United States General Accounting Office
Washington, D.C. 20548

For Release on Delivery
Expected at 10 AM EST
January 19, 1971

STATEMENT OF
ELMER B. STAATS, COMPTROLLER GENERAL OF THE UNITED STATES
BEFORE THE
MONOPOLY SUBCOMMITTEE
SELECT COMMITTEE ON SMALL BUSINESS
UNITED STATES SENATE
ON
DRUG PROCUREMENT SYSTEMS OF FEDERAL AGENCIES

Mr. Chairman and Members of the Subcommittee, I am pleased to appear here today in response to your request to discuss the drug procurement systems of Federal agencies.

As you requested, we plan to discuss the efficacy, economy, and rationality in the drug procurement activities of the Federal Government. Specifically you asked that we discuss the methods of procurement, the degree of competition obtained, participation by small business and the use of section 1498, of title 28 of the United States Code to procure drugs covered by patents.

Our discussion today will focus upon the systems through which the Federal Government directly procures drugs from manufacturers and other suppliers. We would like to mention, however, that since our last appearance before this Subcommittee in May 1967, we have conducted reviews of and issued reports on other aspects of the Government's drug-related

activities. We have attached as Appendix A to my statement digests of these reports for your information.

There is a growing involvement by the Federal Government in drug procurement, encompassing its substantial role both as a direct provider of medical care and treatment to certain classes of persons and as a supporter of federally financed programs which include the provision of drugs for eligible beneficiaries. During the three fiscal years 1967 through 1969, the total estimated Federal expenditures for drugs increased from $514 to $975 million. A substantial portion of these expenditures were indirect in that they consisted of the Federal share of the costs of drugs provided to beneficiaries under the Medicare and Medicaid and certain other programs. Drug costs under the Medicare and Medicaid programs increased from an estimated $350 million in fiscal year 1967 to $750 million in fiscal year 1969.

Although the major portion of Federal drug expenditures are indirect, the expenditures for direct procurements have increased from $161 million in 1967 to $203 million in fiscal year 1969.

Three Federal agencies account for most of the direct drug procurement--the Defense Personnel Support Center, an activity under the Defense Supply Agency; the Public Health Service of the Department of Health, Education, and Welfare; and the Veterans Administration. Each of these agencies operates its own drug supply system.

The Defense Personnel Support Center centrally manages about 1,100 drug items and in fiscal year 1969 procured an estimated $103 million in drugs. The Public Health Service

centrally manages about 600 drug items and in fiscal year 1969 spent an estimated $6 million for drugs, about 86 percent of which were obtained under contractual arrangements made by Veterans Administration. The Veterans Administration centrally manages about 450 drug items and centrally procured an estimated $25 million in drugs in fiscal year 1969.

The Veterans Administration also administers Federal Supply Schedule contracts under which Federal agencies can satisfy their drug requirements through direct purchase from drug manufacturers. Purchases under these contracts for fiscal year 1969 were estimated at $56 million.

In addition to drug procurements which are centrally managed or administered, medical facilities of each of the three agencies can, in certain circumstances, locally procure their drug needs.

Previous testimony before this Subcommittee has highlighted the drug procurement system as an activity supporting physicians' decisions on the most appropriate drug therapy for their patients. Such a system has as its base the professional selection of drugs and, in support of that selection, a complementary supply activity.

The objective of Government drug procurement should be to obtain at fair and reasonable prices, and in a timely manner, the proper and needed quantities of drugs that are of a satisfactory quality.

Specifically, we believe that a drug procurement system should provide for:

--a selection process which emphasizes drug quality, safety, and efficacy and gives appropriate consideration to drug cost.

--comprehensive and accurate drug usage data to facilitate the selection of the most appropriate and economical method of supply with appropriate corresponding restrictions on all other available supply sources.

--the development of product specifications which insure that drugs are capable of producing the desired therapeutic effect while encouraging the widest possible competition and lowest possible cost.

--effective negotiation as the alternative contracting method in instances where competitive procurement is not possible, and

--inspection and testing to establish manufacturer responsibility and capability to produce quality drugs.

We have surveyed Federal drug procurement systems in the light of these criteria and would like to briefly describe our observations.

I would like to emphasize that these observations are based on preliminary studies of the systems involved and cannot be considered as a complete review of such systems. Our work is continuing, however, and we will undoubtedly have more observations and suggestions to offer at a later time.

Drug selection

With respect to the drug selection process, we obtained information at the local level for five Federal medical facilities. Each of the facilities visited has established its own system for judging which drugs are appropriate for use. Each system is under the administration of a central group, the name of which varies but may commonly be referred to as the Pharmacy and Therapeutics--the P and T--Committee.

The P and T committee's membership generally consists of the directors of the various professional services of the medical facility and the chief pharmacist who acts as secretary.

Some committees also have special non-voting members, such as supply specialists and nursing personnel, whose functions range from that of observer to advisor in their areas of expertise.

A principal function of the P and T committees is to administer the system for evaluating and selecting from among numerous drugs those considered most useful in patient care. The committee's selections are reflected in a continuously revised compilation of drugs approved for use within the medical facility--the station formulary. In carrying out this function, the P and T committees generally receive some assistance from headquarters level in the form of policy guidelines, regulations, and information published by various professional medical service groups. Agency policy statements and regulations, where available, are generally limited to setting out the scope and authority of the P and T committees. Headquarters may provide recall and adverse reaction information about specific drugs, and furnish data on the commercial availability and prices of drugs. However, the selection of drugs for inclusion in the station formulary is reserved to the P and T committees. At military hospitals, the hospital commander is responsible for approval or disapproval of drugs recommended by P and T Committees.

