BY THE COMPTROLLER GENERAL

Report To The Chairman, Committee On The Judiciary United States Senate

OF THE UNITED STATES

Federal Government Still Striving To Establish Single Drug Procurement System

For nearly two decades the Federal Government has tried to establish a single system for procuring and supplying drugs and medical devices to eliminate unnecessary duplication and reduce costs.

Only recently have the Office of Federal Procurement Policy, DOD, and VA begun to make progress in establishing and implementing such a system.

A Government-wide system is beginning to take shape. However, much remains to be accomplished.

The Office of Federal Procurement Policy Act Amendments of 1979 established a uniform system for use by Government agencies in procuring goods and services, including drugs. GAO makes recommendations to help Federal agencies fully carry out this congressional direction and the executive branch's policy requiring the purchases of commercial off-the-shelf products when such products will adequately serve the Government's needs and the use of commercial distribution channels in supplying these products.

HRD-80-59
JUNE 30, 1980

COMPTROLLER GENERAL OF THE UNITED STATES
WASHINGTON, D.C. 20548

B-196943

The Honorable Edward M. Kennedy
Chairman, Committee on the Judiciary
United States Senate

SEN02500

Dear Mr. Chairman:

As requested in your January 19, 1979, letter, we have reviewed prescription drug procurement activities in the Department of Defense and the Veterans Administration. We also examined the efforts of these agencies and the Office of Federal Procurement Policy to establish and implement a uniform system for the procurement of drugs among Federal agencies.

As arranged with your office, we gave the principal agencies affected by this report 30 days to comment in writing on its contents. Agencies not able to submit written comments within this time frame were given the opportunity to orally comment on the report; this report reflects all the agencies' comments.

Unless you publicly announce its contents earlier, we plan no further distribution of this report until 10 days from its issue date. At that time we will send copies to the Secretaries of Defense and Health and Human Services; the Administrator of Veterans Affairs; and the Director, Office of Management and Budget; and other interested parties. Copies will be made available to others upon request.

Sincerely yours,

Milton J. Socolar

Acting Comptroller General
of the United States

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COMPTROLLER GENERAL'S REPORT TO THE SENATE COMMITTEE ON THE JUDICIARY

FEDERAL GOVERNMENT STILL STRIVING TO ESTABLISH SINGLE DRUG PROCUREMENT SYSTEM

D I G E S T

Department of Defense (DOD) and the Veterans Administration (VA) spend hundreds of millions of dollars annually in procuring drugs for use in their health care facilities. These drugs are bought centrally through each agency's depot system, through Federal Supply Schedule drug contracts, or locally from drug suppliers.

Since the early 1960s, the Government has attempted to establish a single system for the procurement and supply of medical materiel (drugs and medical devices). This system would eliminate duplication and reduce costs. The Office of Federal Procurement Policy's (OFPP's) Acquisition and Distribution of Commercial Products policy has guided executive agencies in this effort since December 1977.

This policy requires the purchase of commercial off-the-shelf products when such products will adequately serve the Government's needs and the Government's use of commercial distribution channels in supplying these products. The commercial products policy relies on comprehensive market research and analysis to develop a suitable and cost-effective acquisition strategy.

Individual Federal depot systems can continue to exist based on item-by-item determinations of cost effectiveness or to fulfill an assigned agency mission. For example, DOD believes its national security mission necessitates different and higher cost requirements for personnel, packaging and marking, and stockage than VA's system.

The latest executive branch effort to establish and implement a single Federal procurement system for medical materiel began in January 1978. In June 1978, an agreement was reached between DOD and VA to improve the purchasing and supply management of medical materiel by establishing a DOD/VA Shared Procurement Program. (See pp. 10 to 13.)

