

efficacy study. I have the statement here and I will be glad to read it for you.

Senator NELSON. Just so I am clear in my mind, I did not intend to say they endorsed everything. I don't know that. It was my understanding from Dr. Adriani's testimony that the council on drugs, whatever it did, approved or supported recommendations of the five panels on fixed combination antibiotics. Am I correct on that?

Dr. HAYES. You are incorrect on it. They did not endorse, they did not take a position of endorsement. They did make a statement.

Senator NELSON. What did they say?

Dr. HAYES. I will be glad to read it for you. This was at their meeting in May of 1969. I believe it was the 19th and 20th of the month. On the 22d, I transmitted to the board of trustees this statement. As you know, I am the director of the department and the secretary.

Senator NELSON. I understand.

Dr. HAYES. Since I have two heads and one body—fortunately, we talk to each other most of the time—but there are instances when we do not.

In response to the current controversy concerning drug products containing fixed dose combinations of antibacterial agents, the council on drugs at its 1969 spring meeting, took the following action: Fixed combinations of antibiotics. For many years, the council on drugs has held the position that fixed dose combinations of drugs are almost invariably irrational. Recently, the FDA has published in the Federal Register statements declaring that such combinations of anti-infective drugs in fixed doses are "ineffective" as such. Although it is true that a fixed dose combination, for example, tetracycline, 250 milligrams, and novobiocin, 125 milligrams, would be effective against infection susceptible of treatment with tetracycline, the combination is irrational. The council on drugs notes that there are occasions when more than one anti-infective drug is needed in the treatment of disease. However, the amount of each drug must be tailored to the immediate purpose. Fixed dose combinations are not suitable.

That is the end of the statement. My comment is that the council, therefore, voted to authorize a council statement to this effect. It was transmitted to the board and then published in the American Medical News.

Senator NELSON. Was it unanimous?

Dr. HAYES. This was unanimous.

Senator NELSON. Maybe it is semantics that bother us, but I would call that a strong endorsement, or a flat endorsement of the finding of the five panels on fixed combination antibiotics, wouldn't you? They said they were irrational.

Dr. HAYES. No, I would not, because there are some of the judgments that have been made in which the council does not consider the fixed combination to be irrational.

Senator NELSON. In the antibiotics?

Dr. HAYES. The combination of the anti-infective drugs. The combination of the antibiotics and the antifungicides.

Senator NELSON. Which ones? I did not find that in the statement. In listening to that statement, I would assume that the ordinary layman would consider it an endorsement of the findings of the panels on fixed combination antibiotics. On what drug did the council disagree with the NAS-NRC panel?