in the book when it is published, I do not know. If Panalba were withdrawn from the market, obviously, we will not have any hesitancy about Panalba. But as it stands now, in our draft of this book on effective drugs, we do not recommend the drug. We give no dosage information at all. So we have evaluated and, in that instance, our evaluation in a sense affirms that of the Food and Drug efficacy study.

Senator NELSON. I do not want to push the point. I just say that you, in accepting advertising, obviously were not complying with what you state in your principles governing the acceptance of advertising—the type of data needed. Data should include pertinent reports, published and unpublished, favorable and unfavorable, covering relative efficacy, et cetera.

Mr. HARRISON. Senator, all that was required. There is no basis for the statement that we were not complying. We were complying with this. We did receive the information, in many cases the same information which the FDA received which had the authority, which acted upon it. What Dr. Hayes is saying is that we made no independent evaluation of scientific study at the time on these particular combinations. This was done just the other month, in May, for the first time. So that our own evaluation did not rely upon the Council on Drugs for information.

Senator NELSON. You are saying that in the past, in compliance with these principles, you have required submission of this kind of data?

Mr. HARRISON. That is right, Senator.

Senator NELSON. Would you please submit for the record some examples of controlled scientific studies you received from Upjohn to prove the safety and efficacy of Panalba?

Mr. HARRISON. We did not get into Panalba, Senator, simply because this matter is before the courts at this time. Should you require some other source of that information, we may do so, but Senator, we will not discuss that at this time, because it is before the court.

Senator NELSON. Everybody else is discussing it. I do not know why you can't, but that is all right. I will take a letter showing some of the fixed combinations recommended for removal from the marketplace by the National Academy of Sciences-National Research Council and their reasons for removal, failure to submit well controlled studies of efficacy, and then would you send to us the well controlled studies to prove efficacy that the journal used in deciding that they would run these ads?

(Such studies were not supplied by the AMA.)

Mr. HARRISON. Senator, we will send you whatever we possibly can. Keep in mind, if you will, that these drugs were on the market and that the Food and Drug Administration required specific information. We have indicated by statement our requirement with respect to those drugs prior to 1962 and what has developed since 1962. Whatever information we required, what indication in our files at this time with respect to those drugs, we will be happy to provide you with.

(No further information was supplied by the AMA.)

Senator NELSON. I didn't address myself to what the FDA required. I was simply taking your own principles which state that you have to have well controlled studies and high quality evidence to support the claims for any fixed combination.