"The way the FDA has translated the often qualified NAS/NRC findings into summary regulatory action against individual products remains the most controversial aspect of the review process", Stetler declared.

Many contested drugs have been voluntarily withdrawn from the market by manufacturers because the required lengthy clinical trials and studies are not feasible, in part because of a shortage of qualified investigators.

While the PMA did not survey non-PMA member companies producing 67 products on the FDA list, a breakdown would probably be similar to that for PMA companies, it was pointed out.

Senator NELSON. Your statement will be printed in full in the record, doctor.

Go ahead and present it however you desire.

STATEMENT OF DR. JESSE L. STEINFELD, SURGEON GENERAL, PUBLIC HEALTH SERVICE, AND DEPUTY ASSISTANT SECRETARY FOR HEALTH AND SCIENTIFIC AFFAIRS, DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE; ACCOMPANIED BY WINTON B. RANKIN, SPECIAL ASSISTANT TO THE ASSISTANT SECRETARY FOR HEALTH AND SCIENTIFIC AFFAIRS, HEW; AND ALLEN J. BRANDS, PHARMACY LIAISON REPRESENTATIVE, PHS, HEW

Dr. STEINFELD. Thank you, Senator Nelson.

With me on my left is Mr. Winton Rankin, Special Assistant to the Assistant Secretary for Health, HEW, and on my right is Mr. Allen J. Brands, Pharmacy Liaison Representative of the U.S. Public Health Service.

If I may, I would like to proceed with the statement.

Once more, Mr. Chairman, I am pleased to appear before this committee to discuss the drug procurement activities of our Department.

Our Department has adopted the policy that it will not spend Federal funds for purchasing drug products classified as "ineffective" or "possibly effective" by the Food and Drug Administration. This policy applies to our direct care programs, the contract care programs under the direct care programs, the Federal grant programs and the medicare and medicaid programs for both inpatients and outpatients with the following two exceptions:

(*a*) Federal funds may be expended to purchase "ineffective" and "possibly effective" drug products for use in the pursuit of approved clinical research projects.

(*b*) Federal funds may be expended to purchase a "possibly effective" drug product when no alternate means of therapy with drug products in the "probably effective" or "effective" classification is available.

This policy is in full effect now with respect to direct purchases of drugs and we are in the process of making it effective for the reimbursement programs; this latter case takes more time since there are regulations that must be changed and there is the problem of giving adequate notice to numerous individuals and offices that are entitled to seek Federal moneys under the reimbursement programs.

We have already supplied your staff, Mr. Chairman, with a copy of my memorandum of December 11, 1970, stating the departmental