ize the U.S. Food and Drug Administration to determine the effectiveness of drugs." Anti-science is still with us.

Another major confrontation came in 1963 when the FDA, following the recommendations of a panel nominated by the prestigious National Academy of Sciences proposed banning the sale of antibiotics in combination with cold preparations intended for symptomatic relief. The response of the drug industry, the PMA, the APA, and individual physicians constitutes one of the most shocking episodes in the history of American medicine. Although it is documented in the record of the "Humphrey Hearings" (pp. 1502–1530) and has been described by Morton Mintz in *By Prescription Only*, it has received little attention in the medical community.

I had intended simply to mention this episode and give the references. During the preparation of this statement, however, it became clear that we were heading into another major confrontation between the FDA and the drug industry, which is almost exactly the same as the confrontation that took place in 1963. In the hope that it might help to prevent a repetition of the 1963 episode, it seems worthwhile to give some account of the genesis, the life and the death of the proposed ban.

Sometime in 1962 became concerned about the inclusion of antibiotics in mixed cold preparations intended for symptomatic relief and in throat lozenges and troches. Concern about these products had been expressed in the medical literature since 1953. The FDA finally decided that these uses of antibiotics were irrational and should be studied. It requested nominations for a panel of experts from the NAS and selected from the nominations a panel chaired by Dr. Harry Dowling, an internationally recognized expert on infectious diseases and antibiotics.

The report and recommendations of the panel led Dr. Ralph Smith of the FDA to write to his superior recommending (as the law requires) publication in the *Federal Register* of a proposal to remove antibiotic containing cold preparations from the market. In his letter, Dr. Smith said, "the proposal is likely to be met by substantial industry opposition." This will probably stand as one of the greatest understatements of all time.

I doubt that more than a handful of practicing physicians read the *Federal Register* and so the information reached physicians through other channels. These were accounts in the media controlled by the AMA, in throw-away journals that subsist on drug advertising, and in letters mailed to physicians by a large drug company.

I have a clipping from the *J.A.M.A.* of November 23, 1963 which is typical of accounts that help to mold the opinions of the medical profession. It is too long to read it in its entirety, but I request that it be made part of the record. In it both the PMA and the AMA take turns labeling the proposed ban "unauthorized interference with the practice of medicine . . . government fiat . . . governmental dictation . . . regulatory fiat . . . (and) coercion."

To expect the average physician to consider any issue dispassionately when presented in such inflammatory language is equivalent to expecting a bull to become reasonable by waving a red flag at him.

The response of physicians was hardly surprising. One account (*The Pink Sheet* September 16, 1963) stated that "over 100 letters of protest" were received by the FDA. Another account (John Troan, *Washington Daily News*, November 12, 1963) stated "about 1,000 physicians have filed protests with the FDA." This larger figure may reflect the difference that appeared in the month that separated the two reports. It appears that only one physician, Dr. Joseph K. Ackerman, wrote to the FDA approving its proposed action. His letter appears in the record of the "Humphrey Hearings", (p. 1523) and I quote part of it: "The opinion of a minority of experts is of much greater value than the opinion of a majority of practitioners who have had an irregular and inadequate exposure to competent and objective pharmaceutical literature. Whether their opinion has the political leverage is another thing again."

There was one other letter that supported the FDA position but it was sent to *Medical World News* rather than the FDA. I wrote the letter in response to a news article entitled "Curb on Cold Remedies Faces Fight" which appeared in the September 13, 1963 issue of that journal. The letter appears in the record of the "Humphrey Hearings", (p. 1523) and I quote it in part from that source. "If the drug industry is successful in urging medical leaders to lodge a formal protest against the proposed ban on antibiotic mixtures . . . the caduceous should be at half mast . . . If 'thousands of physicians' have found these mixtures useful, it should be easy to collect conclusive data demonstrating that