

Senator NELSON. Is it marketed in this country?

Dr. KUNIN. It is not marketed in this country.

Senator NELSON. Is there any difference—if there is a synergistic effect—by combining two drugs, is this any difference from the synergistic effect that is achieved in a fixed combination versus individual administration of the drug at—

Dr. KUNIN. Theoretically you can give the two drugs separately. But the whole advantage of the combination is that they really do work together. It is nice to get the two drugs in at the same time, the one capsule. If the manufacturers can show evidence that this particular combination has great efficacy, then I believe we should accept it. But we should examine the data. Yes, it would be much more convenient to have them together.

Senator NELSON. But would you get a better effect.

Dr. KUNIN. Yes; you can get a better effect, you can be more sure that the patient took the two drugs at the same time in the appropriate way. One of the major problems that a physician always has in prescribing drugs is: Will the patient have the prescription filled and will he take his medicine properly? These are just small areas. I am just leaving a crack of the door open so that we can have an open mind, and so that we don't, you might say, unnecessarily punish the pharmaceutical industry for past sins.

They may be able to offer us some fixed combinations that are good.

Senator NELSON. What you are really saying is what the law states—if the FDA is presented adequate clinical and testing proof that the drug is safe and efficacious, then it ought to be approved like any other drug?

Dr. KUNIN. Of course. And also I would say that if the manufacturers of the combinations that we condemn can provide new information that is properly conducted by good clinical investigators and good clinical pharmacologists that indicates that any of the combinations that we condemn currently are actually effective in the sense we are talking about, then I believe we should review the material and be judicious about this. I doubt, however, whether they will be able to do this. They have had plenty of time to do this, these combinations have been around a long time, and there has been ample opportunity to investigate these possibilities. But I believe the door always should be open for a hearing of well-conducted scientific study of efficacy.

Senator NELSON. The law was passed in 1962, so we are going on 6 or 7 years in which there has been opportunity for any company to prove efficacy of a drug that was in the marketplace at the time the law was passed.

Dr. KUNIN. Theoretically, in 1957, when Dr. Finland prepared his editorial the pharmaceutical industry could easily have responded at that time—that is 12 years ago—in relation to his condemnation of this combination. He didn't invent this in 1957, this was known in early 1950. There has been ample opportunity to do clinical studies and to support these claims.

They have not been forthcoming. I doubt that, in many instances, will evidence be brought to bear that they are effective as a fixed combination.

Not all fixed combinations are necessarily bad medicine, is what I want to say here. I want to leave that door open. But the claims must