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REPORT TO THE CONGRESS

How To Improve The Procurement And Supply Of Drugs In The Federal Government B-164031(2)

Department of Defense
Veterans Administration
Department of Health, Education,
and Welfare
Office of Management and Budget
General Services Administration

**BY THE COMPTROLLER GENERAL
OF THE UNITED STATES**

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DEC. 6, 1973



COMPTROLLER GENERAL OF THE UNITED STATES
WASHINGTON D C 20548

B-164031(2)

To the Speaker of the House of Representatives
and the President pro tempore of the Senate

This is our report on how to improve the procurement and supply of drugs in the Federal Government.

We made our review pursuant to the Budget and Accounting Act, 1921 (31 U.S.C. 53), and the Accounting and Auditing Act of 1950 (31 U.S.C. 67).

Copies of this report are being sent to the Director, Office of Management and Budget, the Secretaries of Health, Education, and Welfare and of the Department of Defense; the Administrator, General Services Administration; and the Administrator, Veterans Administration.

A handwritten signature in cursive script that reads "James B. Stacks".

Comptroller General
of the United States

C o n t e n t s

		<u>Page</u>
DIGEST		1
CHAPTER		
1	INTRODUCTION	5
	Past efforts to improve Federal management of medical material	7
2	GREATER COOPERATION AND COORDINATION WOULD RESULT IN SIGNIFICANT SAVINGS IN PROCURING DRUGS	8
	DSA-VA supply agreement	8
	Development of requirements data for procurement	9
	Possible savings through joint procurement	9
	Need to promote interagency transactions at the user level	10
	Conclusions	12
	Recommendations	13
	Agency comments and GAO evaluation	14
3	BENEFITS OF SPECIFICATIONS AND CENTRAL MANAGEMENT IN PROCURING PRESCRIPTION DRUGS	17
	Developing specifications	17
	Availability and use of specifications	18
	Coordination potential in developing specifications	20
	Need to revise DOD policy for adopting items for central management	20
	Conclusions	21
	Recommendations	22
	Agency comments and GAO evaluation	22
4	UNIFORM REPORTING AND MORE EFFECTIVE USE OF RELATED REPORTS WOULD IMPROVE SELECTION OF ITEMS FOR CENTRAL MANAGEMENT	24
	Military department reports	24
	VA reports	25
	Need for standardized coding system	27
	Conclusions	28
	Recommendations	28
	Agency comments	29

	<u>Page</u>	
5	OVERLAPPING QUALITY ASSURANCE ACTIVITIES AND OBSTACLES TO ELIMINATING THEM	30
	Differences in approving firms to supply drugs and in inspecting products	30
	Obstacles to eliminating overlapping quality assurance activities	32
	Conclusions	33
	Recommendation	33
	Agency comments	34
6	SCOPE OF REVIEW	35
APPENDIX		
I	Comparison of highest price paid under definite-quantity contract by VA or DPSC with the FSS price for drugs, March 1968 to December 1969	37
II	Letter dated August 14, 1973, from the Assistant Secretary of Defense (Health and Environment), DOD	40
III	Letter dated September 18, 1973, from the Assistant Secretary, Comptroller, HEW	45
IV	Letter dated July 25, 1973, from the Deputy Administrator, VA	46
V	Letter dated July 6, 1973, from the Adminis- trator, GSA	49
VI	Letter dated July 20, 1973, from Assistant Director, Management and Organization, OMB	51
VII	Principal VA and DOD officials responsible for the major portion of the direct pur- chases of pharmaceuticals for the Govern- ment	54

ABBREVIATIONS

DMMB	Defense Medical Materiel Board
DOD	Department of Defense
DPSC	Defense Personnel Support Center
DSA	Defense Supply Agency
FDA	Food and Drug Administration
FSS	Federal Supply Schedule
GSA	General Services Administration
HEW	Department of Health, Education, and Welfare
OMB	Office of Management and Budget
PHS	Public Health Service
VA	Veterans Administration
VAMC	Veterans Administration Marketing Center

D I G E S T

WHY THE REVIEW WAS MADE

Because of congressional interest in, and the magnitude of Federal expenditures for, drugs, GAO reviewed procurement and supply practices of agencies responsible for most of the Government's direct procurement of pharmaceuticals.

Direct drug purchases exceeded \$275 million in fiscal year 1972, and estimated indirect purchases for such programs as Medicare and Medicaid were more than double that amount. Principal agencies concerned were the Department of Defense (DOD) and the Veterans Administration (VA).

FINDINGS AND CONCLUSIONS

Greater cooperation and
coordination in procuring
drugs would result in savings

DOD and VA operate procurement and supply systems largely independently of each other.

Although they stock about 200 of the same drugs--frequently bought from the same suppliers--and support numerous field installations throughout the United States, these two large agencies have had little

exchange of requirements data or coordination in their procurement. (See pp. 8 and 9.)

GAO tests of drug purchases during a 3-year period showed that, in many cases, DOD and VA had paid the same manufacturer different prices for large quantities of the same drugs within the same general time frames.

Since drug prices usually are lower for purchases in large quantities, substantial savings could be realized if VA and DOD were to procure drugs jointly. (See pp. 9 and 10.)

DOD and VA procedures for developing their drug requirements are similar. To consolidate procurement the requirements of the two systems could be coordinated without undue difficulty.

Medical facilities supported by the Defense Personnel Support Center may not order from VA central stocks drugs not stocked by that Center. Similarly, VA medical facilities may not order directly from that Center.

Consequently, these facilities purchase drugs they cannot obtain from their own central supply organization from Federal Supply Schedule

contracts or directly from vendors in small quantities at much higher prices (See pp 10 to 12 and app. I)

About \$420,000 could have been saved in the 3-year period if DOD and VA medical facilities had acquired drugs from one another's central stocks

For example, from July 1970 to December 1971, military hospitals purchased macrodantin directly from the manufacturer for \$555,000 because it was not carried in DOD's central stocks At that time VA was purchasing this drug for its central stock and paying about 48 percent of the amount paid by the hospitals (See p 11)

Uneconomical local procurements of drugs should be avoided whenever practicable The availability of DOD and VA central stocks to all Federal field facilities should reduce the frequency of these procurements

Benefits of specifications and central management in procuring pharmaceuticals

Specifications defining drug product characteristics encourage competitive procurement and should reduce the cost of drugs. Use of these specifications has expanded A revised DOD policy for approving drugs for central management would improve drug procurement

--From October 1970 to June 1972, the VA Marketing Center prepared and used 85 new specifications for procuring drugs As a result it saved nearly \$1 million annually (See pp 19 and 20)

--Under its current policy DOD will not procure a drug by central procurement unless (1) data sufficient to develop specifications is available or (2) all three military services concur in designating a single procurement source.

GAO brought the macrodantin case to the attention of the Defense Medical Materiel Board. The Board's policy resulted in substantial excess costs being incurred because the drug was not bought centrally Although the Board then authorized central management of the drug on a sole-source basis, it did not change its policy. (See pp. 11, 20, and 21)

Savings should continue if specifications are developed for new drugs and those managed centrally for which no specifications have been prepared. DOD could also realize substantial savings if it would amend its policy for approving drugs

Since many drugs for which the Defense Personnel Supply and VA Marketing Centers prepare specifications are basically the same and since the number of these items should increase, duplicate effort could be avoided and technical talent could be better used if the Centers cooperate in preparing specifications (See p 20.)

Uniform reporting of drugs bought locally and more effective use of related reports would improve selection of items for central management

Bulk purchases of drugs for central stocks are substantially lower priced than smaller purchases. The primary method of identifying drug items for central DOD and VA management is through review of reports from field

activities of purchases made directly from vendors. However

--The reporting systems of the military services for local purchases differ in many important respects, exclude certain purchases, and hamper the identification of drugs for potential central management. (See pp. 24 and 25.)

--The voluminous VA report contains no summary by drug items to facilitate a review of purchase information (See p. 26.)

Because of weaknesses in the reporting systems, VA and DOD may be procuring many drugs locally, instead of centrally, at unnecessarily high prices. (See pp. 24, 25, and 27.)

Overlapping quality assurance activities

DOD and VA have different systems for inspecting manufacturers' plants to insure that they qualify as supply sources and that the drugs are of required quality. These inspections are additional to those made by the Food and Drug Administration (FDA), which is responsible for checking manufacturing practices and conditions under which drugs are made in the United States.

RECOMMENDATIONS

To promote Federal agency cooperation in procuring drugs:

--The Director, Office of Management and Budget (OMB), should lead in developing--with representatives of the General Services Administration (GSA), DOD; VA, and the Department of Health, Education, and Welfare (HEW)--policies and procedures, including consolidating requirements, to increase agency

cooperation in buying drugs and achieve substantial savings through large-volume buys. Field installations should be authorized to obtain their drug requirements from any centralized Government supply source (See pp. 13 and 14.)

--The Administrator, VA, should develop specifications for (1) all new drugs which VA decides to manage centrally and (2) centrally managed drugs for which it currently has no specifications. (See p. 22.)

--The Secretary of Defense should revise DOD policy to insure that drugs will be obtained centrally whenever savings would result (See p. 22.)

--The Secretary of Defense and the Administrator, VA, should consider jointly developing specifications which would satisfy all Federal agencies' requirements. (See p. 22.)

--The Secretary of Defense should (1) develop, for reporting local drug purchases, a uniform reporting system aimed at requiring all military activities with individual drug purchases exceeding specified criteria to report their purchases and (2) require centrally managed drugs purchased from other than a central manager to be reported. (See p. 28.)

--The Administrator, VA, should require that VA's Central Office Supply Service (1) prepare lists of summary and exception data from the information reported, (2) require local field stations to report their purchase data correctly and consistently, and (3) see that all vendors report detailed sales data when required by contracts. (See p. 28 and 29.)

--The Secretary of Defense and the Administrator, VA, should consider using a standardized coding system, such as the National Drug Code, for identifying local purchases of drugs not having Federal stock numbers. (See p. 29.)

--The Secretaries of Defense and HEW and the VA Administrator should review the frequency and type of inspections required and the related changes needed to facilitate the transfer to FDA of all quality assurance responsibilities pertaining to purchases of drugs by Federal agencies. (See pp. 33 and 34)

AGENCY COMMENTS AND UNRESOLVED ISSUES

DOD, VA, GSA, and OMB expressed interest in and general agreement with these aims. OMB and VA pointed out the need to consider total economic costs in determining whether consolidated procurement would be economical. This data has not been developed, and it may be a long time before it is available.

Meanwhile, opportunities exist for effecting economies and improvements within the present state of management data and operating methods, and GAO believes that action to take advantage of the opportunities should not be delayed until such data becomes available.

