3. The extent to which drugs not found in the USP and NF are procured and stocked.

As a result of earlier hearings of this subcommittee, the General Accounting Office has prepared for submission to you a listing of Federal stock number drug items which are not listed in USP or NF. The list begins with acetaminophen and ends with zinc sulfate. I am sure you will recognize that the vast majority of the items listed are "bread and butter" preparations needed in daily practice.

4. The possible effect on competition if only the drugs monographed in the USP and NF were purchased.

The effect on competition would be negligible if we limited central procurement to only those drugs monographed in USP and NF. The effect on the taxpayer would be considerable; it would be necessary to purchase many non-monographed drugs locally at a steep increase in prices in comparison to those obtainable by central procurement. It is simply not possible to give the patient full benefit of modern medicine if the therapeutic armamentarium were limited to monographed items.

Drugs selected for inclusion in the compendia are those which are considered to be the "best," or "most understood." It does not necessarily follow, however, that the compendia cover all contingencies, or that a drug not monographed does not have a wide usefulness founded on entirely rational evaluation.

Supplements to the compendia continually add new drugs, but there is always a significant lag time, and some drugs which are frankly essential, or are drugs of "best choice," have not yet been admitted. Many older drugs, of established efficacy and safety, but decreasing popularity, have been dropped from the compendia but still deserve a place in our military formulary.

The compendia refrain, in general, from listing fixed combinations of drugs. Although many irrational combination preparations have been declared "ineffective" or "possibly effective" for good reason, many combinations remain on the market. There is good cause for a wide range of gastric antacid preparations: the proper balance between the constipating effect of aluminum compounds, and the cathartic effect of magnesium compounds, is a fine adjustment which varies for the individual patient. The same holds for the oral contraceptives, which are combinations of various estrogens and progestins. Many of these combinations are not included in the compendia.

There is a call, too, for many dosage forms of standard drugs, and not all of these dosage forms are monographed. For example, the preparation of acetaminophen as a concentrated solution in a dropper bottle permits accurate dosage in small children, while estimation of fractional teaspoon doses of the NF elixir does not.

The negligible effect on competition of limiting procurement to monographed items is readily evident on examining the list we have previously submitted of some 500 drugs which are currently single source items. Over two-thirds of these drugs are included in USP or NF. In some instances we are buying from a single source simply because that source has the know-how and efficiency to meet our standards. Two good examples are aspirin tablets, USP, and alcohol, USP. Here we have already the ultimate in competition, and limiting procurement to USP/NF will not make the competition any better.

Many other monographed items are single source because of patent or NDA limitations. Good examples are: sulfasoxizole; methyldopa; spironolactone; diazepam; methylphenidate; kanamycin; and methylprednisolone.

The military combination preparation of chloroquine and primaquine for suppression of malaria has not been included in the compendia, and possibly never will be. Triamcinolone appears in the compendia as a cream, an aerosol, and a suspension: triamcinolone in a special paste base is widely used by our dentists but has not yet been monographed.

5. The steps taken to insure that FDA pronouncements on less than effective drugs are being effectively implemented.

Our policy and procedures on the handling of less than effective drugs have been reported to you previously and have been published in the record of the 1971 hearings of this subcommittee. We have continued to implement these policies. During the past 16 months since the last hearings, DPSC has declared 13 FSN's to be "limited standard" (issue until exhaustion), and has deleted 17 FSN's with on-hand assets being held for reimbursement and/or replacement.