

## 8086 COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY

mation to FDA. Pending evaluation of that data, the products remain available, and, we believe, will in many cases finally be ruled effective.

Due process requires, it seems to us, that no physician be required to end his use of any of these drugs against his will at this time. We are therefore concerned when we read of the premature elimination of drugs on the November FDA list—and even the elimination of drugs judged “possibly effective” in some instances—from the procurement schedules of Federal agencies. For those products ultimately judged effective, the damage done to them by that premature delisting will have been as unwarranted as it was substantial.

I enclose a copy of a press release which discusses this subject in a little more detail. We would be appreciative if you would make this letter and the release a part of the Subcommittee's printed record at the appropriate place.

Sincerely yours,

C. JOSEPH STETLER, *President.*

Enclosure.

cc: Members of the Monopoly Subcommittee of the Senate Select Small Business Committee.

[Press release]

### PMA CHALLENGES PRODUCT LIST ISSUED BY FDA

WASHINGTON, D.C., January 15, 1971.—Two-thirds of the products made by its member companies that were included in a recent list of so-called “ineffective drugs” issued by the U.S. Food and Drug Administration are already off the market, the Pharmaceutical Manufacturers Association announced today.

President C. Joseph Stetler made public an analysis of the list of 359 products distributed recently by the FDA to federal agencies and to the mass communications media.

The list contained prescription and nonprescription drugs and such assorted other products as tooth pastes and mouth washes, all deemed by the FDA to be lacking “substantial evidence of effectiveness” or having “an unfavorable benefit to risk ratio.”

Representing regulatory actions published by the FDA in the Federal Register for the period from January 1968 to the end of 1970, the list has received wide publicity.

“This publicity has had the effect of giving the public the erroneous impression that a new, large-scale action, based on incontrovertible scientific evidence, is being taken against hundreds of products still in use,” Stetler said.

The FDA list was based on an evaluation for effectiveness of drug products by the National Academy of Sciences-National Research Council. The list in some cases represented varied dosage forms and package sizes for the same drug, which reduces considerably the total of 359 items, the PMA noted.

The PMA analysis showed of the 359 items listed, 292 were manufactured by its member companies. Three of the products made by PMA members were never marketed in the United States. Another 25 ceased to be marketed before January 1968, some as long as 20 years ago.

Eliminating those non-available items, a total of 172 products on the FDA list were removed from the market over the past three years. Ninety-two remain on the market.

In the latter category, in virtually all instances the manufacturer is responding to FDA requests to make available more data to demonstrate effectiveness, Stetler said. Some labeling and formulation changes have been and are being made. A few products have become the subject of regulatory or judicial redress.

“We are confident that a great many of these products, which have been used successfully by doctors for many years, will remain in use,” Stetler said.

The analysis showed that four products rated “effective” by the NAS/NRC showed up on the FDA's ineffective list. Forty-three products rated “effective, but”, five found “probably effective”, and 22 deemed “possibly effective” were placed by the FDA in the same category.

Stetler pointed out that of the group of 292 PMA company products, 59 received an “ineffective” rating by the NAS/NRC and another 159 involved the concept of “ineffective as a fixed combination.”

A considerable scientific debate is underway over the entire fixed combination question, with expert opinion on both sides of the issue.