Most of the information on specific drugs which is made available to members of the P and T committees in their consideration of changes to the station formulary comes from two sources; professional journals and the drug manufacturers. The drug companies supply most of their information to individual physicians through sales representatives (detailmen) and by direct mail advertising.

Recently a series of actions impacting upon the operation of P and T committees and the formulary system have been taken or are planned within each of the major Federal drug procurement agencies. For example each of the agencies has directed the distribution of the Food and Drug Administration's recently published list of "ineffective" drugs to their local medical facilities with the recommendation or requirement that the drugs no longer be used.

Public Health Service has also taken action to more fully develop possible approaches to effective drug utilization reviews, as recommended in the report of the Department of Health, Education, and Welfare's Task Force on Prescription Drugs. A research study of the methodology and feasibility of this technique is currently underway.

We believe that the recent actions related to the drug selection process, if properly implemented, should improve control over drug operations at the local level. In implementing such actions we believe that emphasis should be placed on providing physicians employed by the Federal Government with appropriate information concerning available drugs to assist them in making decisions relating to drug therapy.

Keeping physicians informed is most important because the physicians' decisions guide the drug selection process. Unless this process is based on the best information available, even an otherwise efficient supply function may be uneconomical.

During our visits to local medical facilities we noted specific actions by P and T committees which we believe are

appropriate for wider application. Examples noted were (1) the dissemination of information on drug studies including drug costs and (2) dissemination of information on adverse drug reactions.

Procurement and supply system

Once determinations have been made through the selection process of the drugs which will be used, the drug supply activity must operate effectively to furnish the required items in the most economical manner. Requirements for frequently used drugs are generally met through a central stock system which allows for quantity purchases.

Veterans Administration and the Department of Defense both have reporting systems for identifying drugs for inclusion in their centralized stock systems.

In the Department of Defense, each of the three services has its own system and criteria for reporting, and they vary from each other. One result of this is that Defense-wide usage of a specific drug does not become known until one of the services recommends a drug for inclusion in the central stock system. Approval of only one service is needed to add a drug to the central supply system, but all services must concur in removing an item from the system. In fiscal year 1970, 66 drug items were added to the system and action taken to delete or discontinue procuring 106 drug items on a centralized basis.

We believe that under the current reporting systems, drug items that merit consideration for inclusion in the central

stock system may not be included in the items identified for review and evaluation. This possibility could be removed and the reporting system improved by the use of standard criteria by the three services.

The Veterans Administration's primary source of information in its continuing effort to capture data on drug usage outside of its central stock system is a quarterly drug report based on reports from each of its medical facilities. This report is characterized by the Veterans Administration as an important tool in the management of its drug program and shows all procurements from sources other than central stock. The Veterans Administration uses this report to identify drugs which qualify for inclusion in the central stock system.

We believe that the Veterans Administration could make its comprehensive report more useful by requiring more uniform adherence to its regulations on reporting nomenclature and by providing for the compiling of certain summarizations and exception reports which would make the identification of drugs for central stock management much easier.

Also, available data indicates that the Veterans Administration and the Department of Defense could take advantage of higher quantity drug procurements which could possibly result in lower prices by combining their needs for procurement purposes. For example, the Veterans Administration contracted for 1,404 units of Lincocin at a unit price of $22.30--five days later the Defense Personnel Support Center contracted for 4,464 units of the same drug from the same manufacturer at a unit price of $19.95. In another instance the Veterans Administration contracted for 3,000 units of Tylenol at $6.14

each--about one-month earlier the Defense Personnel Support Center contracted with the same manufacturer for 10,176 units of the same drug at $3.28 a unit.

At least 150 drugs, centrally procured by the Defense Personnel Support Center during calendar years 1968 and 1969, were also centrally procured by the Veterans Administration during fiscal years 1968 and 1969.

Both the Veterans Administration and the Department of Defense have established required priorities of supply sources to be used by their medical facilities. These priorities reflect a policy of using the most economical supply source available. Such a policy is important because the commercial unit prices of drugs available at the wholesale level are generally higher than prices established under Federal Supply Schedule indefinite quantity contracts which, in turn, are generally higher than definite quantity procurements.

To illustrate this fact, we compared prices listed on the Federal Supply Schedule with the highest prices paid under definite quantity contracts for 68 drug items over a recent two year period and found that the Schedule prices averaged 63 percent higher. We recognize that procurements under indefinite quantity contracts have inherently higher manufacturers costs of warehousing and administration which would account for some part of the difference between definite quantity procurements. Also additional warehousing costs are incurred by the Government on procurements for central stock under definite quantity contracts, but considering all these factors, a 63 percent difference seems significant in any event. The average price differential is particularly significant considering the amount of total purchases made under

Schedule contracts and the fact that many centrally stocked drugs are also available under the Schedule contracts.

We see no reason why Federal agencies should independently procure drugs from the same manufacturer and lose the possible price advantages resulting from high quantity purchases. We believe consideration should be given to improving Federal drug procurement practices by providing for an exchange of information between the Department of Defense and the Veterans Administration as to the estimated annual volume of drugs to be procured in order that consideration can be given to combining quantities of certain drugs for procurement purposes, using the most economical method of procurement for each drug item.

Product specifications

Another key requirement to an efficient supply system is its ability to provide, wherever possible, purchase descriptions or product specifications which permit more than one manufacturer to bid effectively.

Both the Defense Personnel Support Center and the Veterans Administration establish their own specifications on drugs. Both agencies require compliance with the applicable standards of the United States Pharmacopeia and the National Formulary to which each agency adds its own additional requirements. The professional personnel assigned this responsibility within the Defense Personnel Support Center and the Veterans Administration are chemists or pharmacists.

The Veterans Administration develops a specification when the demand for a generic product is sufficient to warrant central management or administration and when no patent exists or the patent has expired. The Veterans Administration has established specifications for about 100 of its centrally

managed drugs procured on a generic basis. In addition, specifications have been developed on 46 drug products administered under Federal Supply Schedule contracts.