Initial multiple-use, requirements-type contracts issued by both agencies under the Shared Procurement Program highlighted the incompatibility of the two major supply systems. For example, identical items procured by each agency had, in many instances, different national stock numbers and requirements for shelf life, warranty, packaging, marking, and procedures for inspection and acceptance of the product. Progress has been made in resolving these differences and in establishing an effective Government-wide medical materiel procurement system. However, on the whole, DOD, VA, and OFPP have made only limited progress in fully implementing the Shared Procurement Program. (See pp. 13 to 19.)

As of November 1979, 17 Shared Procurement Program contracts for single-source drugs had been awarded at a total value of $35.8 million. An additional 18 firms had been solicited for price quotations. Another 37 drug firms manufacturing single-source drugs needed by DOD and VA had been identified, but not solicited. No contracts had been awarded for any multisource (competitive) drugs or any single-source or multisource medical devices. DOD and VA officials believe other OFPP-directed efforts and higher priority individual DOD and VA responsibilities contributed to this situation.

Under the Shared Procurement Program, DOD and VA have focused primarily on matters relating to how each agency acquires medical items. Other issues related to the commercial

products policy, such as the duplication between Federal Supply Schedule medical materiel items, nongovernmental procurements of medical materiel, and commercial distribution networks, have hardly been addressed. Consideration of these matters would improve the agencies' market research and analysis efforts. Also, better acquisition strategies for federally managed medical materiel items should result. (See pp. 20 to 22.)

On an individual agency basis, DOD and VA centralized drug procurement programs have attempted to use competitive means to buy drugs. To a large degree, the number of drugs which can be bought competitively has been limited. In several instances, however, GAO identified additional supply sources which had been overlooked and could have been solicited. Action has been taken within DOD and VA to increase competition for drugs. (See ch. 3.)

DOD and VA procured the same prescription drug items at different prices. Savings of about $760,000 during an 18-month period could have been realized if both agencies had paid the lower of the two prices for the same items. (See pp. 34 to 36.)

Also, GAO found that additional savings were possible by substituting lower priced therapeutically equivalent drugs for other higher cost drugs currently stocked by DOD and VA. (See pp. 39 to 43.)

In certain cases, GAO identified non-Federal drug procurers who received lower prices for certain drug items than did DOD and VA. (See pp. 43 and 44.)

In its 1972 report, the Commission on Government Procurement stated that the practice throughout the Government in procuring commercial products was to focus on the price paid for the item rather than on the total costs of procuring, stocking,

and distributing the item. Failure to give consideration to total costs could result in a stronger preference for central stockage and issuance than may be justified. DOD and VA have recently given increased consideration to this overall concept in issues involving drug supply decisions. However, DOD must give more attention to this matter. (See pp. 44 to 47.)

The Office of Federal Procurement Policy Act Amendments of 1979 requires OFPP to transmit to the Congress within 1 year a proposal for a uniform procurement system for all goods and services bought by the Government. This system would strive to have uniform policies, regulations, procedures, and forms for use by all Government agencies. The legislation gives new authority to OFPP to require agency action. (See app. II.)

RECOMMENDATIONS TO OMB

The Director, Office of Management and Budget (OMB), should direct the Administrator, OFPP, to give higher priority to medical materiel-related issues. Also, the authority in the Amendments of 1979 should be used to assure implementation of the DOD/VA Shared Procurement Program.

The Director should institute actions through the Administrator, OFPP, to assure that all OFPP guidance on the commercial products policy is fully considered and implemented by agency personnel throughout all Government procurement and supply activities.

To formally assign Federal agency responsibility and accountability for drug item management, GAO recommends that the appropriate Federal agencies develop a single uniform Federal supply catalog for all drug, biological, and chemical reagent items.

Finally, the Director, OMB, should initiate a study to explore the feasibility of transferring from DOD to VA the responsibility for procuring, stocking, and distributing all drug items not needed for war or contingency purposes which are common to both agencies. (See pp. 53 and 54.)

