientific staff of his organization as to the "medical positioning" of a product, that is their standard of guidance, everywhere in the world. He stated further and specifically that they would not use the standard of what is approved by FDA for that drug in this country if there should be any difference. The more you think about this approach the more puzzling the ethical implications become. It takes quite a bit of self-confidence, and perhaps even arrogance, to be able to ignore completely any findings by the FDA contrary to your own.

While the track record of the FDA includes some questionable judgments in the past that have not held up to the test of time, certainly the vast body of its findings and its regulations are sound, and probably are the production of the most advanced system of drug review operating in the world today. However, if such a policy were actually used, there would be no variation in promotion among different countries except where regulation required some limitation. It would appear from testimony given here that is practically never the case, and variation exists in the promotional claims for the same product among countries which have virtually no regulations at all. Therefore, it is doubtful even a pharmaceutical house with an internal business-research relationship of extraordinary balance and understanding can or does follow any such policy to the letter today.

The second approach is described by a former medical director of a large pharmaceutical house which maintained two different medical staffs, one apparently with a less rigid approach to promotional procedures which could be used overseas. Somehow, I feel this latter approach, or variations of it is the more common, and probably the more easily rationalized of the two.

It must be recognized that there is such a thing as honest difference of informed medical opinion on the evaluation of individual drugs. It seems that there is always available some medical specialist or some source of information to contradict opinions expressed by others. It has been said time and time again that medicine is not an exact science, and certainly drug utilization appears to be one of its more inexact areas. But for the purposes of public health today, a judgment has to be made and a line drawn somewhere. It is suggested that a little line drawing is now indicated.

There are at least two complicating factors which get in the way of a quick and easy solution to this problem. First, is the obviously different opinions that scientists of good reputations and sincerity have about not only the physical qualities of drugs, but also about the whole philosophy of risk versus anticipated therapeutic benefit.

Government regulatory bodies tend toward policies which take absolute safety as the dominant note, while independent scientists tend to evaluate a drug more on a risk-versus-results basis with the individual