Then under submission of data, procedures of the AMA Office of Advertising Evaluation:

Submission of data. The Office of Advertising Evaluation requires that scientific data be submitted to substantiate claims made for new products such as drugs, devices, and foods, or new claims for products which appeared previously in the AMA scientific journal; data should include pertinent reports—published and unpublished, favorable and unfavorable—of clinical and laboratory investigation covering the efficacy and relative safety of the product under consideration. These data should be based upon sound studies and should be sufficiently comprehensive to permit a critical evaluation of the subject matter.

The quality of evidence is regarded as highly important. In this respect, the importance of suitable controls is emphasized. Compilations of subjective individual case reports and testimonials are not considered acceptable evidence.

Now, the Council on Drugs of the AMA has regularly taken the position that they were opposed to fixed combinations and they endorsed unanimously the report of the National Academy of Sciences, National Research Council, on fixed combination antibiotics. In 1957, a signed editorial appeared in the JAMA signed by—one of them was Dr. Dowling, who was, at that time, I believe, chairman of the AMA's Council on Drugs, and a number of others, taking a very, very strong position against fixed combinations.

Now, Panalba has been recommended for removal from the marketplace. The AMA News ran an editorial attacking the FDA for that recommendation. My question is, in compliance with your principles, what proof of efficacy did you have that fixed combination Panalba was efficacious and safe?

Mr. HARRISON. Senator, we have Dr. Tom Hayes, who is, as you know, director of the Council on Drugs and secretary of the Council on Drugs. He will respond directly to that part of your question which deals with the statements by the Council on Drugs of a fixed combination.

I think first I should indicate to you that the principles or guidelines from which you are reading, those have been changed not too long ago—modified, I should say, not too long ago.

Senator NELSON. Since Dr. Annis' testimony on March 18th?

Mr. HARRISON. Since Dr. Annis' testimony.

Senator NELSON. I have not seen the new modification.

Mr. HARRISON. I will be happy to supply you with a copy.

Senator NELSON. If you would.

(Subsequent information follows:)

U.S. SENATE,
SELECT COMMITTEE ON SMALL BUSINESS,
Washington, D.C., October 13, 1969.

DR. ERNEST B. HOWARD,
Executive Vice President, American Medical Association,
Chicago, Ill.

DEAR DR. HOWARD: Enclosed is an unedited transcript of the AMA's testimony before the Senate Small Business Committee's Monopoly Subcommittee on August 7, 1969.

On pages 6851, 6863, 6864, and 6865 references are made to material which your organization is to supply for the printed record, but which has not yet been received.

It would be greatly appreciated if you would send me as soon as possible the material referred to on the above pages.

Sincerely yours,

GAYLORD NELSON,
Chairman, Monopoly Subcommittee.

Enclosure. [Omitted.]