RECOMMENDATIONS TO DOD AND VA

The Secretary of Defense and the Administrator of Veterans Affairs should:

--Establish an effective market research and analysis program for drugs and medical devices.

--Substitute, to the maximum possible extent, lower priced therapeutically equivalent drugs for higher priced drugs currently stocked centrally in each agency's wholesale depot system. (See p. 54.)

RECOMMENDATIONS TO DOD

The Secretary of Defense should instruct DOD supply officials to adopt a total cost methodology for use in management decisions concerning all drug items to be centrally procured, stocked, and distributed and eliminate from DOD's wholesale depot system management control items which can be more cost effectively supplied through alternative methods.

The Secretary should reassess the need for the placement of the national stock number on each unit of issue for all drug items. (See pp. 54 and 55.)

RECOMMENDATIONS TO VA

The Administrator of Veterans Affairs should instruct VA Marketing Center officials to:

--Identify duplicative drug items carried in the Federal depot systems and the Federal

Supply Schedule contracts in ongoing efforts to adopt a suitable single acquisition strategy.

--Eliminate those items identified above from availability through the Federal Supply Schedules if such means of procurement and supply are not the most cost effective. (See p. 55.)

AGENCIES' COMMENTS AND GAO'S EVALUATION

OFPP generally agreed with the report's conclusions and recommendations. However, it believed that the proposed recommendation to transfer to VA the total responsibility for procuring, stocking, and distributing all drug items common to DOD and VA was premature. DOD and VA expressed similar concerns.

DOD believed the report fairly portrayed the difficulties involved in attempting to implement the Shared Procurement Program and use commercial products. However, it said that the report failed to recognize its worldwide security mission.

VA agreed generally with the report's conclusions and the recommendations to the Administrator, VA.

OFPP, DOD, and VA said that the report did not recognize the progress made by the agencies in implementing the DOD/VA Shared Procurement Program.

The Department of Health, Education, and Welfare (HEW) 1/ said that the proposed

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1/On May 4, 1980, a separate Department of Education was created. The part of HEW responsible for the activities discussed in this report became the Department of Health and Human Services. This Department is referred to as HEW throughout this report.

recommendation to establish market research and analysis programs might be misinterpreted. In HEW's opinion, this recommendation might lead to creation of a medical materiel quality assurance program in each agency.

In GAO's opinion, the concerns raised by the agencies regarding VA's assuming overall supply management responsibilities at this time for common DOD and VA drug items have merit. Such a transfer should not be pursued by the Administrator, OFPP, until certain public policy issues can be studied, and GAO has modified the proposed recommendation accordingly.

GAO's review of the DOD and VA drug procurement activities was undertaken with a basic understanding of and appreciation for the missions of each agency. GAO believes that DOD and VA supply officials should continue to strive to acquire medical materiel by relying to the extent appropriate on commercial products and commercial distribution networks.

GAO recognizes the accomplishments made to date by agency personnel. Overall, a Government-wide system is beginning to take shape. However, much remains to be considered and accomplished.

With respect to HEW's comment on GAO's proposal to DOD and VA concerning establishment of individual market research and analysis programs, GAO did not intend that quality assurance programs be established in each agency.

GAO strongly supports efforts by OFPP, DOD, VA, and HEW to establish a single uniform quality assurance program for medical materiel purchased by Federal agencies.

GAO's evaluation of the agencies' comments is on pages 55 to 67.

Contents

ABBREVIATIONS

ADCOP	Acquisition and Distribution of Commercial Products
DAS	Defense Audit Service
DLA	Defense Logistics Agency
DMMB	Defense Medical Materiel Board
DOD	Department of Defense
DPSC	Defense Personnel Support Center
FDA	Food and Drug Administration
FSS	Federal Supply Service
GAO	General Accounting Office
GSA	General Services Administration
HEW	Department of Health, Education, and Welfare
OFPP	Office of Federal Procurement Policy
OMB	Office of Management and Budget
SBA	Small Business Administration
VA	Veterans Administration
VAMKC	Veterans Administration Marketing Center

CHAPTER 1

INTRODUCTION

In response to a January 19, 1979, request from the Chairman, Senate Committee on the Judiciary (see app. I), we reviewed practices used by the Department of Defense (DOD) and the Veterans Administration (VA) in procuring prescription drugs.

