Dr. HAYES. Well, the people who evaluate the advertisements could not draw upon the experience of the Council on Drugs of the AMA. They had to rely on other sources of information. The drug, Panalba, for example, was certified by the Food and Drug Administration as being safe and effective. As I understand——

Senator NELSON. Never as effective.

Dr. HAYES. Yes. As I understand it, because the antibiotic regulations of the Food, Drug, and Cosmetic Act require a certification for safety and efficacy. That antedated the 1962 amendments, as I understand it.

Senator NELSON. I guess I am using the word "efficacy" under the 1962 amendment, which is different apparently from what was meant previously in the use of the word "efficacy."

Dr. HAYES. So far as I understand it, Panalba was batch-certified by the FDA as being a safe and effective drug for many years, until it was reevaluated by the Drug Efficacy Group.

Senator NELSON. Until the 1962 act, the FDA did not have authority to require proof of efficacy. All they had to have was the requirement of safety. Then the 1962 act set up standards to substantiate efficacy. The conditions for certification were quite different from the requirements of efficacy and the intent of Congress as set forth in the 1962 Kefauver amendment to the Food and Drug Act.

Dr. HAYES. But the antibiotic regulations are different. Those are batch-certified, as I understand it. They have to be certified as being safe and effective.

Senator NELSON. Counsel tells me that the use of the word "efficacy" then was being used as potency, not in the sense that the fixed combination is synergistic or the fixed combination is more effective than either one of the ingredients used individually. The standards for tests showing efficacy were not applied to older products.

Dr. HAYES. The point I am making, Senator, is simply that the Council on Drugs had never evaluated fixed dosage combinations of any drugs—there were very few exceptions—and that the people who evaluated the advertisements had to rely on other sources of information, one of which, obviously, was the fact that Food and Drug Administration was constantly certifying this drug as being safe and whatever implication or interpretation you make of the term "effective."

Senator NELSON. Well, I simply go back to your own advertising principles which say that "The Office of Advertising Evaluation requires that scientific data be submitted to substantiate claims made for products." What did Upjohn submit to substantiate its claims for Panalba?

Dr. HAYES. That, I do not know. I might say that now we are evaluating fixed dose combinations of all drugs, we have asked the company for information. They have supplied us with information.

Senator NELSON. Testimonials or well-controlled studies?

Dr. HAYES. They supplied it with information and, let me continue, we evaluated the information that they sent us. I do not know what will happen to Panalba, but we made our evaluation of Panalba some months before the drug efficacy study reports came out and were made available to us. We made a recommendation that we would not recommend the use of this drug. That was our judgment. What will happen