in those programs supported with Federal funds. It does not constitute good medical practice to administer drugs that have not been shown to be effective for the purposes for which they are prescribed.

I do not agree that the Departmental policy is unfair to the drug manufacturing industry as you allege. Even if it were, I would then have to weigh that against the unfairness of giving sick people drugs that have not been shown to be effective. I would have to decide in favor of the sick people.

Sincerely yours,

JESSE L. STEINFELD, M.D.,
Surgeon General.

PHARMACEUTICAL MANUFACTURERS ASSOCIATION,
Washington, D.C., January 21, 1971.

JESSE L. STEINFELD, M.D.,
Surgeon General,
Deputy Assistant Secretary for Health and Scientific Affairs,
Department of Health, Education, and Welfare,
Washington, D.C.

DEAR DOCTOR STEINFELD: We have reviewed with some concern your memorandum of December 11, 1970 setting forth Departmental procedures concerning the handling of drug products classified as "ineffective" or "possibly effective" by the Food and Drug Administration.

We are concerned because it appears that the Department intends to refuse to pay for drugs so listed by FDA even though:

(a) The decision with respect to some of the products is not final, pending FDA evaluation of further information supporting the product's effectiveness, which has been supplied by the drug's manufacturer.

(b) A "possibly effective" rating, as your memorandum itself notes, may involve only a single claimed indication for the product, while other claims for it have not been ruled out, and new studies are being undertaken.

If drug products now said to be "ineffective" are, when the regulatory process is completed, finally judged to be "effective", then your action will have seriously and irreparably harmed the products in question without justification.

If HEW refuses to honor claims for a drug rated "possibly effective" when the claim in question has not been rejected and studies are being initiated in accordance with regulatory policy, HEW will have denied due process to the manufacturers and will have grossly damaged the product's reputation without even the most tenuous of justifications.

Ironically, Doctor Steinfeld, your actions will have their worst effects on the firms that have acted most responsibly in this matter. The drugs involved here are those for which drug companies have provided the material necessary to obtain an approved New Drug Application; and for which they submitted, in accordance with the Government's requests, information showing the claims being made and the supportive evidence upon which those claims rest. Further, these firms cooperated in every way possible with the panels and staff of the efficacy review committee, and with the staff of the FDA.

The result of your action, if prematurely carried out, will be to effectively remove these products from the market; yet similar or identical competitive products, manufactured by firms that have given this effort *no* cooperation, will be rewarded for their irresponsibility by being permitted to continue on sale.

Your memorandum is extremely unfair to this industry, it seems to us, and goes far beyond the intent of the efficacy review and the Department's legal authority. I therefore request that you modify that memorandum to make clear the Department's intention to honor claims for payment for drugs until their effectiveness status has been finally determined in accordance with established prescribed regulations.

Inasmuch as we understand that the Social Security Administration and the Medical Services Administration intend to implement your policy state-