The Defense Personnel Support Center establishes a specification or purchase description on every drug item in its central stock system.

Both agencies informed us that they use a number of sources in constructing their specifications. In addition to the monographs of the United States Pharmacopeia and National Formulary, other sources for constructing specifications include the Food and Drug Administration, drug manufacturers, the National Institutes of Health, and the American Chemical Society.

When a drug is standardized for the military supply system, the manufacturer is contacted and requested to supply sufficient information so that the item's essential characteristics can be prepared.

We explored with Defense Personnel Support Center officials the question of whether, because of the substantial reliance upon information obtained from manufacturers, military specifications or purchase descriptions are restrictive and, in effect, result in a proprietary specification. These officials contend that the specifications and purchase descriptions are constructed in such a manner that any firm knowledgeable in the drug industry could manufacture the drugs. Without a detailed study of the matter, we have no basis upon which to either dispute or validate this contention.

Competition and negotiation

It is clear that the degree of competition obtained in the drug procurement area is less than competition obtained for many other Government supply items. The total dollar value of drug procurements for central stock by the Veterans Administration and the Defense Personnel Support Center in fiscal year 1970, amounted to about $94 million. About 7 percent or $6.4 million of the central stock procurements were made under contracts awarded pursuant to formal advertising procedures. The remainder were made under contracts negotiated with the sole source of supply or under contracts awarded after the solicitation of proposals.

Among the reasons for the limited amount of competitive procurement are of course, the fact that many drugs are patented products and the fact that legal and administrative requirements must be met in order to obtain Food and Drug Administration approval. Also, many procurements are made by brand-name either because only one brand of a particular drug is available or because of the prescribing physicians' preference. For example, about 70 percent of the drug items centrally stocked by the Veterans Administration have been designated for procurement on a sole-source basis in order to obtain specified brand-name drugs.

In addition, competitive contract awards account for about 25 percent of the procurements under the Federal Supply Schedules. Most of the other contracts, which are included for the

purpose of making manufacturers' product lines available to the Government at prices less than market, are negotiated without the benefit of competition.

The Defense Personnel Support Center sought to increase competition on their centrally managed drug items when, in January 1969, approximately 1,000 firms were invited to indicate their interest in bidding on 401 items, 290 of which were classified as single-source. Replies were received from 104 companies. Fourteen companies requested to be added to the bidders list for 35 of the 401 drug items. Two other companies requested to be added to the bidders list for eight drug items not included in the solicitation. The other 88 responding companies either did not produce the item; reaffirmed their interest in supplying the drug items for which they were already on the bidders list; or expressed no interest in supplying any of the products to the Government.

Some of the reasons advanced with respect to the absence of competition on a large number of drug items include

--restrictions imposed by law or regulation, such as patents on new drug applications;

--inadequate plant facilities and no desire to make the required investment to upgrade the facilities;

--the lack of qualified personnel to make many drugs; and

--the expense of introducing a new product with no assurance of reasonable return through sustained contract awards.

The advantages of seeking the widest possible competition in drug procurement can be demonstrated by available data from which we identified 9 drugs procured over a comparable period of time both competitively and on a sole-source basis. The drugs purchased from sole-source suppliers by the Veterans

Administration are estimated to be 60 percent higher than the average price obtained after formal advertising or the solicitation of competitive proposals by the Department of Defense. Appendix B of my statement shows the 9 drugs and comparative prices. It should be noted that the quantities purchased by the two agencies are different which may account for some part of the price differences.

We see no reason why different Federal agencies should independently procure the same drug in a different manner, and possibly from the same manufacturer, and lose the advantages associated with procurement of larger quantities and, where possible, increase competition.

Without effective competition, there is a question of the Government assuring itself that the prices being obtained are fair and reasonable under negotiated procurements. Public information is available on selected areas of drug pricing--an example would be wholesale prices. In determining whether the negotiated price is the best attainable by the Government, comparison of the bid with these prices reflects reasonableness by inference. Although there is no assurance that these prices are reasonable, our survey indicates that these prices serve as the basis for most of the price reasonableness determinations made by the Veterans Administration and the Defense Personnel Support Center.

Small business participation

Competition through formally advertised procurements seems to have a decided effect on the participation of drug manufacturers classified as small business. When drug supply contracts are awarded competitively, small business is often able to effectively compete. For example, in fiscal year 1970 more than half of the dollar volume of the Veterans Administration's formally advertised procurements of centrally

stocked drugs were awarded to drug manufacturers classified as small business concerns. Only 3 percent of the negotiated procurements for centrally stocked drugs were awarded to small business concerns. Since negotiated procurements constituted more than 96 percent of the total, small business received only about 4 percent of the total procurements of centrally stocked drugs.

During fiscal year 1970 the Defense Personnel Support Center initiated 1,076 procurement actions, each having a value of $10,000 or more, with domestic drug manufacturers. Small business was involved in 137 of these actions--representing about 7 percent of the total procurement dollars of about $71.6 million. For contracts amounting to $19 million awarded under advertised procedures or negotiated with competition by the Defense Personnel Support Center during fiscal year 1970, small business received about 17 percent of the dollar volume or a total of $3.3 million.

Drug Procurements From Foreign Sources

The absence of satisfactory prices from domestic drug manufacturers has led both the Veterans Administration and the Defense Personnel Support Center to the procurement of certain drugs from foreign sources. However, neither the Veterans Administration nor the Defense Personnel Support Center are currently making extensive use of foreign sources for their drug procurements.

In recent years the Veterans Administration has bought only one drug from a foreign source and does not actively solicit foreign bids in its procurements.

