

Committee on Protocols for Safety Evaluations, Bureau of Science, 1968- ;
Food and Drug Administration—Chairman, Anti-Infective Agents Advisory Committee, Bureau of Medicine, 1969—

Editorial Boards : The Journal of Infectious Disease, Hospital Practice.

Senator NELSON. You made reference in the beginning, and you specifically state on page 3, that—

We felt that the issues involved were so important that white papers were prepared to present our thoughts in some detail. We also felt that it would be most important for practicing physicians to be aware of our arguments, since the judgment recently taken by the FDA to remove them from the market would affect their practice. To this end the paper was prepared for publication in the New England Journal of Medicine which will appear in the May 22, 1969, issue.

I take it that the objective is to advise the medical community. Why wasn't the paper published by the American Medical Association?

Dr. KUNIN. It was submitted by the National Academy of Science, not by myself personally, but by the executive officer of the National Academy of Science to the Journal of the American Medical Association. It was not accepted by that journal. I informed Dr. Inglefinger, the editor of the New England Journal of Medicine, of this rejection, and he accepted it for publication. In his letter he said :

As much as I regret taking a paper that has been rejected by the JAMA, I am delighted to take this one for the New England Journal.

Senator NELSON. Was any reason given for rejecting it at that time?

Dr. KUNIN. No reason was given for the rejection.

Senator NELSON. I don't expect you to speculate on the reasons for their rejection of the paper. But I think we should call attention in the record to the fact that the Council on Drugs of the AMA has taken the position for years in opposition to fixed combinations, that in the principles of advertising of the American Medical Journal—and I put that in the record yesterday, so I will just paraphrase it at the moment—in their principles of advertising they emphasize that those who wish to advertise must establish standards and they emphasize how important good standards are. And among them they say that there must be proof of efficacy of the drug.

Then we note—which is a serious question I have raised with all the representatives of the various journals here—that they accept advertising which makes claims in the ads that they would find unacceptable in any scientific paper that they print in the text of the magazine, and that in two recent issues the full back page of JAMA was a paneled ad for Panalba. The paper that was submitted to JAMA was a paper by a distinguished scientific panel that rejects Panalba on the ground that it does not meet the statutory requirement of efficacy. And it seems to me, to be perfectly honest and blunt about it, that it throws some kind of cloud over the question of the objectivity of JAMA itself.

I noticed that as far back as 1961 before the Kefauver committee in the hearings on S. 1552, part one, on page 69, that Dr. Hussey, who was then chairman of the board of trustees of the AMA, in answer to a question by Senator Kefauver, said :

I am proposing essentially that this is mainly a job of education, and that this resolves itself into a problem of communication. The physician who has available to him on the market a drug which in extended usage turns out to be inefficacious, although originally thought to be effective, or which turns out to be dangerous, although originally thought to be safe, the physician must learn