

3. A large number of papers purporting to demonstrate clinical efficacy of this combination were reviewed. No properly controlled studies were located and most consisted of reports of a few patients treated with variable results. It is the considered judgment of the panel that this combination has no place in rational therapeutics and should not be marketed.

In light of the National Academy's report that not a single properly controlled study could be found to show that Panalba was clinically effective, it is very strange that this drug is one of the 200 most frequently prescribed drugs in this country. This raises the serious question: On what basis have physicians been prescribing this drug?

The general counsel of the American Medical Association, Mr. Bernard Hirsh, testified before the House Ways and Means Committee on February 26, 1969 that (p. 1535):

A tax-exempt organization by its very nature is dedicated and should be dedicated to performing things that are in the public interest.

Perhaps his organization can tell us how advertising drug combinations benefits the public?

Mr. Hirsh also stated (p. 1400) that—

... drug advertisements often provide an important step in the process through which the physician becomes educated in the therapeutic value and risks of new drugs ...

Do the medical journals seriously consider the considerable advertising of Panalba and other combinations as educational?

Dr. Ernest B. Howard, who is now executive vice president of the AMA, told the Kefauver committee in 1961 (p. 119, part I, Drug Industry Antitrust Act) that at the insistence of the AMA's Council on Drugs, the "board of trustees has reached a decision that the mixtures to which the Council on Drugs has referred during the last 5 years will be gradually withdrawn from the Journal, during the next 2 or 3 years."

He said this 8 years ago. This has not been done.

Could the reason be that advertising these drugs provides an important source of revenue? If so, is this a proper consideration for a professional medical society?

These are some of the questions to be explored in depth during the subcommittee's hearings this month. The issues involved are of grave importance to the health and welfare of the American people. It is our hope that the study we are making will shed some light on these perplexing problems so that we may find the means for correcting them.

Before we proceed, I would just like to mention that in an article in the Wall Street Journal<sup>1</sup> this morning, the writer, Mr. Spivak, commented in a rather lengthy column on the fixed combinations, and in the column he stated that:

Democratic Senator Gaylord Nelson of Wisconsin, who has been holding months of hearings hostile to the industry, is seizing on the FDA action in an effort to embarrass the drug makers further. His Small Business Subcommittee will air criticisms of the antibiotic combinations in a new set of hearings starting today.

<sup>1</sup> See Appendix II, pp. 5253, *infra*.