

joint suit by the American Public Health Association and the National Council of Senior Citizens.

Senator NELSON. That was, I take it, to specifically implement the provisions of the 1962 amendment.

Mr. AHART. I think the thrust of the suit was to require FDA to speed up the effort and to require the publication of the National Academy of Sciences evaluational report on drug efficacy.

Senator NELSON. All right, thank you.

Mr. STAATS. As of January, 1974, FDA's initial ratings on all but one of the more than 4,000 drug products included in the study have been published in the Federal Register.

However, in accordance with the procedures of DESI, FDA has revised its ratings for specific drugs as new information is submitted by the drugs' sponsors.

We inquired into the status of Federal agency actions to insure that only effective drugs are purchased with Federal funds and noted that, in general, definitive actions taken have been limited to direct Federal health care programs.

We testified in May, 1972, that as of November 18, 1971, the Defense Medical Materiel Board had initiated action to stop further procurement and to eliminate from the supply system all items that FDA had then pronounced "ineffective" or "possibly effective." Also, the surgeons general of the military departments had emphasized through instructions to medical organizations the DOD policy on such drugs, which became effective January 21, 1971.

This policy provided that remaining stocks of "ineffective" drugs withdrawn from the market were to be destroyed or other appropriate action was to be taken to remove them from the inventory. For items categorized "ineffective," but awaiting final determination of FDA, further use of remaining stocks was suspended until the final status was announced by FDA. P. & T. committees were required to question all prescriptions for "possibly effective" items, but local procurement of such items could be made if no alternative means of therapy was available.

On June 11, 1973, DOD announced a revised policy which is a bit less stringent with respect to the use of "ineffective" and "possibly effective" drugs. According to DOD, the original policy was revised because the completion schedule for the DESI had been substantially extended from that originally anticipated and because some of the FDA's more recent drug classifications would be revised following only minor changes in labeling or formulation of certain widely-used items.

The revised policy provides that procurement of items classified by FDA as "ineffective" and ordered withdrawn from the market continues to be prohibited. However, for items which FDA classified as "ineffective" but has permitted to remain on the market pending final resolution of the items' classification, the policy permits the Defense Medical Materiel Board, in conjunction with the Surgeons General, to determine whether centrally-procured stocks are to be discontinued.