

terms of the background information and reasoning that we think the physician should have to help him provide the best possible patient care.

One of the releases, issued last April, concerned our intention to start action to end the marketing of 78 combination antibiotic drugs found by the National Academy of Sciences to be ineffective as fixed combinations. Attached to the release was a list of the drugs involved, and their manufacturers.

The American Medical News summarized the release and did not print the list of drugs. The Journal of American Medical Association contained no mention of the FDA proposal, although I had suggested in a letter to AMA representatives that the Academy comments on the 78 combination antibiotics be publicized.

Early in May 1969, I went to AMA headquarters in Chicago to talk personally with a top AMA official about improving communications between the FDA and physicians. The official agreed on the need to promote the flow of accurate drug information to doctors and on the desirability of using AMA publications to help achieve this purpose. Since that time, however, I have noticed no change in coverage of our drug actions by the Journal of American Medicine and the American Medical News.

In all fairness, I must say that there have been occasions when the AMA through its publications has cooperated fully in presenting fair and adequate coverage of drug issues. On April 1, for instance, I called the Director of the AMA's Division of Scientific Activities to acknowledge with thanks the coverage given Chloramphenicol toxicity in the March 1 issue of AMA News.

Generally speaking, however, I feel the space devoted by AMA publications to important drug issues, particularly that of the NAS/NRC evaluation of the combination antibiotics, has been scanty and not at all commensurate with the public and medical interest in them.

With respect to Panalba, I responded in a detailed letter of July 3, 1969, to a request by Dr. Ernest B. Howard, Executive Vice President of the AMA, for evidence we considered in deciding to withdraw the product from the market.

In a note attached to the letter, I told Dr. Howard that I had no objection to his publicizing my reply in an AMA publication but, indeed, that I would welcome it. To date, as far as I know, this letter has not been published.

As I stated in my July 13 speech before the American College of Legal Medicine, we will continue our efforts to persuade the AMA leadership that the interests of the medical profession are intimately involved with a wider and more balanced coverage of important drug questions in AMA publications.

I should add that in addition to the AMA publications, we have provided the editorial staff of 12 other medical specialty publications with the same material provided to the AMA. One of these, *THE BULLETIN OF THE AMERICAN COLLEGE OF PHYSICIANS*, 10:5 (May 1969) (226-30), did provide detailed coverage of antibiotic acitons which were so briefly summarized by American Medical News.

I hope the above provides an answer of sufficient detail to your request. We will be pleased to provide additional information if desired.

Sincerely,

HERBERT L. LEY, Jr., M.D.
Commissioner of Food and Drugs.

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE,
Washington, D.C., July 3, 1969.

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

DEAR DR. HOWARD: Thank you for your letter of June 6, 1969, in which you request any evidence which was considered by the Food and Drug Administration in reaching the conclusions concerning Novobiocin-Tetracycline Combination Drugs; Calcium Novobiocin-Sulfamethizole Tablets, which were published in the Federal Register of May 15, 1969.

The National Academy of Sciences/National Research Council, Drug Efficacy Study Group, recommended to this Administration, after reviewing all data the manufacturer submitted to the Group to support its claims of efficacy for the products, that tetracycline-novobiocin and sulfamethizole-novobiocin were ineffective as fixed combinations. Copies of the Panels' reports on these products are attached for your information.