

I will provide the committee with a copy of these principles. I think this describes both the intent and the content of the change.

Senator NELSON. Do I understand that—

Mr. HARRISON. Dr. Hayes will continue, if you like, with respect to the information about the Council on Drugs.

Senator NELSON. I would like to have him address himself to the Panalba case.

Mr. HARRISON. As you know, that is before the courts right now. There has been a temporary injunction issued and an injunction sought, I believe, and granted with respect to that particular drug. The ads do not run at the present time in the Journal. This was a drug that was approved by the FDA prior to that time. It was when new information came to the attention of the Food and Drug Administration that it determined the drug should be withdrawn or the advertising should be withdrawn or changed. I am not quite sure as to the facts involved here. But in any event, since that did arise, the Journal no longer publishes the advertising of this particular drug. Keep in mind, if you will, that prior to that time, it was an approved drug, approved by the Food and Drug Administration.

Senator NELSON. Just for clarification, then, JAMA did run ads on Panalba, full page, back cover, after the National Academy of Sciences-National Research Council recommended or found the drug ineffective as a fixed combination.

Mr. HARRISON. As to the question of whether it is ineffective or not, there may be some question on that. That is also before the court at the present time. The point I am trying to make, the only point, is that this was an approved drug by the Federal agency which had the authority to approve drugs. Subsequently, this agency determined that there was some element involved in its advertising or in its effectiveness that perhaps should be challenged. Since that time, JAMA has not run the ads. If I am mistaken, it may be only by a matter of a couple of days, which accounts only for the transitional time.

Senator NELSON. I have not seen any recently, but after the finding of the National Academy of Sciences-National Research Council, I saw two Panalba ads.

Let's get at this question: the AMA's own council on drugs has taken a position against fixed combinations. Dr. Adriani appeared before this committee and stated the council supported the finding of the National Academy of Sciences. How do you explain accepting ads for drug combinations in the Journal when your own council on drugs opposes them and when your principles on advertising say that you will not accept an ad unless efficacy and safety is proved, and they have never submitted anything that proved efficacy or safety of Panalba?

Dr. HAYES. First of all, let me address myself to the statement Dr. Adriani made in his testimony, the statement that you allude to that the council endorsed the report of the drug efficacy of the NAS-NRC. They did not unanimously endorse the reports of the drug efficacy study.

Senator NELSON. Did they on the fixed combination antibiotics?

Dr. HAYES. They did make a statement on the fixed dosage combinations of antibiotics, but it was not an endorsement of the drug