The Defense Personnel Support Center furnished this Subcommittee with information relative to its foreign procurement of five drug items during 1968 and 1969. During 1970 only one

of these items, tetracycline hydrochloride, has been procured from a foreign source. Another of these items has been obtained during 1970 from a domestic manufacturer because the bid by the foreign sources were not considered low after considering the Buy American Act provisions and related policies. The remaining three items were not procured from any source during 1970.

One factor in the small use of foreign sources is the Government's exposure to possible action under section 1498 of title 28, United States Code. This section provides that whenever an invention described in and covered by a patent of the United States is used or manufactured by or for the United States without license of the owner, the owner's remedy shall be by action against the United States in the Court of Claims for the recovery of his reasonable and entire compensation for such use and manufacture.

Since our last report to you on this subject, dated July 12, 1967, in which we explained the background and purpose of section 1498 of title 28, there have been two suits against the Government by drug patent holders for infringement of their patents rights. One of these suits involving purchases of nitrofurantoin was settled by the parties for $192,500 in September 1969 and the other one involving purchases of meprobamate is still pending.

Federal inspection and testing programs

An an integral part of their drug procurement systems both the Veterans Administration and the Defense Personnel Support Center have established programs for assuring the capability of Government contractors to supply a drug product of acceptable quality. These programs vary somewhat in their approach but have a common objective.

The quality assurance program at the Defense Personnel Support Center includes an evaluation, through pre-award surveys of the plant and pre-award testing of product samples, of the contractor's ability to supply a specific drug item.

Pre-award surveys and pre-award samples may be generally required when (1) the contractor has never before furnished the item being procured; (2) a doubt exists as to the quality control, housekeeping procedures, or financial position of the prospective contractor; or (3) the item is to be furnished from or manufactured in a different plant.

The Defense Contract Administration Service has about 80 quality assurance representatives, who are either chemists, chemical engineers, or pharmacists, and function as drug inspectors. They perform pre-award surveys at the request of the Defense Personnel Support Center and are charged with the responsibility for inspecting and approving all drug items manufactured under Defense contracts. In performing their inspections the quality assurance representatives are required to inspect each drug lot.

During fiscal year 1969 a total of 168 pre-award surveys were made--149 of which were performed on domestic manufacturers which were classified as either small or large business. Sixty-two small business firms were subjected to 90 surveys. Forty-seven of these surveys resulted in disqualifications. Twenty-six large businesses were subjected to 59 surveys, 25 of which resulted in disqualifications. Reasons for disqualification included poor quality control; poor housekeeping; sample failure; unacceptable subcontractor; and inadequate capacity.

The Veterans Administration inspects each contractor plant with regard to its entire operation and for its entire

product line. This is done prior to the contractor being awarded any contracts so that the Veterans Administration can be assured that the supplier is suitable for any of the products it may offer to the Government. These initial contractor plant inspections represent about 60 percent of all inspections.

The remaining inspections are reinspections on a cycle basis. All inspections evaluate such areas of contractor operations as the adequacy of quality control, test facilities, and sanitation.

All plant inspections are made by two Veterans Administration pharmacists.

During fiscal year 1970, the two pharmacists performed 134 inspections at 122 contractor's plants. The inspections resulted in 37 disapprovals, the most common reason being the lack of following adequate quality control procedures. Veterans Administration does not utilize military inspections of domestic plants except as a supplement to its own inspection. Veterans Administration does rely upon Department of Defense inspections of foreign plants.

The Food and Drug Administration performs testing of selected drug samples for the Veterans Administration. Brand-name drug items which are centrally stocked are tested on a sample basis once a year. Each order of generic drug items which are centrally managed is tested.

Drug items under Federal Supply Service Contracts administered by the Veterans Administration are rarely tested except that the products of any new contractor under Schedule contracts are tested.

A compilation of testing reports received by the Veterans Administration from the Food and Drug Administration for 1970 through December 29th shows a total of 784 tests made--254 brand-name and 530 generic. The total rejections were 29 for a rate of 3.7 percent. All rejections were on generic drug items.

The Department of Defense and the Veterans Administration exchange inspection information only upon specific request. The Department of Defense previously supplied the Veterans Administration with a list of plants inspected by it but this practice was discontinued about 2 years ago. At present there is no routine exchange of inspection information.

We believe that consideration should be given to establishing appropriate guidelines to facilitate the routine exchange of contractor inspection and product testing information among Government agencies involved with the control or procurement of drug products. Also we believe that consideration should be given to the possibility of eventually turning over the entire responsibility to the Food and Drug Administration for drug contractor plant inspections and product testing including testing of contract quality control procedures in order to satisfy each procuring agency's requirements and take the greatest advantage of the food and drug inspection system that has been established.

Mr. Chairman, this concludes my statement. I shall be happy to answer any questions that you or other members of this Subcommittee may have.

COMPTROLLER GENERAL'S REPORT TO THE CONGRESS

CONTROLS OVER THE MEDICAID DRUG PROGRAM IN OHIO NEED IMPROVEMENT
Social and Rehabilitation Service
Department of Health, Education, and Welfare B-164031(3)

D I G E S T

WHY THE REVIEW WAS MADE

Under Medicaid, the Department of Health, Education, and Welfare (HEW) shares with the States the costs of providing medical care to persons unable to pay. Because Medicaid expenditures for drugs, nationally, amounted to about $307 million in fiscal year 1969, the General Accounting Office (GAO) reviewed the Medicaid drug program. About $14 million of that amount was spent in Ohio where GAO made its review.

FINDINGS AND CONCLUSIONS

GAO sought answers to three basic questions:

--Are recipients of drugs eligible under Medicaid?
--Are drugs reasonably priced?
--Are controls over drugs adequate?