DOD and VA expressed reservations as to whether FDA could provide the types of inspections they require on a timely basis. HEW stated that it would discuss with DOD and VA officials the quality assurance requirements, needed resources, and other pertinent matters. HEW also said that it would take necessary action to transfer to FDA all quality assurance activities if it found that this would be in the best interest of the Government

MATTERS FOR CONSIDERATION
BY THE CONGRESS

This report shows how Federal drug procurement, supply, and inspection functions could be improved and could save the Government money.

CHAPTER 1

INTRODUCTION

Government procurements of pharmaceuticals directly from drug companies are estimated to have exceeded \$275 million in fiscal year 1972. The two largest buyers were the Defense Supply Agency (DSA) and the Veterans Administration (VA), but the Public Health Service (PHS) of the Department of Health, Education, and Welfare (HEW) also made fairly large purchases.

The Defense Personnel Support Center (DPSC), Philadelphia--a DSA activity--buys and stocks drugs for the Department of Defense (DOD) and provides supply support to military medical field facilities, to other DOD components, and to Federal agencies under interagency support agreements. DPSC bought about \$95 million worth of drugs during fiscal year 1972.

The Defense Medical Materiel Board (DMMB), composed of the Surgeons General of the Army, Navy, and Air Force, in coordination with the military medical services and DPSC, adopts drugs for and deletes them from the DOD central supply system.

The General Services Administration (GSA) is responsible, under the Federal Property and Administrative Services Act of 1949 (40 U.S.C. 471), for procuring medical supplies for civil agencies. In 1960 GSA delegated to VA the buying and supplying of drugs, biologicals, and official reagents¹ for all civil agencies.

The VA Marketing Center (VAMC), Hines, Illinois--an activity of the VA Central Office Supply Service in Washington, D.C.--is the central VA purchasing organization. During fiscal year 1972 it bought about \$37 million worth of drugs for central stock. VAMC determines which drugs should be adopted for or deleted from the VA supply system subject to approval of VA's Central Office. VA field stations requisition centrally stocked medical items from VA depots.

¹Chemical substances used in testing drugs.

VAMC also awards and administers Federal Supply Schedule (FSS) contracts--those for supplying articles or services at stated prices for a given period--in accordance with regulations prescribed by the GSA Administrator.

PHS operates a central supply organization at Perry Point, Maryland, which purchases, stocks and issues drugs to all PHS hospitals, clinics, and outpatient offices.

The following table summarizes operations of DPSC, VAMC, and PHS within their own agencies.

	<u>Number of drugs centrally managed</u>	<u>Number of depots where drugs are stocked</u>	<u>Number of medical facilities supported</u>	<u>Cost of fiscal year 1972 drug procurement</u>	<u>Drug inventory June 30, 1971</u>
	(millions)				
DPSC	1,100	6	1,672	\$95	\$59
VAMC	450	3	^a 182	37	^b 18
PHS	600	1	60	^c 9	.5

^aVA also sells centrally stocked drugs to other Government agencies and administers FSS contracts used by all agencies. In fiscal year 1972 VA sold about \$3.5 million worth of depot drugs to other Government agencies. VA services about 270 additional medical facilities in this way.

^bIncludes about \$9 million worth stored in VA field stations.

^cIncludes undetermined purchases from VA and DPSC.

The medical facilities supported by these agencies also buy drugs directly from manufacturers, under FSS contracts, and from local vendors. During fiscal year 1971 total drug purchases under FSS contracts totaled about \$64 million. The cost of local purchases could not be ascertained because of limitations in the reporting by medical facilities. (See ch. 4.) PHS obtains a large part of its drug requirements from, or under contractual arrangements made by, VAMC and DPSC.

PAST EFFORTS TO IMPROVE FEDERAL MANAGEMENT
OF MEDICAL MATERIAL

Between 1963 and 1971 DOD and GSA separately and with other interested Government agencies studied the possibility of a single agency's having Government-wide responsibility for managing various categories of supplies, including medical material which includes pharmaceuticals.

Late in 1964 GSA and DOD entered into an agreement governing the supply management functions and relationships between the two agencies. Essentially the agreement contemplated studies to develop a unified national supply system eliminating unnecessary duplication between military and civil agencies in five commodity areas, including medical material.

The study on medical material concluded that further review and evaluation was necessary. Further review was completed during 1969 and 1970, and in February 1971 GSA and DOD approved a new agreement governing their supply management relationships.

Under the new agreement, several Federal stock classes were assigned to GSA and DSA for integrated management. The agreement provides for joint development of plans for assigning, identifying, and subsequently transferring necessary resources, funds, and personnel. Although medical material is included among the commodities assigned to DSA for integrated management, that assignment has been deferred pending the outcome of still another study.

This new study, proposed in June 1971 by the Office of Management and Budget (OMB), recognized that, although several agencies purchase and use medical items and although studies were previously made, no decision regarding unified management or a national system was reached. OMB believed that a further investigation should be undertaken before a final decision could be made on the best means of providing medical support to all Federal agencies. To reach a decision OMB has set up a steering group composed of a representative from OMB and each of four agencies--VA, DSA, GSA, and HEW--to study the functions, organization, and management practices in all Federal agencies involved in medical supply. The study was started in January 1972, the OMB representative chaired the study group. A report on this study was expected in June 1973 but has not yet been issued

CHAPTER 2

GREATER COOPERATION AND COORDINATION

WOULD RESULT IN SIGNIFICANT SAVINGS

IN PROCURING DRUGS

Lack of coordination between the central buying agencies and certain restrictions on interagency transactions increase the costs of drugs to the Government. In reviews of a limited number of the procurements during a 3-year period, we identified (1) costs of about \$420,000 which could have been avoided through greater coordination between the procuring agencies and (2) price variances of \$447,000 on Government purchases of the same items. A substantial portion of the differences could have been avoided and lower prices realized through greater coordination.

Although DOD and VA have established policies of using the most economical supply sources and have prescribed priorities of supply sources to be followed by their medical facilities, they operate their drug procurement and supply systems largely independently of each other. Further, there is little exchange of requirements data or coordination in procurement, even though the agencies centrally buy and stock about 200 of the same drugs and one or the other often obtains a lower price for the same item.

DSA-VA SUPPLY AGREEMENT

DSA and VA have an agreement whereby VAMC can purchase from DPSC medical material which DPSC manages centrally. The agreement establishes the procedures for requirements planning, material requisitioning and release, billing and collection, and other matters.

VAMC does not use the agreement extensively; in fiscal year 1970 it purchased only about \$207,000 worth of drugs from DPSC. A drawback to more extensive use of the agreement is DPSC and VAMC surcharges which can total nearly 20 percent of the cost for drugs supplied to VA field stations. Also, the flow of drugs from DPSC depots or manufacturers to VAMC depots and then to VA field stations is cumbersome and results in extra handling and added transportation costs.

The agreement does not provide for DPSC to buy drugs from VAMC. We noted no procurements by DPSC from VAMC

Military medical facilities may not obtain from VAMC stocks those drugs which DPSC does not carry, and VA facilities may not buy from DPSC those drugs that VAMC does not carry. In these cases these medical facilities have to buy such drugs under the FSS contracts or directly from vendors at much higher prices than those available from the central buyers.

DEVELOPMENT OF REQUIREMENTS DATA FOR PROCUREMENT

When either DPSC or VAMC approves a drug for central management, it procures an estimated quantity to cover anticipated needs for a limited period. Thereafter, quantities to be procured are based primarily on the quantity issued by depots since the last inventory replenishment. Computer reports are prepared periodically--monthly by VAMC and quarterly by DPSC (more frequently if predetermined reorder points or critically low inventory positions are reached)--and reviewed to determine items for which procurement or other supply action should be taken. Both agencies try to maintain inventory levels representing a number of months' use--in VAMC 5 to 7 months' supply and in DPSC about 9 months' supply--plus any special requirements.

Quantities of each drug are purchased to replenish stocks and fill requisitions. DPSC includes unfilled orders in calculating its reorder points, but VAMC does not.

Procedures for developing requirements under each system are quite similar, and it appears that, to consolidate procurement, requirements data under the systems could be coordinated without difficulty.

POSSIBLE SAVINGS THROUGH JOINT PROCUREMENT

DPSC and VAMC independently purchased, at different prices, many of the same drugs for central stock--in many cases from the same manufacturer and at about the same time. Several manufacturers have told us that large-volume purchases will generally reduce prices.

If VAMC and DPSC cooperated, they could forecast their annual drug requirements; consolidate their procurements, providing for any special needs for such things as packaging, labeling, and inspection; and, under joint procurement arrangements, take advantage of the most economical methods of contracting and supply sources. Apparently, if their requirements had been consolidated and bought under joint procurement arrangements, VA and DPSC could have realized significant savings.

For example, procurement records for 43 drugs showed that, during fiscal years 1970 and 1971, DPSC and VAMC paid different prices for the same drugs purchased within 30 days of each other. These variances totaled about \$246,000, and each agency obtained the lower price in about half the cases.

We furnished information on these cases to DPSC and VAMC officials so that they could determine the reasons for the differences. Some vendors made voluntary refunds totaling \$15,000 to DPSC because of pricing mistakes they had made during negotiations. Other vendors claimed that the differences were due to the type of contract negotiated, the varying quantities ordered, the frequency of orders, special labeling and packaging requirements, or additional quality control and testing requirements. One vendor suggested to DPSC that it and VAMC combine their buys to obtain lower prices.

Because of the possibility of long-term storage and shipments to countries with extreme climates, DPSC generally requires more protective wrapping for the drugs it buys than other buyers do. Despite this, DPSC has often paid identical or lower prices than VAMC for the same drugs purchased in similar or smaller quantities in the same period.

We also examined the sales records of four manufacturers. DPSC and VAMC paid two of them \$91,000 additional because of different prices charged for the same items.

