The applicable Federal policy states that "where either is employed, there must be standards for quality, safety, and effectiveness, under the supervision of professional personnel."

Although SRS discusses the use of a formulary system as a means of reducing overall drug costs, the use of formularies is not required. Presently 20 States use some type of formulary.

SRS, in its Medical Assistance Manual, points out the arguments for and against the use of generic drugs, but does not emphasize their use.

Although the States generally accumulate data concerning the specific drugs being dispensed under the medicaid program, the data is not normally provided to SRS.

As you know, Secretary Weinberger recently announced that HEW will be publishing regulations for public comment which, if adopted, would limit drug reimbursements under programs administered by the Department to the lowest cost at which the drug is generally available, unless there is a demonstrated difference in therapeutic effect.

The reimbursement policy is intended to result in major savings in the cost of providing prescription drugs under medicare and medicaid. The announcement prompted the Chairman of the Senate Subcommittee on Health, Committee on Labor and Public Welfare, to hold another hearing on February 1, 1974, to provide representatives of the administration and the drug industry the opportunity to clarify their positions concerning this significant new HEW policy. To date, the proposed regulations have not been published.

Now, thirdly, and finally, we turn to the status of actions taken by the Federal agencies to assure that only effective drugs are procured with Federal funds.

During our last appearance before this subcommittee, we commented on actions taken by DOD, HEW and VA with respect to the FDA's pronouncements on drug efficacy. 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 the Drug Efficacy Study Implementation, which is known as DESI.

In October 1972, the Federal District Court for the District of Columbia ordered the FDA to meet specific target dates for various phases of DESI and to submit 6-month status reports to the court concerning its progress.

It required the FDA to make final determination on drug efficacy or to rule on drug sponsors request for hearings, by October 1976.

Senator NELSON. Let us see, who initiated the lawsuit? You say the Federal District Court ordered the FDA to do certain things? Who was the complainant?

Mr. STAATS. I will have to ask one of my colleagues, Mr. Chairman.

Mr. AHART. Mr. Chairman, the information I have is it was a