On the basis of a statistical sample, GAO estimates that, during the year ended March 31, 1969, the welfare recipients comprising at least 4,300, and possibly as many as 9,300, welfare cases in Ohio were ineligible for Medicaid services, including drugs. That situation is attributable primarily to a need for more timely and accurate determinations of eligibility, on a continuing basis, by the county welfare departments. (See pp. 7 to 11.)

Certain drugs purchased under Ohio's Medicaid program were not reasonably priced because of several factors.

--The State's policy of paying pharmacies for drugs on a cost-plus-a-percentage-of-cost basis is contrary to Federal and HEW policy because it gives the pharmacies an incentive to sell high-cost drugs to obtain a greater profit. GAO noted that 11 other States and the Virgin Islands paid for drugs on that basis. (See pp. 12 and 13.)

--The State's controls were not adequate for ensuring that prices billed to the State conformed to its formula for determining

payment for drugs, that is, cost plus 50 percent. For example, average markups were 159 percent for Lanoxin, 233 percent for milk of magnesia, and 248 percent for digoxin. The State's policy of permitting pharmacies to charge a minimum of $1 for each prescription increased the difficulty of controlling costs. (See pp. 13 to 20.)

--Nursing homes were not obtaining long-term maintenance drugs in economical quantities, because the State limits to a 30-day supply the drugs prescribed for welfare patients in nursing homes. (See pp. 23 and 24.)

Also there is a need for HEW, in its studies of drug efficacy, to give priority to certain lower cost, frequently used drugs identified by the HEW Task Force on Prescription Drugs as offering potential for considerable savings. (See pp. 20 to 22.)

Ohio's controls over drugs under its Medicaid program were inadequate for either the State or HEW to determine whether (1) drugs obtained by nursing homes were administered to welfare patients and were effective in their treatment, (2) drugs dispensed and billed by pharmacies were actually received by welfare recipients, and (3) only needed drugs were provided to welfare recipients. For example:

--At four of six nursing homes visited, controls were not adequate for ensuring that drugs paid for by the State had been authorized by a physician. (See pp. 26 to 29.)

--At five of 14 pharmacies visited by GAO, controls were not adequate for ensuring that prescriptions were complete as to quantities, dosages, forms, strengths, or dates. (See pp. 29 to 32.)

--The State had not given county welfare departments adequate information for determining whether recipients were receiving only needed drugs. (See pp. 33 and 34.)

RECOMMENDATIONS OR SUGGESTIONS

GAO is recommending that the Secretary of Health, Education, and Welfare:

--Provide assistance to Ohio and other States in revising their drug-payment policies to conform to HEW policy. (See p. 24.)

--Give priority in the conduct of HEW's drug-efficacy studies to those drugs identified by the HEW Task Force on Prescription Drugs as having considerable potential for savings and furnish physicans with information on the results of the studies. (See p. 24.)

--Issue guidelines for utilization reviews of drugs so that the States will have a uniform system for accumulating, analyzing, and reporting data for use by HEW and the States in evaluating this aspect of the Medicaid program. (See p. 34.)

--Monitor the implementation of these guidelines and give assistance to Ohio and other States, as needed. (See p. 34.)

AGENCY ACTIONS AND UNRESOLVED ISSUES

HEW stated:

--that guidelines for payments of reasonable charges for prescribed drugs were expected to be issued in the next several months; Ohio planned to abolish the $1 minimum for each prescription; and the States not in conformity with HEW regulations on drug prices had adopted, or were working toward adoption of, policies to bring them into conformity. (See pp. 24 and 25.)

--that it agreed that its efficacy studies of brand-name and chemically equivalent drugs should be completed and the results should be given to physicians. HEW, however, must make certain of the safety and effectiveness of all available drugs. GAO believes that giving priority, in HEW's drug-efficacy studies, to relatively low-cost, chemically equivalent drugs would not be inconsistent with HEW's responsibility and could result in significant economies in Medicaid drug costs. (See p. 25.)

--that utilization review guidelines would be issued in the near future; contracts had been awarded to four States for a pilot medical surveillance and utilization review program which was expected to strengthen the ability of States to plan, administer, and monitor the Medicaid program; and, the model system developed through the pilot program would be made available for adoption by all participating States. (See p. 35.)

--that it planned to institute a closer monitoring and liaison program in each regional office to bring about a closer relationship with State agencies and to include more frequent visits and detailed reviews of State Medicaid operations. (See p. 35.)

MATTERS FOR CONSIDERATION BY THE CONGRESS

GAO is sending this report to the Congress because of congressional interest in the Medicaid program. The report should be useful to the Congress in considering legislative changes to the program.

Tear Sheet

COMPTROLLER GENERAL'S REPORT TO THE CONGRESS

OPPORTUNITIES FOR BETTER SERVICE AND ECONOMIES THROUGH STANDARDIZATION OF PHARMACY ITEMS AND CONSOLIDATION OF BULK COMPOUNDING FACILITIES
Veterans Administration B-133044

D I G E S T

WHY THE REVIEW WAS MADE

The General Accounting Office (GAO) reviewed certain operations of the Veterans Administration (VA) pharmacies in the Los Angeles, Chicago, and New York metropolitan areas to determine whether the economies and improved pharmacy service realized from pharmacy bulk compounding operations could be increased by greater standardization of drugs and medicinals for patient treatment and by consolidation of such pharmacy activities at centralized facilities.

FINDINGS AND CONCLUSIONS

Although each VA station where GAO made its review had a therapeutic agent committee, only the stations in the Los Angeles area had formed an interstation therapeutic agent committee to increase the standardization of medications commonly used for patient treatment and had established a centralized facility for the bulk compounding of drugs.

GAO believes that there are opportunities for reducing the costs of drugs used by VA stations in metropolitan areas by the establishment of interstation therapeutic agent and pharmacy committees and centralized bulk compounding and purchasing facilities.