NEED TO PROMOTE INTERAGENCY TRANSACTIONS AT THE USER LEVEL

If drugs stocked by DPSC and VAMC could be made available to medical facilities of the system which does not stock such drugs, substantial savings could be realized. As shown

below, savings would result from eliminating buys through FSS contracts and buys directly from vendors at prices which, almost invariably, are substantially higher than those paid by central managers (See app I)

The military departments have not arranged for their activities to purchase from VAMC depots drugs not centrally managed by DPSC Also, VAMC has negotiated several special contracts which military and, in some cases, civil agencies cannot use. The prices under these contracts are lower than those for the same drugs sold under FSS contracts. VA field stations may not requisition directly from DPSC

Effects on medical facilities

When individual medical facilities cannot obtain their required drugs from central stocks because of interagency restrictions or impediments, they purchase them through FSS contracts or directly from vendors in relatively small quantities and usually at much higher prices. Following are examples of the additional costs incurred in such circumstances

1. From July 1970 to December 1971, military hospitals purchased macrodantin through FSS contracts for \$555,000 because DPSC did not stock it. At this time, VAMC was purchasing the item for central stock and paying about 48 percent of the FSS price. After allowing for VAMC's 8-percent surcharge, the hospitals would have saved about \$270,000 by purchasing the item from VAMC, which had procured it centrally in bulk quantities. After we brought this situation to DMMB's attention, it arranged for DPSC to centrally procure, stock, and manage this drug, and the prices negotiated were comparable to those negotiated by VAMC.
- 2 Sales records of purchases totaling about \$6.1 million made from four vendors during a recent 2-year period showed that the Government incurred over \$214,000 in excess costs because military and VA medical facilities bought many drugs directly from them or under FSS contracts at prices higher than those paid by DPSC and VAMC for the same drugs for central stock Even after allowing for DPSC and VA

surcharges--amounting to 10-1/2 percent and 8 percent, respectively--about \$150,000 would have been saved had the military and VA medical facilities purchased directly through DPSC or VA central supply points. For example, during calendar year 1970, VA field stations paid \$46.07 for an 8-ounce jar of Aristocort Cream under the FSS contract. DPSC stocked this item and could have supplied it for \$39.85 a jar, including all surcharges (18-1/2 percent), a savings of \$6.22 a jar. Total savings on this item alone during calendar year 1970 would have amounted to over \$4,600.

The need to promote interagency transactions extends to Government medical organizations other than those of VA and DOD. Our review at the four vendors' plants identified price variances of \$110,000 because PHS and the National Institutes of Health, HEW, purchased drugs directly from these vendors at prices higher than those paid by DPSC and VAMC for the same items.

Under the existing GSA and DOD agreement, DOD issued a catalog, effective October 1, 1972, of selected items managed by its Defense Supply Centers for the use of civil agencies. About 600 drugs are listed which any Government agency can order from the cognizant Defense Supply Centers. The catalog states that other DSA-managed items included in supply catalogs may also be requisitioned so long as a Federal stock number is provided and appropriate requisitioning procedures are followed.

This is a step toward fostering interagency transactions. However, use of the catalog is not mandatory, consequently, the agencies will not necessarily use it as an alternative to more expensive local purchases.

CONCLUSIONS

Substantial savings and other advantages could result from an effective joint effort--including planning, consolidating procurement, and centrally procuring and supplying drugs--among DPSC, VAMC, and other agencies that buy drugs. Coordination should also enable these agencies to improve inventory management and better serve medical facilities. Further, availability--under an interagency agreement--of the

VAMC and DPSC central supply stocks to all field facilities should reduce costly buys through FSS contracts and buys directly from vendors. Because central supply organizations supply drugs to other Federal agencies, as well as to the medical facilities they support, the overall benefits to the Government could be considerable.

To facilitate coordination, DPSC, VAMC, and other affected agencies may have to adjust their methods of determining requirements to insure that all work together with compatible supply levels and frequencies of review of inventory status. Contracts for procuring common drugs should include each agency's special requirements and delivery needs

OMB should resolve the question of the type of joint arrangements that should be made for buying the common items and should make the solution a matter of record, in a DPSC-VAMC agreement or in appropriate regulations, by clearly setting forth the arrangements and how they should be implemented. The objectives of the arrangements should include (1) the elimination of avoidable duplication between the DPSC and VAMC procurement and supply systems and those of other Federal agencies that buy, store, and supply drugs and (2) a management plan permitting DOD and VA medical facilities to order from each other's central stocks when this would be beneficial.

Such an agreement could be patterned after the existing DSA-VA agreement, which prescribes necessary funding and material-requisitioning arrangements. To obtain maximum benefit from interagency transactions, the agreement should provide that interagency purchases be mandatory, except in emergencies.

Procurement consolidation would be a good first step toward eliminating duplication in procurement. This, and making the supply services available to all agencies, should also improve supply support for medical activities.

RECOMMENDATIONS

We recommend that the Director, OMB, lead in developing--with GSA, DOD, HEW, and VA representatives--policies and procedures to provide greater coordination and cooperation among Federal agencies in buying drugs. These policies and procedures should include agreements between the parties

or appropriate regulations providing for (1) periodic determinations of the joint requirements of the agencies--and others they support--for individual drugs and (2) joint procurement arrangements so that the most advantageous prices can be negotiated with suppliers for bulk quantities, with specified quantities delivered during a specified period (or other bases) direct to agency facilities where the drugs will be used or to Government storage and redistribution depots.

Within this framework, provision could be made for special requirements of the agencies, such as the special packaging and specifications for longer shelf life sometimes required for items for military use. Field installations should be authorized, except in emergencies or other justifiable circumstances, to obtain their drug requirements from any centralized Government supply source.

AGENCY COMMENTS AND GAO EVALUATION

DOD cited its current agreements with VA, GSA, and other civilian agencies as evidence of its interest in fostering interagency cooperation and coordination in the best interest of the Government. DOD stated that

"Pending final resolution of this matter DOD is willing to discuss further arrangements to prevent purchases of an item by one agency when the item is available from stock of the other agency, and to obtain the most advantageous prices in the purchase of pharmaceutical drugs."

In its comments VA stated that

"We agree with the major recommendation that there should be greater cooperation and coordination among Federal agencies buying drugs. Since the actual items involved will be determined by the nature of the programs served and will reflect the differences in mission, the degree of standardization will be limited by those factors. However, this should not limit other advantages to the Government which would stem from a viable program of interchange of procurement and supply techniques, ideas, and innovations "

In commenting on this report, OMB stated that it generally agreed that significant improvements could be made and economies could be achieved in procuring, inspecting, storing, and supplying drugs. However, OMB questioned whether mere consolidation of DOD and VA drug requirements and joint procurement would insure economies. Further, both OMB and VA pointed out that the total economic costs of procuring, storing, and issuing drugs under central procurement and local procurement systems and their relative cost effectiveness should be determined and considered before arriving at a decision to centrally buy and stock drug items. OMB also pointed out that quantity was only one of the factors which influenced drug prices.

We agree with the concept of relative cost effectiveness based on total economic costs, but " * * * the Government has failed to develop the data and techniques needed to measure the 'total economic cost' of fulfilling a Government need "¹ Further, it appears that substantial time may elapse before such management data for selecting the most cost-effective supply system for drugs will become available. We also agree with the Commission on Government Procurement's view that local procurement should be used whenever it is found to be economically feasible.

Since total economic cost data is not expected to be available in the near future, we believe the Government should use those opportunities which, with current management data and methods of operating, seem to indicate economies and improvements.

We are advocating the joint procurement of consolidated requirements, which does not necessarily include central storage and reissue. The decision whether or not to centrally stock drug items should be made on an item-by-item basis after considering all cost factors. Deliveries could be made direct to users, as is often done under centrally procured requirements-type contracts, thus obviating storage and related costs.

¹"Report of the Commission on Government Procurement," vol 3 (Dec 1972), p 65.

We agree with OMB that quantity is not the only factor that affects the prices the Government pays for drugs. However, we believe that ordinarily it is a major factor, as evidenced by the differences in prices paid for the same drugs bought in relatively small quantities under FSS contracts or local procurements and those paid by a central procuring organization for large definite quantity contracts (See app I) Our analysis of the prices paid for 68 drug items showed that the FSS prices for 29 items were from 5 to 366 percent higher than the definite-quantity-contract price Also, in a study (B-164031(2), Nov 22, 1972) comparing prices paid for the same drug items by DPSC and VA with those paid by nonprofit organizations that buy drugs on a group basis for private hospitals, we found that the Government paid lower prices for 28 of the 31 leading drug items which these organizations and the Government bought The Government bought substantially larger quantities of 25 of these drug items We believe this undoubtedly had some effect on the prices paid

OMB stated that the preferable approach would be to combine the best aspects of each existing procurement system into one system We do not disagree, however, as stated on page 7, the possibility of a single system has been under consideration since 1963 without result We believe that, until a viable single system is designed, actions in line with our recommendations would improve the existing drug procurement and supply operations

CHAPTER 3

BENEFITS OF SPECIFICATIONS AND CENTRAL MANAGEMENT IN PROCURING DRUGS

Efficient procurement and management of drugs depend largely on obtaining effective competition and sound policies for approving items that warrant central management. VA has improved its drug procurement by increasing the number of specifications available for procurement personnel to use in obtaining competition for VA's requirements. DOD could save more in procuring drugs by revising its policy for adopting items for central management.

DEVELOPING SPECIFICATIONS

VAMC and DPSC prepare drug specifications for procurement personnel to use in advising potential suppliers of the characteristics that drugs must meet and to generate competition for the Government's requirements. In many cases, however, due to patents or regulatory restrictions on the products the Government requires, procurement is limited to a single source.

However, our comparison of central procurements of 13 drugs by competition based on specifications and on a sole-source basis demonstrates the advantages of seeking broad competition. During a 2-year period lower average prices were obtained on 11 of these items when they were obtained competitively, and we estimated the Government would have saved about \$338,700 on these 11 items had they been bought competitively in all instances. The quantities purchased by each method were different. This probably accounts for some of the price variation, but the primary reason seemed to be competition.

Preparing specifications can be difficult. For instance, the data for writing them is ordinarily obtainable only from manufacturers. Sometimes the manufacturers furnish incomplete information or none at all, especially for proprietary items, because they recognize that disseminating complete and accurate data in specifications will probably result in greater competition for Government, and possibly commercial, requirements for their drugs.

A further difficulty concerns data for formulating a drug. Even when the proper ingredients and quantities to be used are known, a product having a therapeutic effect different from that desired may be manufactured.

Thus, because of inadequate or incomplete data or the existence of patents, specifications are issued for many drugs that the Government buys which do not increase competition. Frequently, only one source can provide what the Government wants.

The degree of competition obtained in procuring drugs is less than that obtained for many other Government supply items. In fiscal year 1970 only about 7 percent of VAMC and DPSC dollar procurements for central stocks were made under formal advertised procedures. Much of the balance was procured under contracts negotiated with the sole source of supply or under contracts negotiated and awarded after proposals were solicited.

The primary reasons for the lack of competition are the large number of patented drugs and the Food and Drug Administration's (FDA's) requirements for approving drugs for manufacture. Some manufacturers have difficulty meeting these requirements because of the technical requirements and costs involved.

AVAILABILITY AND USE OF SPECIFICATIONS

DPSC generally will not approve a drug for central management unless (1) data sufficient to develop a competitive procurement specification is available or (2) all three military services concur in designating a single procurement source. Consequently DPSC has prepared specifications for nearly all the 1,100 drugs it manages. Only 1 percent of these items are intentionally bought noncompetitively from preselected sources.

