"This concept was not unlike a suggestion that I made some years ago," Dr. Gilman said, "in which I urged prospective surveillance by outside experts so that an NDA could be corrected during the course of investigation."

Dr. Gilman voiced the hope that "by the time the new NDA procedures get rolling, much of the criticism by the academic community and by the drug industry will have been answered."

[Editorials from the Medical Tribune, April 19, 1972]

FOR MORE OUTSIDE CONSULTANTS . . .

The present FDA has been more vigorous, more hard-nosed, denied more New Drug Applications. and removed more medicinals from the market than any of its predecessors. The one man whom the drug executives have singled out, more than any other, as zealous to the point of therapeutic nihilism is the very director now attacked by consumerists on the use of outside consultants and also accused of having "arbitrarily reassigned important officers to modify the drug industry" (*New York Times*, April 3). To observe a consumer group attacking the Director of the Bureau of Drugs of the FDA recalls the spectacle of the French Revolution devouring its own leaders.

The irony goes further. Before the passage of the 1962 food and drug amendments, virtually every physician or scientist testifying pointed out the importance of the use of consultant committees and the resource of experts. MEDICAL TRIBUNE has for years advocated the use of advisory scientific committees and outside experts to assure both scientific input into and review of regulatory decision making. MEDICAL TRIBUNE has opposed extension of regulatory intrusion into research and the practice of medicine through utilization of such regulatory concepts as "comparative efficacy." MEDICAL TRIBUNE has opposed Government partisanship in scientific controversy as a manifestation of American Lysenkoism. In the last few months, a groundswell of rebellion has built up in the scientific community on these issues. It is of interest that among the recommendations put forth to correct such regulatory excesses has been the use of more outside clinicians, clinical pharmacologists, and other experts.

Today one can report the beginnings of a response to the demands of leaders in medicine and science. Of 26 current FDA advisory committees, 13 are advisory to the Bureau of Drugs. In 1972 there will be 60 meetings of these committees as compared to 12 in 1969. An FDA advisory group of one type or another will meet on the average of every two to three days. In addition, the FDA is beginning to use outside consultations in almost as great numbers as the members of the advisory committees.

As to FDA advisory committee members, in 1971, 62.5 per cent came from the academic community, 16 per cent from hospitals, clinics, medical institutes, and nonmedical foundations or institutions, 12.5 per cent were state and Government officials other than from the FDA, but only 2 per cent medical practitioners. In 1971, 7 per cent of the committees came from the drug industry; in 1972 it will be 10.5 per cent.

A general accusation of conflict of interest in the review of NDAs is difficult to assess. But the make-up of the FDA committees, the present FDA's regulatory history, and its "adversary type" relationship with the drug industry just do not seem to add up to charges that it is "mollifying" the industry.

. . . AND AFFIRMATIVE ACTION

"NO NEW ANTIHYPERTENSIVE COMPOUND HAS BEEN INTRODUCED IN THIS COUNTRY IN 10 YEARS"

(Dr. Edward D. Freis)

Dr. Freis won his 1971 Lasker Award for his studies of hypertension. He and many other clinicians and leaders in clinical pharmacology have been deeply disturbed by the developments that have brought important therapeutic research to a "virtual standstill in the Uuited States." Dr. Freis's comments were made prior to the accusation by consumerists that the Director of the Bureau of Drugs had transferred two medical officers of the FDA. As best we are able to