Dr. HAYES. They disagree in part with the judgment of the panel with regard to the combination of tetracycline and amphoteracin B, which is marketed under the trade name of Mysteclin F. That involves a technicality because of the fact that the amphoteracin B is not available as an oral dosage form by itself.

Senator NELSON. So what you are saying is that they disagreed with one of the five panels what was something of a technicality. Is there any other they disagreed with them on?

Dr. HAYES. Not to my recollection at the present time. But we have not finished our entire evaluation of all of the fixed dosage combination antibiotics that the FDA has acted on. But in general, we would agree with their judgment.

As a matter of policy, the AMA periodically will review its advertising principles with a view of keeping pace with changes that may occur in the industry and in the profession. It is hoped by this practice of continuous review and reevaluation to insure and improve the timeliness, relevancy and appropriateness of the advertising concept of AMA scientific publications.

Senator NELSON. I guess we might differ over what's an endorsement. I guess we should take a look at Dr. Adriani's testimony, but I thought he was pretty clear on the panels. But you state there is one, Mysteclin F, that is disagreed with on a technicality.

This returns us to the question that for years it has been the policy of the Council on Drugs to oppose fixed combinations and the principles require proof of efficacy. How do you explain the widespread advertising of these fixed combination anti-infectives in the JAMA?

Dr. HAYES. Well, let me go back into the history of it just a little bit. As you know, we are hard at work on a book of drug information which relates to descriptive information on all drugs commonly used by physicians. This is the first time that the Council has ever taken under consideration the evaluation of fixed dosage combinations of all drugs, including anti-infective agents. They have never, in the past 64 years, up until the last couple of years ever evaluated fixed dosage combinations of drugs except in a couple of very special instances. The oral contraceptive was the principal one.

Senator NELSON. You would agree, then, that that principle which says they must submit evidence of efficacy is a principle that has not been followed, because you have been unable to follow it, I assume.

Dr. HAYES. Yes; they could not follow the matter of efficacy because the Council did not evaluate mixtures. They had to rely on other sources of information, other evaluations.

Senator NELSON. So that statement in the principle really does not mean anything.

Dr. HAYES. What statement is that?

Senator NELSON. The statement that new drugs in combination have to prove the efficacy. You say you have never had any mention of giving any proof of efficacy. I would think you could require the company to produce it. That is what happened to Upjohn on Panalba. The National Academy of Science asked for scientifically controlled studies to prove the efficacy of the drug and Upjohn couldn't produce any. It would seem to me that if you were going to apply a principle, if that principle means anything, you would say to the advertiser, submit to us your scientifically controlled studies that prove efficacy.