Although DPSC attempts to buy competitively virtually all the drugs it manages, it has been successful only for about 51 percent of 1,100 items and the degree of competition on many of them is quite limited. The remainder, about 535 items, is supplied by single sources. FDA regulations, which disallow marketing without approved new drug applications or antibiotic certificates, or patents preclude or

restrict competition for 386 of these. But no apparent laws or regulations preclude interested firms from bidding for the remaining 149 drugs.

Thus, although DPSC has developed specifications for virtually all the 1,100 items, it has obtained competition for only about half of them. The specifications on the remainder, although not necessarily generating competition, do define what is wanted and minimize misunderstanding and contractor failure to satisfy Government requirements. DOD considers this benefit of specifications to be significant. It further believes that specifications should be developed in restricted competitive procurement so that DOD will be ready to go into the competitive market when a patent expires, when it legally buys around a patent, or when additional manufacturers conform to the regulations for manufacturing a drug.

Before October 1970 VA generally bought its required drugs on a brand-name basis and did not develop specifications for drugs it bought on a sole-source basis.

At that time about 70 percent of the drugs VA centrally stocked were designated for sole-source procurement to obtain specified brand-name drugs. Also, a large percentage of FSS contracts were for making manufacturers' product lines available to the Government at less than market prices. However, these contracts were negotiated without specifications or competition.

At that time also, VA ordinarily developed specifications only when the demand for a generic drug was sufficient to warrant central management or for drugs for which no patents existed or the patents had expired. Generally this meant that procurement was made from preselected sources which obviated the need for specifications.

In October 1970, however, VA began to develop specifications for 110 of the 450 drugs it managed centrally, for which it considered competition feasible. This effort has primarily consisted of obtaining industry comments on DPSC specifications which VA has rewritten as proposed VA specifications. After suggested revisions were considered, the specifications were written in final form.

On June 21, 1972, VA officials testified before the Subcommittee on Monopoly, Senate Select Committee on Small Business, concerning VA efforts to expand competitive procurement of its centrally managed drugs. VA indicated that it had developed specifications for 85 of 133 items it had determined suitable for competitive procurement and that specifications for 34 of the items were being developed. VA officials stated that 14 of the 133 items were being deleted and that, although it was too early to establish the total potential savings, annual savings of almost \$940,000 had resulted from using the 85 specifications that had been issued as of June 1972.

COORDINATION POTENTIAL IN DEVELOPING SPECIFICATIONS

Several Government agencies buy many of the same drugs, and, as new drugs are developed and adopted for use, this number should increase. As previously indicated, specifications are extremely beneficial in obtaining competition and drugs that conform to required quality standards.

VA and DPSC are not required to coordinate in preparing specifications for identical or nearly identical drugs they both manage centrally. This situation leaves potential for duplicate effort in preparing specifications (1) for new items for which neither organization has yet prepared specifications and (2) for those items currently managed centrally by VAMC without specifications if VAMC decides it can, and should, issue specifications for such items and if DOD also decides to use and centrally manage the same items.

When identical and near-identical items are adopted for central management, DPSC and VAMC, and possibly other agencies, should jointly develop specifications for such items to avoid possible duplicate effort and to make the best possible use of the available talent to do this important work.

NEED TO REVISE DOD POLICY FOR ADOPTING ITEMS FOR CENTRAL MANAGEMENT

In considering an item for central management, DMMB requests the manufacturer to furnish information on the item's essential characteristics. DPSC evaluates this

information to determine whether it can prepare a specification. DMMB's policy provides that an item not be adopted for central management unless (1) data sufficient to develop acceptable specifications is available or (2) all three military services concur in designating a single procurement source. Substantial costs were incurred because of this policy.

The macrodantin case (see p. 11) illustrates the effect of this policy. In June 1969 the Air Force proposed this drug for central management. The Navy concurred, but the Army did not because it considered satisfactory a similar drug which was centrally managed. The brand-name manufacturer of the proposed items refused to provide technical data, and, because specifications could not be developed, the Air Force and Navy withdrew their recommendations.

Without concurrence by all three services, DMMB did not adopt the item for central management on a sole-source basis. Consequently, military activities continued to purchase it under the FSS contract, and during the 18 months from July 1, 1970, through December 31, 1971, they purchased \$555,000 worth of the drug. During this time VAMC was purchasing the drug for its central stocks at less than half the FSS price. Had the military adopted the item for central management, military medical activities could have saved about \$291,000, assuming the purchases could have been made at the same price VA paid.

We brought this matter to DMMB's attention in March 1971, and after DMMB concurred it authorized DPSC in July 1971 to centrally manage and procure the item on a sole-source basis. The first contract was awarded in December 1971

CONCLUSIONS

Substantial savings resulted from VA's expanded use of specifications in procuring its centrally managed items. Savings should continue if specifications are developed to the extent practicable and beneficial on new items and on those centrally managed items for which specifications have not been prepared. DOD could also realize substantial savings by revising its policy for adopting items for central management. Further, since many drugs Federal agencies use

for which DOD and VA prepare specifications are basically the same and since the number of such items should increase, VA and DOD could cooperate in preparing specifications for such drugs. Such cooperation would avoid duplicate effort and best use technical talent in preparing specifications.

RECOMMENDATIONS

We recommend that the VA Administrator arrange, as soon as practicable and beneficial, for specifications to be developed for (1) all new items which VA decides to manage centrally and (2) centrally managed items for which it currently has no specifications.

Also, since cooperation and coordination can be valuable in developing specifications, we further recommend that the Secretary of Defense and the Administrator consider jointly developing specifications which will satisfy all agencies' requirements. The effort should consider the requirements of all Federal agencies which procure drugs so that specifications will be issued, when possible, for those items for which the aggregate quantity required justifies central management.

We recommend that the Secretary of Defense revise DOD policy to insure that drugs will be adopted for central management whenever savings will result. Controls on sole-source drugs will be necessary to (1) insure that the sole-source designation is not misused, (2) insure that specifications are developed as soon as possible, and (3) encourage, when appropriate, the use of lower cost alternative drugs.

AGENCY COMMENTS AND GAO EVALUATION

VA stated that it considered joint development or mutual use of specifications an important element of the increased agency cooperation advocated in our report. It did not, however, comment on the need to develop specifications for some of the items it currently manages centrally and for new items it selects to manage centrally in the future.

DOD stated that DMMB would be specifically asked to coordinate the development of specifications with DSA and VA and to recommend appropriate action providing for the " * * * joint coordination/preparation of medical material having common usage within DOD and VA "

Regarding the recommendation that DOD revise its policy for adopting items for central management, DOD stated that, in addition to monetary savings, decisions were based on such factors as drug efficacy and storage requirements. However, it said that it would review the criteria and the standardization procedure used for adopting items for central management.

Although DOD policy provides for central procurement when savings apparently will result, the policy can be nullified by the requirement that the three military services concur in a sole-source designation. We believe that DOD should evaluate this requirement in its review of the standardization and procedures.

CHAPTER 4

UNIFORM REPORTING AND MORE EFFECTIVE USE OF RELATED REPORTS WOULD IMPROVE SELECTION OF ITEMS FOR CENTRAL MANAGEMENT

The primary method of identifying drugs for possible DPSC and VAMC central management is reviewing field activities' reports of purchases from FSS contracts and local suppliers. Each military service has a different system for reporting medical items purchased locally, and neither DMMB nor DPSC reviews these reports. VAMC reports local procurements, but its voluminous reports contain many errors and no summary. VAMC could use these reports more effectively.

MILITARY DEPARTMENT REPORTS

The following table summarizes pertinent aspects of the systems the military services use to obtain data from their medical facilities on procuring medical items, including drugs.

	<u>Number of medical facilities reporting</u>	<u>Frequency of reporting</u>	<u>Medical items required</u>
Army	19	Semi- annually	Those on which expenditures totaled \$1,000 or more
Navy	93	Quarterly	Those accounting for the highest expenditures during the reporting period. The number ranges from 10 to 50, depending on the reporting facility, but at least 50 percent must be drugs.
Air Force	26	Semi- annually	Those representing the top 15 items purchased with locally assigned stock numbers
Air Force	70	Semi- annually	Those listed in a special catalog of non-centrally stocked medical material

These reports are sent to field offices which organize the data and consolidate the reports for each service, but the field offices do not review and evaluate the items reported. The offices of the respective Surgeons General that select and recommend items to DMMB for centralized management make such reviews and evaluations. No single authority reviewed all of these reports at the time of our review, but a DOD official advised us that, after we examined this situation, arrangements were made for all the military departments to send their consolidated reports to DMMB for its review and use in evaluating new items for standardization.

The Army and Navy Surgeons General have no written definitive criteria for evaluating and selecting drugs to be recommended for central management. The Army, however, does have a written procedure stating that reports of local purchases will be reviewed to identify items used in sufficient quantity to warrant central management, but what constitutes such a quantity is not defined.

The Air Force has definitive written criteria for identifying drugs as candidates for central management. Generally the Air Force considers recommending items purchased by three or more facilities which have aggregate semiannual expenditures exceeding \$1,000.

The Army's and the Navy's lack of these definitive criteria can result in failure to identify drugs purchased by their medical facilities in sufficient quantities to warrant DMMB evaluation. For example, Army and Navy medical organizations may purchase a drug exceeding \$1,000 in value and the item may not be considered for central management, whereas, in similar circumstances, the Air Force normally considers the item for central management. Also, reports do not include purchases of centrally managed items from sources other than the central manager. The services could use this information to monitor field activities to insure that they were purchasing such drug items from DPSC as prescribed by service regulations.

VA REPORTS

Under authority GSA delegated in 1960, VA awards and administers FSS contracts and obtains semiannual reports

from vendors on the volume of drugs they have sold Federal agencies under (1) advertised contracts and (2) negotiated FSS contracts.

VA requires its field stations to report all local purchases of drugs to the VA Data Processing Center, Austin, Texas, which lists the data in the quarterly Drug Acquisition Report. This report is sent to VAMC for review and evaluation to determine whether the field stations are (1) purchasing locally drugs which could be supplied more economically if they were available in depot stocks or (2) purchasing in ways VAMC previously designated, such as from depot stocks, through special contracts providing for decentralized procurement and through FSS contracts.

VA's basic criterion for considering whether a drug should be centrally stocked is that local purchases should amount to \$10,000 or more a year. All items that qualify under the criterion are not assured of being considered. In part, this is due to (1) the sheer volume of the Drug Acquisition Report--approximately 120,000 transactions listed on 4,500 pages, (2) the lack of item summaries and exception data, and (3) errors and inconsistencies due to VA field stations' failure to adhere to prescribed reporting requirements. One individual reviews the report.

