dence in HEW General Counsel Willcox's words? Surely individual drug firms are not expected to be more perceptive than the sum of the opinions of the panels of consultants to the National Academy of Sciences.

The virtually complete change in the FDA's posture on the effectiveness question was not evident during the years between 1962 and 1968. On September 19, 1969, FDA proposed new regulations. District Judge Latchum, in his January 16, 1970, opinion called them "new standards of evidence necessary to demonstrate the effectiveness of drug products . . . applied retroactively so as to place in jeopardy the continued marketing of thousands of drug products introduced before 1962 with FDA approval and the effectiveness of which FDA has not yet challenged".

The fact that FDA had changed the rules was recognized by Judge Latchum, who noted that, among other things, FDA had not uniformly insisted on evidence of the kind laid down in the September 19 regulations in the past, that its 1966 calls for information supporting claims was very broad and that they "did not indicate that consideration . . . was to be limited to evidence derived solely from closely controlled clinical investigations. . . ." He also observed that the NAS/NRC panels plainly relied on opinion and impressions in some evaluations, so that if the regulations were to have been enforced uniformly and literally, FDA might well challenge drugs which the NAS/NRC panels had rated as totally effective.

Finally, with the May 8, 1970 publication of regulations on this issue, FDA made final its intention to selectively reject well-documented clinical experience as a test of effectiveness. Companies were then clearly on notice that unless a special exemption from the new criteria were successfully sought, they could be required by FDA to provide 1970-quality evidence for any pre-1962 drug, the clinical record of the product being of no significant moment in deciding the fate of that medication.

I submit that this record shows that the industry has made reasonable attempts to work with the Agency to meet the intent of the law, contrary to your letter's assertions, and that the ground rules have been changed substantially by FDA so as to make the industry's efforts to comply over the last several years appear inconsequential.

One final point. We note that the Food and Drug Administration never fails to cite the Food and Drug Act in justification of its actions. May we remind you that it is this same statute which provides industry with the right to hearings and court review. Yet when we exercise this right, we are criticized by you and other representatives of FDA.

In view of the need for the Record to reflect some balance on this issue, I am asking Senator Nelson to insert a copy of this letter in the transcript of the February 1, 1971 hearings of the Monopoly Subcommittee of the Senate Small Business Committee.

Sincerely yours,

C. JOSEPH STETLER,
President.

PHARMACEUTICAL MANUFACTURERS ASSOCIATION,
Washington, D.C., February 10, 1971.

CHARLES C. EDWARDS, M.D.,
Commissioner of Food and Drugs, Department of Health, Education, and Welfare, Rockville, Md.

DEAR DOCTOR EDWARDS: We have read with considerable interest your testimony of January 18, before the Subcommittee on Monopoly of the Senate Small Business Committee. While we found several points with which we are in agreement, we also noted a number of comments that are quite disturbing.

I am referring not only to portions of your prepared statement, but to the overall tenor of your remarks, as well as those of Dr. Simmons and Mr. Goodrich. They revealed, or so it seemed to us, a thrust that goes beyond the statutory authority given the Food and Drug Administration by the Congress. This includes a tendency to unduly escalate the role of the agency in drug therapy. I trust you will agree with me that there are high risk factors—to medicine and to patients—if the FDA attempts to expand its mandate into arbitrary, wide-ranging dictates in such matters as relative efficacy, certification of all drugs, class labeling, drug equivalency, and even marketing. Given the subtleties of