On the basis of the Los Angeles experience, GAO believes also that a centralized facility would contribute to improved patient care by providing needed medications not commercially available, more assurance of the quality of drugs compounded, and better support for research and training activities.

It is GAO's opinion that the use of interstation committees to encourage coordination and cooperation in pharmacy operations has applicability in many metropolitan areas, such as Boston, Chicago, New York, Philadelphia, and San Francisco, each of which has several VA medical facilities.

RECOMMENDATIONS OR SUGGESTIONS

GAO is recommending that the Administrator of Veterans Affairs require the formation of interstation therapeutic agent and pharmacy committees in geographical areas which have several VA medical facilities.

Tear Sheet

JUNE 30, 1969

GAO is recommending also that the committees, when established, and with the encouragement and assistance of the VA Central Office, study the feasibility of establishing centralized bulk compounding and purchasing operations within their respective geographical areas.

AGENCY ACTIONS AND UNRESOLVED ISSUES

VA stated that it concurred in GAO's recommendations and would establish such interstation committees.

MATTERS FOR CONSIDERATION BY THE CONGRESS

GAO is reporting this matter to inform the Congress of the action planned by VA to provide better medical service to veterans and to effect economies in the pharmacy program.

GENERAL ACCOUNTING OFFICE
REPORT TO THE SECRETARY OF
HEALTH, EDUCATION, AND WELFARE

OPPORTUNITIES FOR ECONOMIES
IN DRUG PROCUREMENT IN
INDIAN HEALTH PROGRAM
B-164031(2)

D I G E S T

WHY THE REVIEW WAS MADE

The Division of Indian Health (DIH), of the Health Services and Mental Health Administration has the responsibility for providing health services to Indians and to Alaska natives.

Previous reports issued by the General Accounting Office (GAO) on drug purchases by Federal and State agencies with Federal funds showed that there were opportunities for reducing drug costs by revising procurement procedures.

Since there appeared to be a similar opportunity for economies in the program providing health care to Indian beneficiaries, GAO reviewed the drug procurement policies and practices of DIH. In fiscal year 1968, the DIH purchased $2.7 million worth of drugs for the benefit of Indians.

FINDINGS AND CONCLUSIONS

GAO found that DIH could realize economies by making several improvements in its management of drug procurement.

Opportunities exist for savings if DIH places greater emphasis on the benefits of centralized and competitive buying through the Public Health Service (PHS) supply center or through Veterans Administration (VA) supply depots. GAO believes that the volume of drug products purchased by field installations directly from manufacturers and local wholesale establishments--which is approaching $1 million a year--can be reduced. (See p. 5.)

DIH has not adopted a system for determining which drug products are, or could be, commonly used at field installations. GAO believes that there is a need for considering the benefits to be derived from the establishment of a program-wide drug formulary which together with better information on drug usage by field installations would help in determining the drugs that could be procured centrally on a competitive basis and generally at lower prices than for drugs purchased directly by field installations. (See p. 6 and p. 9.)

Tear Sheet

Drug pricing methods in some contracts with private pharmacies which furnish prescriptions to Indian beneficiaries were based on cost-plus-percentage-of-cost features that GAO believes are not conducive to economical drug purchasing. This pricing method may encourage the dispensing of higher cost drug products than may be needed to meet the requirements of prescriptions because the amount of markup by a pharmacy is contingent upon its acquisition cost of the drugs. (See p. 12.)

In some locations, recurring or repetitive-type prescriptions for Indian patients treated outside DIH facilities have not been filled by Indian health pharmacies. Present policy established by the DIH central office permits, but does not require, that this method of furnishing needed medications be used to achieve the benefit of lower cost than obtainable from private pharmacies. (See p. 16.)

RECOMMENDATIONS OR SUGGESTIONS

GAO recommends that action be taken to strengthen controls over drug procurement by requiring officials responsible for administering the Indian health program to

--maximize the use of centralized and competitive buying of drugs by purchasing them through the PHS supply center or VA supply depots.

--establish a program-wide system, and consider adoption of a program-wide drug formulary, to determine which drug products are, or could be, commonly used by field installations and could be purchased at lower prices through the supply depots.

--revise pricing methods in contracts with private pharmacies by requiring that the reimbursement to the pharmacies be based on actual acquisition cost of the drug plus a fixed professional fee; and

--use DIH pharmacies, whenever feasible, to fill recurring or repetitive-type prescriptions.

During the review, GAO discussed its findings with DIH officials who indicated that consideration would be given to the above recommendations.

APPENDIX B

COMPARISON OF DRUG PROCUREMENTS
VA SOLE-SOURCE PROCUREMENT VS DPSC COMPETITIVE PROCUREMENTS

SUMMARY

Total Actual VA Amount	$1,421,459
Total Potential VA Amount Using DPSC Average Unit Price At VA Quantity	887,185
Total Difference in VA Actual Amount and VA Potential Amount	$534,274
Total Percentage Difference	60%