To test the report's effectiveness, we had to devise a special computer program to isolate and summarize purchase data on potential candidates for central management. This test covered the reports for September 1970 through May 1971 and revealed 273 items which were not being centrally stocked although they satisfied the local purchase criterion. VA officials explained that 219 of the items were inappropriate for central stocking because some needed refrigeration, some were blood derivatives, and different intravenous systems required various types and sizes of intravenous solutions. VA officials said that, of the remaining 54 items, 24 were already being studied for central stocking and 30 would be considered.

In September 1972 VA officials informed us that, of the 30 items, 8 had not been selected for central stocking for such reasons as declining purchases, insufficient price break for bulk procurement, and the delay in waiting for FDA efficacy determinations. Of the remaining items, 9 were still being studied and 13 had been or were being centrally

stocked. Of the 13 items, 5 had been centrally purchased, VA forecasted savings of almost \$36,000 for fiscal year 1973 on these items.

FSS contracts for pharmaceuticals are let in two sections and are labeled section A and section B contracts. Section A contracts are generally used for generic items and section B contracts for brand-name items. Section A contracts ordinarily are let for individual drugs, but section B contracts generally are let for the complete product lines that drug manufacturers produce.

The reports to be submitted by FSS contractors on section A contracts are useful to VA in considering items for central management because VA needs information on individual items in determining whether the volume of procurement of single items warrants consideration for central management. The reports on section B contracts are generally not usable because they relate to a complete product line.

Some contractors were not furnishing the reports of orders received, contrary to contract requirements. To the extent the reports are not received, the volume of purchases Federal agencies make is understated, therefore, drugs that qualify may not be identified or considered for central procurement. Also, the lack of usable data submitted in reports on a product-line basis under section B contracts could result in failure to identify items with potential for substantial savings through central management.

NEED FOR STANDARDIZED CODING SYSTEM

Under current reporting practices of both VA and military medical facilities, reports may include data for drugs under identification methods when an item does not have a Federal stock number. For such items the manufacturer's number, the hospital's number, or other types of identification are used.

In such a situation, purchase data on the same item may possibly be reported in two or more ways and the fact that the same drug is involved may be overlooked. If such purchase data is not consolidated, potential items for central management may be bypassed. A national drug code

number has been assigned to every drug, and these numbers could be used when a Federal supply number has not been assigned.

CONCLUSIONS

Both the military services' and VA's reporting systems for local purchases have weaknesses. Specifically, the lack of uniform reporting, the lack of evaluation criteria, the failure to evaluate many items that qualify for consideration for central management, and omissions from the local purchase reports suggest that many items that should be centrally managed are not and are therefore being procured locally at unnecessarily high prices.

To implement its stated policy of buying from the most economical source, DOD should establish a uniform reporting system for local drug purchases, including centralized review and evaluation of the reports of all the services, probably by DPSC. Candidates for central procurement should be recommended to DMMB.

RECOMMENDATIONS

We therefore recommend that the Secretary of Defense have DMMB:

- Develop, for reporting local drug purchases, a uniform system aimed at requiring all activities which made specified total dollar purchases of individual drugs during the reporting period to report their purchases.
- Require that centrally managed drugs purchased from other than the central manager be reported.

Although the basic concept of VA's Drug Acquisition Report is sound, it could be more effectively used. We therefore recommend that the Administrator, VA, require (1) the Central Office Supply Service to prepare lists of summary and exception data from the information reported and (2) local field stations to report their purchase data correctly and consistently. Further, we recommend that the Administrator see that vendors report their sales under FSS contracts on an individual-item basis when this is required by such contracts and, when not required, negotiate such

requirements into future FSS contracts when reasonable and practicable.

We also recommend that DOD and VA, to improve reporting, consider using a standardized coding system, such as the National Drug Code, for identifying, in their reports of local purchases, those drugs which do not have Federal stock numbers. This would avoid the possibility under current procedures of either the manufacturer's or possibly some other identification number's being used for a particular drug. In this case data relating to identical items may not be recognized, and as a result, potential items for central management may be overlooked.

AGENCY COMMENTS

DOD stated that all military departments now submit consolidated reports to DMMB for its review and use in evaluating new items for standardization action.

DOD stated also that one of its objectives was a uniform reporting system incorporating the points in our recommendation. However, it considers near-term achievement impracticable and too costly because of the differing systems. DOD further stated that action would be taken to insure that each military department followed standard reporting criteria and that, as soon as practicable and cost effective, a uniform reporting system for all local purchases of pharmaceuticals would be implemented.

VA acknowledged the need for the recommended improvements in its reporting system on field station drug purchases but did not comment on our recommendation to use a standardized drug coding system. DOD stated that it had been considering using the National Drug Code. There has been coordination among the military departments, DSA, and FDA. The intent is to implement either the National Drug Code or a comparable system which will facilitate consolidation of purchase data on pharmaceuticals.

CHAPTER 5

OVERLAPPING QUALITY ASSURANCE ACTIVITIES

AND OBSTACLES TO ELIMINATING THEM

FDA monitors the manufacturing practices and conditions under which drugs are made by inspecting the plants of drug firms, reviewing their quality assurance controls, and testing product samples. Under the Food, Drug, and Cosmetic Act (21 U.S.C. 301), antibiotics, insulin, and certain veterinary drugs may not be marketed until FDA has tested each batch for strength, quality, and purity and has issued individual certificates of approval to the manufacturer. For all other drugs, FDA periodically tests products through surveillance sampling programs to insure that the items meet the purity, strength, and identity standards provided in the act.

DPSC and VAMC also operate quality assurance programs to insure that the drugs they buy are acceptable in purity, safety, strength, and other considerations. These programs differ both in qualifying manufacturers as supply sources for drugs and in procedures for insuring that the respective supply systems accept only quality products.

In these circumstances, two or all three agencies could be conducting quality assurance inspections simultaneously at the same plant.

DIFFERENCES IN APPROVING FIRMS TO SUPPLY DRUGS AND IN INSPECTING PRODUCTS

Qualification of suppliers

The DPSC quality assurance program includes evaluating the contractor's ability to supply each required drug. This is done by surveying manufacturing plants and by testing product samples before awarding contracts.

Preaward plant surveys and preaward samples are generally required when a firm's ability to manufacture a specific drug is unknown or a doubt exists about the firm's quality control, housekeeping procedures, or financial position. A manufacturer may be disqualified for failing to satisfy certain requirements of quality control, housekeeping, acceptability of subcontractors, plant capacity, or

financial condition, but the disqualification pertains only for the specific procurement for which the manufacturer failed to meet DPSC requirements. A satisfactory plant inspection or demonstrated ability to manufacture a specific item is not a prerequisite for being placed on the the DPSC bidders list.

Unlike DPSC, VAMC requires that a plant survey or inspection be made of each prospective supplier before it can be placed on the list of approved suppliers for VA contracts, including FSS contracts. Reinspections are made approximately every 5 years, unless required sooner because of customer complaints or other problems.

DPSC and VAMC inspection procedures use standards for manufacturing and processing drugs patterned on the Good Manufacturing Practices published by FDA. However, although VA and FDA standards are essentially the same, DPSC standards are more specific. For example, FDA and VA personnel standards require that persons who direct the manufacture and control of a drug be adequate in number, education, training, and experience to insure that the drug has the safety, identity, strength, quality, and purity that it purports to possess. DPSC standards go further and set specific personnel requirements, qualifications, and responsibilities.

The following table summarizes the results, during fiscal years 1969 through 1971, of preaward surveys by DPSC and plant inspections by VAMC to qualify suppliers for their bidders list.

	DPSC		VAMC	
	<u>Number</u>	<u>Percent</u>	<u>Number</u>	<u>Percent</u>
Qualified	238	53	265	76
Disqualified	<u>213</u>	<u>47</u>	<u>84</u>	<u>24</u>
	<u>451</u>	<u>100</u>	<u>349</u>	<u>100</u>

DPSC disqualifies more manufacturers partially because of its policy of surveying individual products, which may result in disqualifying a firm only for one item being purchased

Product inspections

After a contract has been awarded, DSA, through the Defense Contract Administration Services, monitors the quality of products being bought by inspecting the contractor's plant during the contract period. This quality assurance concept is designed to determine, before supplies are accepted, that the contractor has fully complied with contractual requirements for product quality.

Detailed instructions give procedures for the Quality Assurance Representatives to follow in inspecting products. Basically, they must review the contractor's manufacturing and testing procedures and verify that control of manufacturing processes is adequate and that deficiencies are corrected. The inspections are performed on a lot-by-lot basis using statistically selected samples. Deficiencies are reported to the contractor. During fiscal year 1971, 67 deficiency reports were issued, copies were sent to FDA.

In contrast to the DSA product inspection system, VAMC requires that items purchased for depot stockage be inspected after receipt in the depot but before Government acceptance. FDA performs these inspections on a cost-reimbursable basis, and they are required for each lot of generic drugs purchased but for only one lot of each brand-name product purchased during the year. Items purchased through FSS contracts are not subjected to any Government inspections other than those normally performed by FDA under the Food, Drug, and Cosmetic Act.

During fiscal years 1969 through 1971, FDA tested for VAMC 544 brand-name drugs and 1,882 generic lots of drugs furnished by commercial suppliers. FDA rejected 78 lots (all generic drugs), or 3.2 percent of all lots inspected.

OBSTACLES TO ELIMINATING OVERLAPPING QUALITY ASSURANCE ACTIVITIES

We discussed the overlapping DOD, VA, and FDA quality assurance efforts with responsible officials. The officials indicated that they were prepared to consider a centralized quality assurance program under FDA direction.

Officials of DOD and VA have reservations, however, and stated that it would be imperative that such a program (1) be at least as effective as their present programs and (2) fully recognize the agencies' special requirements, for example, shelf life and packaging of items for military use.

The FDA Commissioner testified on January 19, 1971, before the Subcommittee on Monopoly, Senate Select Committee on Small Business, that drug inspection by three Federal agencies was duplicative and that the resources used by other agencies for drug inspection should be allocated to FDA.

CONCLUSIONS

The present DSA, VA, and FDA drug inspection systems are not as efficient as they could be, because several Federal agencies survey the plants and inspect the products of the same vendors and sometimes the same items. Also the agencies differ in their degrees of inspection for both plants and products.

DSA makes preaward surveys and in-plant product inspections for the majority of the drugs bought for military use--those items that are centrally managed. However, military hospitals make substantial procurements commercially, either under FSS contracts or from local vendors, of which no inspections are made, other than those by FDA. VA augments FDA inspection to a lesser degree than DSA does and still seems to obtain satisfactory results.

RECOMMENDATION

Advantages should stem from having a single agency responsible for quality assurance activities pertaining to purchases of drugs by Federal agencies. Since FDA has statutory responsibilities pertaining to the manufacture of drugs, it seems to be the logical choice for this centralized responsibility. The additional responsibility should facilitate the performance of its other responsibilities relating to drug manufacturers.