We examined these agencies' centralized and, to the extent possible, local prescription drug purchasing practices. We also identified several factors that limit further competition on drug procurement contracts and determined the status of the executive branch's efforts to establish a single system for the procurement of drugs. Finally, we obtained pricing information from a number of sources (Federal and non-Federal) to give the Committee a basis for comparing the prices paid for selected drug items common to each agency.

DOD AND VA DRUG PROCUREMENT PROGRAMS

In fiscal year 1978, centrally procured drugs by the Defense Logistics Agency (DLA) and VA were reported to be about $110.8 million and $98.7 million, respectively. These amounts 1/ do not include purchases made by DOD and VA facilities from local drug supply sources and/or Federal Supply Service (FSS) drug contracts. 2/ DOD does not collect this type of information for all its health care facilities. The VA medical facilities reported combined procurements of $91.6 million of drugs from these two sources in fiscal year 1978.

The missions of the DOD and VA medical materiel supply systems are different. Although the primary mission of both

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1/The total procurements for each agency are for centralized depot procurements for Federal Stock Class (FSC) 6505. FSC 6505 includes drugs (prescription and nonprescription), biologicals, and chemical reagents.

2/The Federal Property and Administrative Act of 1949 (40 U.S.C. 471) made the General Services Administration (GSA) responsible for procuring personal property, including medical supplies. GSA has delegated to VA responsibility for buying, among other things, drugs for all civil agencies.

systems is to support the requirements of their respective professional medical staffs, DOD's supply system must stand ready to assure the operating forces of a viable worldwide support structure in wartime as well as peacetime, no matter where the forces may be located. As a result, DOD supplies items for overseas customers that normally would be supplied from retail distributors if the customers were in the United States and buys and holds war reserve items in their depot inventories. To accomplish its mission, DOD believes different personnel requirements, different packaging and marking requirements, and different stockage requirements are necessary. Such factors result in higher operating costs for DOD than are required by the VA medical supply system to meet its mission needs.

The Defense Personnel Support Center (DPSC), a DLA supply center, is responsible for managing DOD's procurement and supply of drugs. Each of the three military departments determines its requirements for medical supplies and materiel, including those managed by DPSC. DPSC computes the consolidated requirements for these items and procures the items in sufficient quantities from commercial sources to satisfy the military departments' projected needs. DPSC "sells" these items to the military departments at the DPSC procurement cost, plus a surcharge of 10.8 percent (in fiscal year 1980) to cover transportation costs, inventory losses, and price increases from suppliers. DOD personnel costs are not recovered. Reimbursements from customers replenish the stock fund which, in turn, provides the working capital for DPSC medical procurement actions.

The Defense Medical Materiel Board (DMMB), composed of the Surgeons General of the Army, Navy, and Air Force, in coordination with the military medical departments and DPSC, selects drugs for, and deletes them from, the DOD central supply depot system. In this regard, DMMB fulfills its responsibilities by monitoring the drugs procured by the individual military medical facilities and reported through the medical materiel support commands of the Army, Navy, and Air Force to determine what drugs, because of the annual demand value and/or use by a certain number of medical facilities, should be considered for centralized procurement and supply.

The Veterans Administration Marketing Center (VAMKC) in Hines, Illinois--an activity of the VA Central Office Supply Service in Washington, D.C.--is the central VA purchasing

organization. VAMKC, subject to approval of the VA Central Office, determines which drugs should be added to or deleted from the VA supply system.