COMPARISON OF DRUG PROCUREMENTS
VA SOLE SOURCE PROCUREMENT VS DPSC COMPETITIVE PROCUREMENTS

Date of Contract	Procurement Method	Quantity Purchased VA	Quantity Purchased DPSC	Unit Price VA	Unit Price DPSC	Amount of Contract VA	Amount of Contract DPSC
		GLYCERYL GUAIACOLATE SYRUP 650-064-8765					
1-17-68	Negotiated	40,824		$ .35		$14,288	
5-29-68	Negotiated	16,224		.35		5,678	
7-29-68	Negotiated	14,256		.35		4,940	
10-25-68	Negotiated	6,312		.35		2,209	
12- 9-68	Negotiated	24,456		.35		8,560	
1-30-69	Negotiated	25,200		.35		8,820	
4- 2-69	Negotiated	45,912		.35		16,069	
6- 3-69	Negotiated	77,712		.35		27,199	
4-10-68	Negotiated[a]		120,304		$ .32		$54,497
7- 3-68	Negotiated[a]		123,840		.28		34,675
8-15-68	Formal Advertised		174,528		.25		42,759
8-15-68	Option[b]		87,264		.25		21,380
2- 5-69	Formal Advertised		197,568		.22		43,084
4-25-69	Formal Advertised		345,600		.18		60,760
5-21-69	Formal Advertised		175,680		.21		36,014
6- 2-69	Negotiated[a]		376,320		.16		59,241
Total		250,896	1,601,104			$87,763	$352,410
Average Unit Price				$ .35	$ .22		
Potential VA Amount Using DPSC Average Unit Price at VA Quantity						$55,197	
Difference in VA Amount and VA Potential						$32,566	
Percentage Difference						59%	
		GLYCERYL GUAIACOLATE SYRUP 6505-079-6269					
11-13-67	Negotiated	1,032		$11.99		$12,374	
12-11-67	Negotiated	864		11.99		10,359	
2-16-68	Negotiated	1,456		11.99		17,457	
5- 1-68	Negotiated	1,680		11.99		20,143	
7-29-68	Negotiated	760		11.99		9,112	
1-30-69	Negotiated	156		11.99		1,870	
4- 2-69	Negotiated	1,272		11.99		15,251	
2- 6-68	Negotiated[a]		3,000		$11.14		$33,420
3-29-68	Negotiated[a]		5,200		10.86		56,446
7- 3-68	Negotiated[a]		7,424		7.33		54,414
7- 3-68	Option[b]		3,712		7.33		26,355
7-16-68	Negotiated[a]		5,132		7.75		39,773
Total		7,220	24,468			$86,568	$210,408
Average Unit Price				$11.99	$ 8.60		
Potential VA Amount Using DPSC Average Unit Price at VA Quantity						$62,092	
Difference in VA Amount and VA Potential						24,476	
Percentage Difference						39%	

[a] Competition solicited - one or more bids received
[b] Option exercised under preceding contract

COMPARISON OF DRUG PROCUREMENTS
VA SOLE-SOURCE PROCUREMENT VS DPSC COMPETITIVE PROCUREMENTS

Date of Contract	Procurement Method	Quantity Purchased VA	Quantity Purchased DPSC	Unit Price VA	Unit Price DPSC	Amount of Contract VA	Amount of Contract DPSC
			TRIAMCINOLONE ACETONIDE CREAM, USP				
			6505-682-8194				
10-23-68	Negotiated	3,312		$1.25		$4,140	
1-23-68	Negotiated[a]		16,780		$1.04		17,451
1-23-68	Option[b]		10,320		1.04		10,733
6-13-68	Negotiated[a]		49,752		.90		44,237
3- 5-69	Negotiated[a]		58,752		.86		50,527
3-28-69	Option[b]		73,440		.86		63,158
3-28-69	Option[b]		43,968		.86		37,812
8-28-69	Formal Advertised		53,760		.81		43,546
Total		3,312	306,772			$4,140	$267,464
Average Unit Price				$1.25	$ .87		
Potential VA Amount Using DPSC Average Unit Price at VA Quantity						$ 2,881	
Difference in VA Amount and VA Potential						$ 1,259	
Percentage Difference						44%	
			ACETAMINOPHEN TABLETS, NF				
			6505-985-7301				
8-29-67	Negotiated	1,656		$9.31		$15,417	
11-8-67	Negotiated	1,632		9.31		15,194	
12-11-67	Negotiated	1,440		9.31		13,406	
2-16-68	Negotiated	854		9.31		7,951	
5-24-68	Negotiated	2,160		6.14		13,262	
9-11-68	Negotiated	2,712		6.14		16,652	
10-29-68	Negotiated	2,568		6.14		15,768	
2-13-69	Negotiated	3,000		6.14		18,420	
3-21-69	Negotiated	6,456		6.14		39,640	
6-13-68	Negotiated[a]		3,792		4.45		$16,874
8-19-68	Negotiated[a]		3,552		4.20		14,918
10-15-68	Negotiated[a]		5,760		3.45		19,872
1- 9-69	Formal Advertised		10,176		3.28		33,377
2-17-69	Option[b]		5,088		3.28		16,689
9- 9-69	Formal Advertised		6,816		2.90		19,766
10-10-69	Negotiated[a]		6,624		2.75		18,216
Total		22,478	41,808			$155,710	139,712
Average Unit Price				$6.93	$3.34		
Potential VA Amount Using DPSC Average Unit Price at VA Quantity						$75,077	
Difference in VA Amount and VA Potential						$80,633	
Percentage Difference						107%	

[a] Competition solicited - one or more bids received
[b] Option exercised under preceding contract