Accordingly, we recommended that the Secretary of HEW, the Secretary of Defense, and the Administrator, VA, review the frequency and type of inspections required and the related staffing, organization, and administration changes

that would be needed to facilitate the transfer to FDA of all quality assurance responsibilities pertaining to purchases of drugs by Federal agencies.

AGENCY COMMENTS

DOD doubted FDA's capability to perform the types of inspections it requires.

VA stated that it would use the service when FDA was capable of performing inspections on a timely basis. HEW stated that it would discuss the requirements, resources needed, and pertinent issues for carrying out our recommendation with the interested agencies, and, if it found that it would be in the best interests of the Government, it would take the necessary actions to arrange for the transfer to FDA of all quality assurance responsibilities pertaining to purchases of drugs by Federal agencies.

We believe there is a demonstrated need for serious consideration of transferring drug procurement quality assurance inspection activities to FDA. Although discussions of requirements, resources needed, and pertinent issues are a first and important step, we believe that such discussions should be held with the objective of exploring alternatives that, if proven feasible, would facilitate the transfer to FDA.

CHAPTER 6

SCOPE OF REVIEW

We limited our review primarily to pharmaceuticals and did not include medical equipment and other supplies. We:

- Reviewed the direct procurement of drugs by Federal agencies.
- Compared selected aspects of the procurement and supply systems of DSA and VA--the two major buyers and suppliers of drugs to Federal medical facilities.
- Evaluated DSA and VA procurement philosophies and practices and determined the extent of interagency coordination and its effect on drug prices paid.
- Reviewed laws and other authorities which control or influence the manufacture, inspection, and sale of drugs.
- Reviewed pertinent policies, procedures, and practices and talked with representatives of organizations involved directly or indirectly in Federal drug procurement.
- Examined records and transactions concerning the matters reviewed

The organizations we visited or with whose officials we talked were:

DOD.

DMMB, Washington, D C.

Department of the Army.

Office of the Surgeon General, Washington, D.C.

U.S. Army Medical Materiel Agency, Phoenixville, Pa.

Walson Army Hospital, Fort Dix, N.J.

Department of the Navy.

Bureau of Medicine and Surgery, Washington, D.C.

Bureau of Medicine and Surgery, Field Branch, Philadelphia, Pa.

U S. Naval Hospital, Philadelphia, Pa

Department of the Air Force:

Office of the Surgeon General, Washington, D.C.
Medical Materiel Field Office, Phoenixville, Pa.
Malcolm Grow United States Air Force Medical
Center, Andrews Air Force Base, Washington,
D.C

DSA

Headquarters, Cameron Station, Alexandria, Va.
Defense Personnel Support Center, Philadelphia,
Pa

VA

Department of Medicine and Surgery, Washington, D.C.
VAMC, Hines, Ill.
Veterans Administration Hospital, Washington, D.C
Veterans Administration Hospital, Hines, Ill.

OTHER ORGANIZATIONS·

Committee on National Formulary, Washington, D C.
(prepares the National Formulary drug compendia)
Committee of Revision, The United States Pharmaco-
peial Convention, Inc., Washington, D.C. (prepares
the U.S. Pharmacopeial drug compendia)

HEW·

Social Security Administration, Washington, D.C
FDA, Rockville, Md.

GSA.

Federal Supply Service
Arlington, Va.
OMB, Washington, D.C.

We also visited (1) four pharmaceutical firms and exam-
ined their records of sales to Federal agencies, to evaluate
the agencies' procurement practices, and (2) three private
hospitals, to discuss their drug selection, drug procurement,
and quality control procedures.

COMPARISON OF HIGHEST PRICE PAID UNDER
DEFINITE-QUANTITY CONTRACT BY VA OR DPSC WITH THE
FSS PRICE FOR DRUGS, MARCH 1968 TO DECEMBER 1969

	Definite-quantity contract		FSS price	Difference	
	Buying agency	Highest price		Amount	Percent
Psyllium hydrophilic mucilloid with dextrose 6505-050-4567	VA	\$ 0 87	\$ 2 22	\$ 1 35	155
Carisoprodol tablets 6505-062-4833	DPSC	3 79	6 60	2 81	61
Isoproterenol hydrochloride (HCL) and phenylephrine 6505-071-7861	DPSC	2 10	2 64	54	26
Chlorthalidone tablets 6505-074-9914	DPSC	4 19	4 38	19	5
Quinidine sulfate tablets 6505-138-7400	DPSC	1 96	2 50	54	28
Tripeleminamine HCL tablets 6505-148-9000	VA	6 32	22 41	16 09	254
Chloramphenicol capsules 6505-160-0495	VA	5 41	8 03	2 62	48
Prednisolone tablets 6505-559-6734	DPSC	5 69	10 00	4 31	77
Phenazopyridine HCL tablets 6505-582-5344	VA	32 16	39 84	7 68	24
Sodium diphenylhydantoin capsules 6505-584-2338	VA	2 89	4 65	1 76	61
Pentaerythritol tetranitrate tablets 6505-584-4297	VA	9 05	12 45	3 40	38
Pentaerythritol tetranitrate tablets 6505-597-7341	VA	4 72	8 30	3 58	76
Potassium phenoxymethyl penicillin tablets 6505-656-1612	DPSC	1 60	7 46	5 86	366
Sodium aminobenzoate, sodium salicylate and ascorbic acid 6505-660-1746	VA	7 49	8 81	1 32	17
Pentaerythritol tetranitrate tablets 6505-680-2326	DPSC	15 36	24 90	9 54	62
Nitrofurantoin tablets 6505-685-1972	VA	75 54	180 00	104 46	138
Ethioleptazine citrate and aspirin tablets 6505-687-7901	DPSC	14 71	20 50	5 79	39
Propoxyphene HCL capsules 6505-725-6992	DPSC	6 45	13 62	7 17	111
Phenelzine sulfate tablets 6505-753-9702	VA	3 11	3 98	87	28
Theophylline ephedrine HCL and phenobarbital tablets 6505-753-4766	VA	8 61	23 74	14 13	147
Povidone-iodine solution 6505-754-0374	DPSC	9 86	9 90	04	-
Ampicillin capsules 6505-770-8343	DPSC	5 40	10 45	5 05	93
Methocarbamol and aspirin tablets 6505-775-5708	DPSC	18 47	21 00	2 53	14
Propoxyphene HCL, aspirin, caffeine and phenacetin 6505-784-4976	DPSC	12 75	28 97	16 22	128
Chlorpropamide tablets 6505-817-2279	DPSC	12 39	17 28	4 89	39
Imipramine HCL tablets 6505-853 4799	DPSC	4 47	4 81	34	8
Erythromycin estolate capsules 6505-890-1388	DPSC	3 43	14 98	11 55	308
Sodium phosphate and sodium citrate solution	DPSC	28	30	02	7

	Definite-quantity contract		FSS price	Difference	
	Buying agency	Highest price		Amount	Percent
Sodium coliatimethate for injection 6505-890-1582	VA	\$ 3 51	\$ 5 23	\$ 1 72	50
Carisoprodol tablets 6505-904-3256	VA	4 65	6 40	1 75	37
Dexbrompheniramine maleate and pseudo- ephedrine sulfate tablets 6505-926-9019	DPSC	3 82	6 00	2 18	57
Propoxyphene HCL capsules 6505-458-2364	DPSC	12 38	27 79	15 41	124
Nystatin, gramicidine, neomycin sulfate and triameinolone 6505-961-5504	VA	1 70	2 05	35	21
Butalbital, aspirin, caffeine and phenacetin tablets 6505-962-4375	DPSC	8 58	16 40	7 82	91
Propoxyphene HCL, aspirin, caffeine and phenacetin 6505-967-8735	DPSC	6 82	15 92	9 10	133
Isoproterenol sulfate inhalation, nonaqueous 6505-023-6481	DPSC	1 23	1 68	45	37
Guanethidine sulfate tablets 6505-062-4829	DPSC	6 23	7 84	1 61	26
Triamcinolone acetonide cream 6505-064-3940	DPSC	39 20	48 00	8 80	23
Glyceryl guaiacolate syrup 6505-064-8765	VA	35	53	18	51
Isosorbide dinitrate tablets 6505-072-9346	DPSC	2 03	2 80	77	38
Glyceryl guaiacolate syrup 6505-079-6269	VA	11 99	15 04	3 05	25
Nitrofurazone ointment 6505-130-1960	VA	2 28	5 10	2 82	124
Neomycin sulfate powder 6505-299-9527	VA	48	90	42	88
Dibucaine ointment 6505-299-9535	VA	22	52	30	136
Test paper and color chart 6505-559-6859	DPSC	81	1 10	29	36
Diphenhydramine HCL capsules 6505-582-4868	VA	2 94	7 22	4 28	146
Propantheline bromide tablets	DPSC	14 10	36 00	21 90	155
Promethazine HCL injection 6505-584-3280	DPSC	63	1 00	37	59
Perphenazine tablets 6505-584-3669	DPSC	17 15	27 87	10 72	63
Acetone test tablets 6505-616-7861	DPSC	1 48	1 67	19	13
Chlorpheniramine maleate tablets 6505-655-8460	VA	7 02	27 90	20 88	297
Senna pad extract tablets 6505-656-1468	DPSC	1 27	1 70	43	34
Triamcinolone acetonide cream 6505-682-8194	DPSC	86	1 52	66	183
Meglumine diatrizoate injection 6505-734-0658	VA	1 31	1 81	50	38
Simethicone aluminum hydroxide gel 6505-735-1742	DPSC	80	1 10	30	37
Isosorbide dinitrate tablets 6505-761-1506	DPSC	11 21	15 46	4 25	38
Dipyridamole tablets 6505-764-9014	DPSC	42 93	49 68	6 75	16
Acetylcysteine solution 6505-767-9111	DPSC	4 38	5 60	1 22	28
Isosorbide dinitrate tablets 6505-781-3111	DPSC	6 04	8 33	2 29	38
Oxyphenbutazone tablets 6505 786-8747	DPSC	42 29	49 68	7 39	17
Bisacodyl tablets 6505 889-9034	DPSC	21 98	25 92	3 94	18

