STATUS OF ACTIONS TAKEN BY FEDERAL AGENCIES TO ASSURE THAT ONLY EFFECTIVE DRUGS ARE PROCURED WITH FEDERAL FUNDS

During our last appearance before this Subcommittee in May 1972, we commented on actions taken by DOD, HEW, and VA with respect to FDA's pronouncements regarding drug efficacy. As you are aware, FDA has categorized drugs as "effective," "probably effective," "possibly effective," and "ineffective" for one or more therapeutic indications claimed on the drug's labeling.

Legal action was brought against FDA in an effort to expedite FDA's completion of its determinations of drug efficacy under its Drug Efficacy Study Implementation (DESI). In October 1972, the Federal District Court for the District of Columbia:

--ordered FDA to meet specific target dates for various phases of DESI and to submit 6-month status reports to the Court concerning its progress.

--required FDA to make final determinations on drug efficacy or to rule on drug sponsors' request for hearings by October 1976.

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