APPENDIX B

COMPARISON OF DRUG PROCUREMENTS
VA SOLE-SOURCE PROCUREMENT VS DPSC COMPETITIVE PROCUREMENTS

Date of Contract	Procurement Method	Quantity Purchased VA	Quantity Purchased DPSC	Unit Price VA	Unit Price DPSC	Amount of Contract VA	Amount of Contract DPSC
			AMPICILLIN CAPSULES 6505-770-8343				
7-14-67	Negotiated	5,400		$12.48		$ 67,392	
8-31-67	Negotiated	9,600		12.48		119,808	
10-13-67	Negotiated	11,400		9.97		113,658	
12- 7-67	Negotiated	16,800		9.97		167,496	
5-23-68	Negotiated	17,568		9.77		171,639	
7-23-68	Negotiated	15,168		9.19		139,394	
1- 9-68	Negotiated[a]		4,800		$ 9.62		$ 46,176
1- 9-68	Negotiated[a]		9,600		9.45		90,720
3- 6-68	Negotiated[a]		24,000		9.24		221,736
4-23-68	Negotiated[a]		22,752		8.86		201,559
4-23-68	Option[b]		11,376		8.86		100,780
9-25-68	Negotiated[a]		26,112		7.18		187,484
11-14-68	Option[b]		52,224		7.18		374,968
4-23-69	Formal Advertised		31,128		5.95		185,212
7-22-69	Formal Advertised		23,346		5.40		126,068
10-21-69	Formal Advertised		26,784		5.23		140,054
Total		75,936	232,122			$779,387	$1,674,757
Average Unit Price				$10.26	$ 7.22		
Potential VA Amount Using DPSC Average Unit Price at VA Quantity						$ 548,258	
Difference in VA Amount and VA Potential						$ 231,129	
Percentage Difference						42%	

[a] Competition solicited - one or more bids received

[b] Option exercised under preceding contract

APPENDIX B

COMPARISON OF DRUG PROCUREMENTS
VA SOLE-SOURCE PROCUREMENT VS DPSC COMPETITIVE PROCUREMENTS

Date of Contract	Procurement Method	Quantity Purchased VA	Quantity Purchased DPSC	Unit Price VA	Unit Price DPSC	Amount of Contract VA	Amount of Contract DPSC
			PSYLLIUM HYDROPHILIC MUCILLOID WITH DEXTROSE 6505-050-4567				
9-14-67	Negotiated	2,880		$1.52		$4,378	
10-13-67	Negotiated	10,800		1.52		16,416	
12- 8-67	Negotiated	11,520		1.52		17,510	
2-19-68	Negotiated	12,432		1.52		18,896	
5- 9-68	Negotiated	14,640		1.52		22,253	
7-31-68	Negotiated	12,768		1.52		19,407	
9-18-68	Negotiated	18,184		1.52		27,640	
10-29-68	Negotiated	4,560		1.52		6,931	
2-18-69	Negotiated	22,320		1.52		87,905	
11-15-68	Negotiated[a]		71,040		$.85		$60,029
2-12-69	Option[b]		106,560		.85		90,043
12- 8-69	Negotiated[a]		35,136		.87		30,709
Total		110,104	212,736			$221,336	$180,781
Average Unit Price				$1.52	$.85		
Potential VA Amount Using DPSC Average Unit Price at VA Quantity						93,588	
Difference in VA Amount and VA Potential						$ 127,748	
Percentage Difference						136%	
			KAOLIN MIXTURE WITH PECTIN 6505-299-9678				
8-11-67	Negotiated	756		$5.50		$4,158	
1-17-68	Negotiated	756		5.50		4,158	
9-24-68	Negotiated	750		5.50		4,125	
12-12-68	Negotiated	750		5.50		4,125	
4- 1-69	Negotiated	1,510		5.30		8,003	
1-19-68	Formal Advertised		22,162		$2.30		$50,973
Total		4,522	22,162			$24,569	$ 50,973
Average Unit Price				$5.43	$2.30		
Potential VA Amount Using DPSC Average Unit Price at VA Quantity						$10,401	
Difference in VA Amount and VA Potential						$ 14,168	
Percentage Difference						136 %	

[a] Competition solicited - one or more bids received
[b] Option exercised under preceding contract

COMPARISON OF DRUG PROCUREMENTS
VA SOLE-SOURCE PROCUREMENT VS COMPETITIVE PROCUREMENTS

Date of Contract	Procurement Method	Quantity Purchased VA	Quantity Purchased DPSC	Unit Price VA	Unit Price DPSC	Amount of Contract VA	Amount of Contract DPSC
			DIBUCAINE OINTMENT 6505-299-9535				
10-16-67	Negotiated	12,480		$.22		$2,746	
12-11-67	Negotiated	12,000		.22		2,640	
5-22-68	Negotiated	7,956		.22		1,750	
9- 6-68	Negotiated	6,708		.22		1,476	
10-24-68	Negotiated	8,400		.22		1,848	
12- 5-68	Negotiated	6,480		.22		1,426	
3-26-69	Negotiated	21,612		.22		4,755	
2-27-68	Formal Advertised		157,896		.14		$21,316
3-14-68	Formal Advertised[c]		157,896		.14		21,316
Total		75,636	315,792			$16,641	$42,632
Average Unit Price				$.22	$.14		
Potential VA Amount Using DPSC Average Unit Price at VA Quantity						$10,589	
Difference in VA Amount and VA Potential						$ 6,052	
Percentage Difference						57%	
			ISOPROTERENOL HYDROCHLORIDE INHALATION, USP 6505-299-9661				
9- 1-67	Negotiated	11,232		$.67		$7,525	
10-13-67	Negotiated	1,440		.67		965	
12-11-67	Negotiated	12,096		.67		8,104	
5- 8-68	Negotiated	10,656		.67		7,140	
9-24-68	Negotiated	11,376		.67		7,622	
12- 9-68	Negotiated	8,496		.67		5,692	
2-27-69	Negotiated	12,384		.67		8,297	
1- 3-68	Formal Advertised		54,864		$.45		$24,415
1- 3-68	Option[b]		27,432		.45		12,207
4-16-68	Negotiated[a]		46,224		.41		18,859
12-18-69	Negotiated[a]		28,944		.41		11,867
Total		67,680	157,464			$45,345	$67,348
Average Unit Price				$.67	$.43		
Potential VA Amount Using DPSC Average Unit Price at VA Quantity						$29,102	
Difference in VA Amount and VA Potential						$16,243	
Percentage Difference						56%	

[a] Competition solicited - one or more bids received

[b] Option exercised under preceding contract

[c] Set aside for small business