	Definite-quantity contract		FSS price	Difference	
	Buying agency	Highest price		Amount	Percent
Isoxsuprine HCL tablets 6505-890-1321	DPSC	\$ 29 99	\$ 42 91	\$ 12 92	43
Flurandrenalone cream 6505-890-1554	VA	98	1 25	27	28
Diocetyl calcium sulfosuccinate capsules 6505-890-1627	VA	32 65	44 80	12 15	37
Fluocinolone acetonide cream 6505-905-9041	VA	24 00	30 60	6 60	28
Sodium ampicillin for injection 6505-946-4700	DPSC	37	1 10	73	197
Methenamine mandelate tablets 6505-982-5429	DPSC	3 48	4 65	1 17	34
Fluocinolone acetonide cream 6505-985-7110	DPSC	<u>1 10</u>	<u>1 52</u>	<u>42</u>	38
Total		<u>\$655.31</u>	<u>\$1,067.31</u>	<u>\$412.00</u>	74



ASSISTANT SECRETARY OF DEFENSE
WASHINGTON D C 20301

14 AUG 1973

HEALTH AND
ENVIRONMENT

Mr Gregory J Ahart
Director, Manpower and Welfare Division
United States General Accounting Office
Washington, D C 20548

Dear Mr Ahart

On behalf of the Secretary of Defense we have carefully reviewed the findings, conclusions, and recommendations contained in the GAO Draft Report, dated 1 June 1973, "Opportunities to Improve the Procurement and Supply of Pharmaceutical Drugs" (OSD Case #3636)

The Department of Defense subscribes to the principles set forth in your report that greater cooperation and coordination between the Veterans Administration and the Department of Defense in the development of drug requirements data for procurement purposes, development of common specifications and the possibility of joint procurements for centrally managed common drug items could result in savings to the government. The following discussion provides specific comments on each of the report's recommendation

DEVELOP POLICIES AND PROCEDURES DESIGNED TO PROVIDE
GREATER COORDINATION AND COOPERATION AMONG FEDERAL
AGENCIES BUYING DRUGS

As stated in your report, interagency agreements between DoD and civil agencies are now in being which provide for supply support to civil agencies to include centrally managed drug items. Specifically, the following documents are currently in existence relative to interagency support of medical materiel: (a) DoD/GSA Agreement, February 1971, subject Agreement Between the Department of Defense and the General Services Administration Governing Supply Management Relationships Under the National Supply System, (b) Federal Supply Catalog (C2510 to 9999CA), effective 1 October 1972, a catalog provided by DSA for use by Federal civil agencies which

includes items in Federal Supply Group 65 (Medical Materiel) that are available to civil agencies, (c) DSA/VA Interagency Supply Support Agreement, 4 November 1968, subject Medical and Non perishable Subsistence, which provides for DSA support of VA with drug items centrally managed by DPSC. These are evidence of DoD interest in fostering interagency cooperation and coordination in the best interests of the government.

Your report notes that the 1971 DoD/GSA Agreement specifically assigns Government-wide support for medical materiel, which includes pharmaceuticals, to DoD and that the Agreement pertaining to this commodity has not been implemented pending the outcome of a study being led by the Office of Management and Budget. Pending final resolution of this matter DoD is willing to discuss further arrangements to prevent purchases of an item by one agency when the item is available from stock of the other agency, and to obtain the most advantageous prices in the purchase of pharmaceutical drugs.

DEVELOP SPECIFICATIONS ON ITEMS CENTRALLY PROCURED BY VA

DoD will assist the VA in any manner deemed appropriate. The DSA currently provides VA a copy of all specifications developed on pharmaceuticals.

REVISE DOD POLICY ON ADOPTING ITEMS FOR CENTRAL PROCUREMENT

DoD policy provides for central procurement whenever the expected volume/demand indicates a savings will result. There are other factors such as generic equivalency, drug efficacy, expiration periods, and special storage requirements which influence the adoption of pharmaceuticals and must be considered in arriving at the final decision to catalog a pharmaceutical item. The Defense Medical Materiel Board (DMMB) is currently receiving and reviewing consolidated reports on local purchases from the military departments. The Board evaluates this data along with the above mentioned factors in finalizing a decision on standardization. DoD will again review the criteria used and the standardization procedure for cataloging pharmaceuticals to insure compliance with the intent of the basic policy.

DEVELOP JOINT DOD/VA SPECIFICATIONS

A joint effort between the VA, GSA, DOD and other federal agencies to use common specifications for drug procurement has been implemented on a limited degree through the Intra-Governmental Professional Advisory Council on Drugs and Devices (IPADD) and the exchange of DoD developed specifications with VA. While this effort results in a separate specification for each agency, the technical data contained in the specification is normally the same for all agencies. Also, a mechanism is currently available to assist in the development of common Federal Specifications. DSM 4120 3M, Defense Standardization Manual, January 1972, prescribes policies and procedures for the preparation of specifications within DoD. In part, this reference states that "Federal specifications shall be developed for materials, products or services, used or for potential use by two or more Federal Agencies, at least one of which is an agency other than DoD. The common policy of the GSA and DoD provides a basis for determining whether a standardization document is eligible for inclusion in the Federal series. DoD policy governs military participation in the preparation and coordination of Federal specifications and standards, and prohibits the issuance of a military document which duplicates a suitable Federal document.

The Defense Medical Materiel Board has the function to maintain liaison and coordinate with the Defense Supply Agency and other government agencies in all professional-technical matters involving medical materiel. This activity will be specifically tasked to coordinate this matter with DSA and VA and recommend appropriate policy/agreements which will provide for the joint coordination/preparation of specifications for medical materiel having common usage within DoD and VA.

ESTABLISH A UNIFORM REPORTING SYSTEM FOR LOCAL PURCHASES

A uniform reporting system incorporating the points contained in your report is a DoD objective. To completely achieve this objective in the near term is considered impractical and too costly since the automated supply systems of the military departments differ and many of the smaller medical supply activities are operating a manual system. Currently the USAF reports all purchases while the U S Army and U S Navy report high dollar value purchases. As a result

of the DMMB action in April 1972 all military departments submit consolidated reports to the Board for review and their use in evaluating new items for standardization action. Continued action will be taken to insure standard reporting criteria are followed by each military department and that as soon as it is considered practical and cost effective a uniform reporting system for all local purchases of pharmaceuticals will be implemented.

IMPROVE THE VA'S DRUG ACQUISITION REPORT

No comment

CONSIDER UTILIZING A STANDARDIZED CODING SYSTEM

The utilization of the National Drug Code (NDC) for identifying all purchases of non-cataloged pharmaceuticals has been and is under consideration. Coordination with the military departments, Defense Supply Agency and the Food and Drug Administration has been effected and as a result a future meeting is being planned. Several system and other procedural matters remain to be resolved, however, the intent is to implement either the NDC system or a comparable system which will facilitate the consolidation of purchase data for pharmaceuticals.

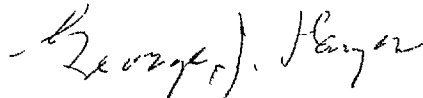
ASSUMPTION OF THE PHARMACEUTICAL PROCUREMENT INSPECTION FUNCTION BY HEW

Reservation is expressed regarding your recommendation that the FDA assume quality assurance responsibilities pertaining to purchases of pharmaceuticals by Federal agencies. The basic questions as to whether this consolidation would result in savings or whether the FDA would be able to meet the unique ASPR and operational requirements of DoD have not been resolved. The report does not provide a sufficiently detailed analysis for decision concerning these matters, therefore, suggest that the recommendation be modified to require a further examination of the feasibility of consolidating this function. The fundamental concerns of DoD are responsiveness to the needs of the military departments and the maintenance of an effective quality assurance program. DoD cannot concur in any course of action which would fragment the current integrated procurement

APPENDIX II

and quality assurance system or detract from the high quality inspection standards currently maintained

We appreciate the objectivity and the many helpful comments regarding means to improve the procurement and supply of pharmaceuticals contained in the draft report



George J Hayes
Major General, MC USA
Principal Deputy

BEST DOCUMENT AVAILABLE



DEPARTMENT OF HEALTH EDUCATION AND WELFARE
OFFICE OF THE SECRETARY
WASHINGTON D C 20201

SEP 18 1973

BEST DOCUMENT AVAILABLE

Mr. Gregory J. Ahart
Director, Manpower and
Welfare Division
General Accounting Office
Washington, D.C. 20548

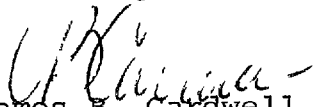
Dear Mr. Ahart:

The Secretary asked that I respond to your letter of June 1 which requested our views and comments on your draft report to the Congress entitled, "Opportunities to Improve the Procurement and Supply of Pharmaceutical Drugs". As you may know, Department officials met with General Accounting Office representatives to discuss the report; in particular, the conclusions reached that the Food and Drug Administration of this Department should assume quality assurance responsibilities pertaining to purchases of pharmaceutical drugs by Federal agencies.

This will confirm for your records that we agreed to discuss this matter with other interested agencies (Defense and Veterans Administration). At such time we will determine their particular requirements; discuss the resources needed; and other like pertinent issues. If, based on these discussions we find it will be in the best interest of the Government to do so, we will take such actions as are necessary to arrange for transfer to FDA all quality assurance responsibilities pertaining to purchases of pharmaceutical drugs by Federal agencies.

The opportunity to review this report in draft form has been much appreciated.

Sincerely yours,


James B. Cardwell
Assistant Secretary, Comptroller



VETERANS ADMINISTRATION
OFFICE OF THE ADMINISTRATOR OF VETERANS AFFAIRS
WASHINGTON, D C 20420

JULY 25 1973

Mr. Frank M. Mikus
Assistant Director, Manpower
and Welfare Division (801)
U. S. General Accounting Office
Room 137, Lafayette Building
811 Vermont Avenue, N. W.
Washington, D. C. 20420

Dear Mr. Mikus :

We have reviewed your draft report entitled "Opportunities to Improve the Procurement and Supply of Pharmaceutical Drugs - Department of Defense and Veterans Administration" (Code 88016).

We agree with the major recommendation that there should be greater cooperation and coordination among Federal agencies buying drugs. Since the actual items involved will be determined by the nature of the programs served and will reflect the differences in mission, the degree of standardization will be limited by those factors. However, this should not limit other advantages to the Government which would stem from a viable program of interchange of procurement and supply techniques, ideas, and innovations.

The report rests heavily on the premise that consolidation of the agencies' requirements will result in larger quantities purchased at lower prices, and that a mandatory requirement for use of control stocks would be economical. However, the need should be stressed to consider all costs involved in procurement decisions. Savings would not result until the centralized agency sources prove to (1) be economic in terms of their location and number, (2) price their items to recover all costs to the Government, and (3) be competitive with alternate sources of supply. It is possible that more consideration would need to be given to shelf-life, special packaging, and labeling for respective agencies before blanket standards could be set and before specific savings could be ascertained.

Mr. Frank M. Mikus
 Assistant Director, Manpower
 and Welfare Division
 U. S. General Accounting Office

BEST DOCUMENT AVAILABLE

Also, the coordination of stock requirements and monitoring of stock levels could offset some of the advantages of inventory consolidation.