VA finances all supply operations through a revolving supply fund. The agency charges customers a percentage markup, in addition to an item's purchase price. The markup, which is currently 6 percent for drugs, is used by VAMKC to balance the VA supply fund. The markup recovers out-of-pocket costs, such as personnel, transportation, and other operating expenses. All direct costs are recovered.

Some cost elements, such as depreciation and an imputed rate of return on investment, are not included in VA's 6-percent markup. Partly to consider these costs in purchase decisions, VA has established a 15-percent minimum savings criterion which it uses to decide when an item should be entered in the supply system.

In VA's decision process, the cost of an item is solicited from commercial vendors who quote prices based on VA's estimated annual demand. VA compares the quoted prices with its current costs of procuring, stocking, and distributing the items. If the quotations meet or exceed VA's minimum savings criteria, VA will stock the item. The process is also applied to items already stocked when VA wants to see if an item should be kept in the system.

The following table summarizes the operations of DPSC and VAMKC as they relate to the procurement of drugs.

	Number of drugs centrally stocked and managed (note a)	Cost of fiscal year 1978 drug procurements	Drug inventory Sept. 30, 1978
		(thousands)	(millions)
DPSC	b/1,180	c/$110,798	$49.8
VAMKC	d/837	98,682	22.8

a/Includes biologicals and chemical reagents in FSC 6505.

b/As of February 1979.

c/Represents DPSC-reported procurement actions of more than $10,000 in fiscal year 1978. Procurement actions for drugs of $10,000 or less are not reported separately by DPSC.

d/As of December 1978.

PAST EFFORTS TO IMPROVE FEDERAL MANAGEMENT OF DRUGS AND MEDICAL DEVICES

Between 1963 and 1971, several Government agencies, including DOD and GSA, studied the possibility of giving a single agency Government-wide responsibility for managing various categories of supplies, including drugs and medical devices.

Late in 1964 DOD and GSA entered into an agreement governing the supply management functions and relationships between the two agencies. The agreement specified studies relating to five commodity areas to develop a unified national supply system eliminating unnecessary duplication between military and civil agencies. Drugs and medical devices were studied as one commodity.

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

Under the 1971 agreement, several Federal stock classes were assigned to GSA and DLA (formerly the Defense Supply Agency) for integrated management. The agreement provided for joint development of plans for assigning, identifying, and later transferring necessary resources, funds, and personnel. Although drugs and medical devices were included among the commodities assigned to DLA for integrated management, that assignment was deferred pending the outcome of still another study.

The study, proposed in June 1971 by the Office of Management and Budget (OMB), recognized that, although several agencies purchased and used medical items and although studies were previously made, no decision regarding unified management or a national system had been 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. OMB set up a steering group composed of a representative from OMB and four other agencies--VA, DOD, GSA, and the Department

of Health, Education, and Welfare (HEW) 1/--to study the functions, organization, and management practices in all Federal agencies involved in medical supply. The study was started in January 1972. A report, endorsed by the four agencies involved, was sent in 1974 to the Director, OMB, for his review and approval.

Findings included in the report concerning drugs and medical devices were as follows:

1. Evidence of considerable overlap and duplication of item management.

2. Evidence of a lack of Government-wide leadership in the management of existing supply systems.

3. No unified Government reporting system or centralized market research effort to determine agency requirements or new market trends.

4. Insufficient agency participation in the Federal cataloging program (i.e., improper use of Federal stock numbers).

5. Independently operated medical materiel (including drugs) quality control programs by various agencies.

6. Unreliability of agency reports on procurement actions.

In a June 4, 1974, memorandum from the Director, OMB, to the heads of DOD, HEW, VA, and GSA, the report and its recommendations were formally approved, and implementing responsibilities were assigned. The recommendations were that:

1. A single system be established for Government-wide management of medical supplies.

1/On May 4, 1980, a separate Department of Education was created. The part of HEW responsible for the activities discussed in this report became the Department of Health and Human Services. This Department is referred to as HEW throughout this report.

