Senator NELSON. What is the rationale given by the purchasing agency for such a high percentage of purchases made on a negotiated basis?

Mr. CROWTHER. This goes back to the sole-source manufacturers. So many brand names are selected by the prescribing physicians that it leaves very little for competition.

Senator NELSON. Certainly nowhere near 96 percent is sole source unless you use the brand name and call that a sole source.

Mr. CROWTHER. In some cases that has occurred, sir.

Senator NELSON. Well, that puzzles me. If you take the various therapeutic categories, there are relatively few in which there is only one drug for the treatment of a particular ailment, unless you are saying as Colonel Breyfogle suggested, that specifications have been drawn up that only a brand-name manufacturer can fulfill. That would, therefore, become a sole source.

Mr. CROWTHER. Well——

Senator NELSON. I do not understand that.

Mr. CROWTHER. In the Defense Personnel Support Center, for all of their drugs in central supply they write specifications and put them out for competitive bids, if possible. They do not receive a great deal of competition, but at least, they go out for competitive bids on most drugs they stock centrally.

The Veterans' Administration writes specifications only on those drugs that are outside of a patent. Either the patent has expired or there is no patent. Drugs with specifications constitute a small number of the total drugs managed or administered by the Veterans' Administration.

Senator NELSON. When you say the Defense Supply Agency writes specifications, what do you mean by that? All you have to do is ask for a drug by its generic name and say that it must meet USP or NF standards. Are there any more requirements than that?

Mr. CROWTHER. Well, quite often——

Senator NELSON. Well, aside from the fact you want certain milligrams dosage and certain dosage forms, what is the complication about the specifications?

Mr. CROWTHER. This is quality control more than anything else.

Senator NELSON. USP standards.

Mr. CROWTHER. They go a little tighter than USP standards in several circumstances, tightening even the manufacturer's standards in several circumstances. The Defense Department itself goes in and inspects the plants and does batch testing of drugs.

Senator NELSON. Does the Defense Department have certain standards that have been published that are different on potency, for example, than USP?

Mr. CROWTHER. Well, it is not the potency as much as the procedures, the mechanisms of how the drug is manufactured in order to get consistency throughout the drugs, throughout each batch. They are concerned with the precision with which the drug is manufactured.

They are satisfied with the potency and its therapeutic value but they want to make certain that they obtain that potency and therapeutic value, so they are very concerned in writing the specifications to——

Senator NELSON. What standards do they use for potency?