[22]¹

With regard to the recommendation on page 34b, we consider the joint development of specifications or the mutual use of existing specifications as an important element of the increased interagency cooperation advocated by this report.

We acknowledge the need for improvement of our reporting system on field station acquisitions, as recommended on page 40.^[28] With reference to the recommendation on page 50,^[33] the VA will utilize such service exclusively when the Food and Drug Administration is capable of performing inspections on a timely basis and furnishing us with copies of its reports.

With reference to the leadership role of the Office of Management and Budget, we have been informed that all OMB personnel involved with supply programs and management were recently transferred to the General Services Administration. This reorganization could have a marked effect on future interagency coordination efforts.

[6]¹

On page 13 of the report, 182 is listed as the number of medical facilities supported by VA; apparently, no credit has been given to our serving other civil agencies, under the GSA assignment, which would raise the VA total to approximately 450. Also, on the same page, under the "Drug Inventory" entry, it should be noted that VA's central stocks are turned four times a year, instead of twice as is the case with the Defense Personnel Support Center.

[7]¹

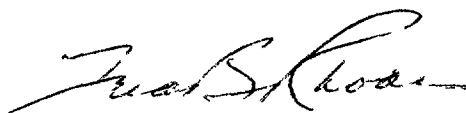
On page 14 of the report, reference is made to a review which preceded a February 1971 agreement between the General Services Administration and the Department of Defense. Having understood, from involvement in studies previous to that date, that we, as a party of interest, would be involved in any future determinations, we were surprised by the February 1971

Mr. Frank M. Mikus
Assistant Director, Manpower
and Welfare Division
U. S. General Accounting Office

action. We have not been able to determine what studies were made and would appreciate a copy of the review.

Thank you for the opportunity to review this draft. If you have any questions concerning our comments my staff will be available.

Sincerely,



FRED B. RHODES
Deputy Administrator

GAO note 1. Numbers in brackets refer to page numbers in this final report.

BEST DOCUMENT AVAILABLE

UNITED STATES OF AMERICA
GENERAL SERVICES ADMINISTRATION
 WASHINGTON, D C 20405



JUL 6 1973

Honorable Elmer B. Staats
 Comptroller General of the
 United States
 General Accounting Office
 Washington, D C 20548

Dear Mr Staats

Thank you for the opportunity to comment on the draft report to the Congress on "Opportunities to Improve the Procurement and Supply of Pharmaceutical Drugs "

The draft report cites efforts to improve the management of medical material made by the General Services Administration (GSA) and other Federal agencies in the past and in conjunction with the recent Office of Management and Budget study of medical and nonperishable subsistence commodities. In addition, the General Accounting Office report should note that GSA currently is working closely with the Veterans Administration (VA) on a project to improve the present method of procuring drugs.

A coordinated study has been made to identify high dollar volume items and to utilize this information to improve the method of contracting. We are also addressing ourselves to the feasibility of developing a continuing system for accumulating demand data to support continued efforts to improve our contracts

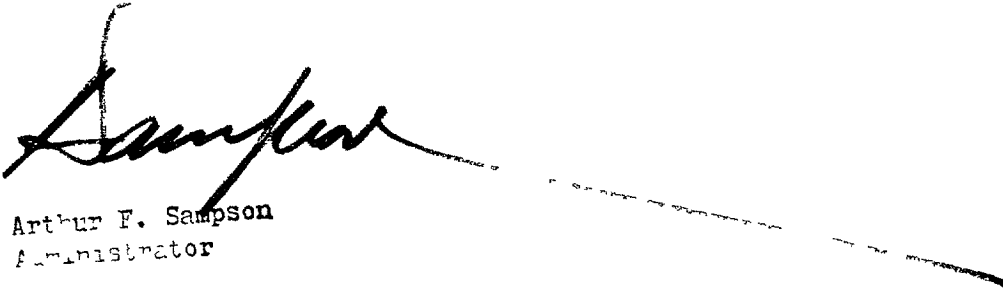
The collection of data on high dollar volume drug items required developing coding techniques for item identification. The preliminary experience and information gained on this study should be useful

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APPENDIX V

Although we have assigned the procurement responsibility for drugs and pharmaceuticals to the VA, we do retain broad responsibility for management of this class and are very much concerned about the resolution of the problems outlined in your report.

Sincerely,

A handwritten signature in cursive script, appearing to read "A. Sampson", with a long horizontal line extending to the right.

Arthur F. Sampson
Administrator

E. EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET
WASHINGTON D C 20503

JUL 20 1973

Mr. Gregory J. Ahart, Director
United States General Accounting Office
Washington, D.C. 20548

Dear Mr. Ahart:

This is in response to your letter to the Director requesting our comments on the GAO draft report entitled "Opportunity to Improve the Procurement and Supply of Pharmaceutical Drugs."

We are in general agreement with the thrust of the draft report that significant improvements can be made and economies achieved in the procurement, inspection, storage and supply of pharmaceutical drugs. While we have no objection to the recommendation in the draft report that the Office of Management and Budget take the leadership in an inter-agency effort to effect these improvements, it should be pointed out that such an effort has been underway for some time under OMB leadership, and we expect the results to provide the basis for decisive action with respect to the procurement and supply of medical material and non-perishable subsistence as well as drugs and pharmaceuticals.

The conclusions and recommendations contained in the draft report with respect to the consolidation of requirements, single procurement, central storage and inventory management seem more far-reaching than a careful examination of the facts may warrant. Specifically, we question whether there is adequate support for the conclusion that mere consolidation of requirements would assure more economical procurement. The analysis in the draft report of the reasons for different prices received by DOD and VA for similar purchases does not indicate that the lower price in each instance was related to a larger quantity procurement.

APPENDIX VI

If, as the facts seem to indicate, the lower prices were due to other causes, then the act of consolidating procurement would be not only an inappropriate response to the problem but would also remove the advantage of the current practice which permits the measuring of relative cost effectiveness of the DOD and VA supply support operations through comparative examination of the competing systems. We do not question that some savings can normally be achieved by consolidating requirements, but we believe the procurement system or technique used in many instances can have even greater impact on the total economic cost of the procurement. It would seem preferable to seek the best from each of the procurement systems and only after these are identified for incorporation in a single system should we recommend consolidated procurement with reasonable assurance that it would be an appropriate and timely step.

In addition to the above, we would also suggest that further consideration be given to portions of the draft report which encourage central storage and issue as the means of providing supply support. By omitting any recognition of the expenses of the Government that should be weighed in comparing costs of local purchase versus central storage and issue the draft report would give undue emphasis to the latter method of support to the detriment of total cost effectiveness. The omission in the draft report is one that commonly occurs in Government according to the report of the Commission on Government Procurement. In Part D, Chapter 6 of the Commission's report which deals with total economic costs, the Commission states its finding that the practice throughout the Government in the procurement of commercial products was to focus on the price paid the supplier rather than on the total cost of satisfying a requirement. The result, according to the Commission, is that "the Government has failed to develop the data and techniques needed to measure the total economic cost of fulfilling a Government need." Generally, these costs should include the price of the product, procurement personnel costs, warehousing, distribution, obsolescence, taxes foregone, and costs arising through use or consumption.

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Failure of the draft report to give consideration to these factors results in a stronger preference for central storage and issue than may be justified. As a minimum, it would seem desirable for the draft report to refer to the results of the Commission's extensive study in this problem area.

We appreciate this opportunity to comment on the draft GAO
- - - - report. If you would like to discuss this matter with OMB
staff or if there are any questions regarding the above
comments, please contact Mr. James D. Currie, 395-5193.

Sincerely,



Dudley C. Mecum
Assistant Director
Management and Organization

APPENDIX VII

PRINCIPAL VA AND DOD OFFICIALS RESPONSIBLE FOR THE
 MAJOR PORTION OF THE DIRECT PURCHASES OF
 PHARMACEUTICALS FOR THE GOVERNMENT

	Tenure of office	
	From	To
<u>VETERANS ADMINISTRATION</u>		
ADMINISTRATOR OF VETERANS AFFAIRS:		
Donald E. Johnson	June 1969	Present
DIRECTOR, SUPPLY SERVICE:		
Donald P. Whitworth	Jan. 1965	Present
<u>DEPARTMENT OF DEFENSE</u>		
SECRETARY OF DEFENSE:		
James R. Schlesinger	July 1973	Present
Elliot L. Richardson	Jan. 1973	July 1973
Melvin R. Laird	Jan. 1969	Jan. 1973
ASSISTANT SECRETARY OF DEFENSE (HEALTH AND ENVIRONMENT) (note a):		
Dr. Richard S. Wilbur	Aug. 1971	Present
Dr. Lewis H. Roussetot	Jan. 1968	July 1971
DIRECTOR, DEFENSE SUPPLY AGENCY:		
Lt. Gen. Wallace H. Robinson, Jr., USMC	Aug. 1971	Present
Lt. Gen. Earl C. Hedlund, USAF	July 1967	Aug. 1971
COMMANDING OFFICER, DEFENSE PERSONNEL SUPPORT CENTER:		
Maj. Gen. Abraham J. Dreiseszun, USAF	July 1972	Present
Maj. Gen. Robert E. Hails, USAF	Aug. 1971	July 1972
Col. Donald J. Bussey, USAF	June 1971	Aug. 1971
Brig. Gen. William M. Mantz, USAF	Nov. 1967	May 1971

Tenure of officeFrom ToDEPARTMENT OF THE ARMY

SECRETARY OF THE ARMY:

Robert F. Froehlke	July 1971	Present
Stanley R. Resor	July 1965	June 1971

SURGEON GENERAL:

Lt. Gen. H. B. Jennings, Jr.	Oct. 1969	Present
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DEPARTMENT OF THE NAVY

SECRETARY OF THE NAVY:

John H. Chafee	Jan. 1969	May 1972
John W. Warner	May 1972	Present

SURGEON GENERAL OF THE NAVY.

Vice Adm. George M. Davis	Feb. 1969	Feb. 1973
Vice Adm. D. L. Custis	Feb. 1973	Present

DEPARTMENT OF THE AIR FORCE

SECRETARY OF THE AIR FORCE:

Robert C. Seamens, Jr.	Jan. 1969	Present
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SURGEON GENERAL:

Lt. Gen. Robert A. Patterson	Aug. 1972	Present
Lt. Gen. Alonzo A. Towner	May 1970	July 1972
Lt. Gen. K. E. Pletcher	Dec. 1967	Apr. 1970

^a This position was formerly entitled "Deputy Assistant Secretary of Defense (Health and Medical)" under the Assistant Secretary of Defense (Manpower and Reserve Affairs). The change was effective in June 1970. Dr. Rousselot occupied the position under both titles.

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