2. DOD's and VA's operational competence and capability for purchasing drugs and medical devices be used.

3. The Administrator, GSA, assume lead responsibility for developing the system through an interagency committee composed of DOD, VA, and HEW representatives. First orders of priority were (a) eliminating duplicative and overlapping purchasing efforts by fixing in a single purchasing office all purchasing responsibility for a single family of items, (b) collecting essential usage data on items obtained from other than central depot distribution to improve the procurement from other than stores' depots, and (c) improving supply management activities by consolidating warehouse facilities.

4. A Government-wide quality assurance program for drugs be developed.

Responsibility for implementing the first three recommendations cited above was assigned to an interagency committee composed of representatives of DOD, HEW, VA, and GSA. Responsibility for developing an implementation plan for the fourth recommendation was assigned to HEW.

EFFORTS OF OFFICE OF FEDERAL PROCUREMENT POLICY TO IMPROVE MANAGEMENT OF DRUGS

In 1969 the Commission on Government Procurement was created by Public Law 91-129 to study and recommend procurement methods that would promote economy, efficiency, and effectiveness in executive branch purchase decisions. The Commission sent its final report to the Congress in December 1972. In that report, the Commission said the purpose of the Federal Government's procurement system should be to provide users with required goods and services in the most efficient and economical way. The Commission recognized the need for a shift in the Government's fundamental philosophy relative to commercial product procurement.

In this regard, it was agreed that the Government had to emphasize the acquisition of commercial, off-the-shelf, products to achieve optimum effectiveness in supply support operations. Several recommendations were made in the Commission's report to bring about this change.

The Commission's first recommendation proposed establishing an organization within the executive branch to improve the economy, efficiency, and effectiveness of the procurement processes by providing overall direction of procurement policies, regulations, procedures, and forms. To implement this recommendation, the Congress enacted Public Law 93-400 in August 1974 to create the Office of Federal Procurement Policy (OFPP). OFPP was placed organizationally within OMB. The Administrator, OFPP, assumed the responsibilities of the Administrator, GSA, in developing a single system for Government-wide management of medical supplies.

In May 1976, the Administrator, OFPP, in response to several recommendations of the Commission on Government Procurement, issued a memorandum to the Secretary of Defense and the Administrators of Veterans Affairs and GSA establishing the executive branch's Acquisition and Distribution of Commercial Products (ADCOP) policy. This policy stated:

> "The Government will purchase commercial, off-the-shelf, products when such products will adequately serve the Government's requirements, provided such products have an established commercial market acceptability. The Government will utilize commercial distribution channels 1/ in supplying commercial products to its users."

On December 6, 1976, the Administrator, OFPP, published the policy's objectives, definition of terms, procedures, and general guidance for drawing down warehouse inventories, changing regulations, eliminating specifications, and accomplishing other required incremental steps.

A number of other projects were undertaken to implement OFPP's ADCOP policy of May 1976. On December 27, 1977, OFPP brought the separate projects and efforts of the executive branch agencies together under the guidance of the ADCOP policy. One of these projects was the previously mentioned effort, initiated in June 1974, to establish a single system for Government-wide management of medical supplies.

1/DOD and VA supply systems have been granted exceptions from exclusively using commercial distribution channels in supplying commercial products. These exceptions must be justified on an item-by-item basis based on cost effectiveness or fulfilling an agency mission.

OFPP directed each agency to review its acquisition and distribution regulations, procedures, practices, and methods to identify institutional impediments to the ADCOP policy. The agencies were to implement the policy by developing uniform regulations, procedures, practices, and methods to assure effective market research and analysis, specification management, and the best method of acquisition and distribution for a product or group of products.

Analysis of products that the agencies stocked in their depot systems was the means by which problems and solutions would be identified, goals and objectives would be met, and implementation of the policy would take place. The agencies were encouraged to solve problems by using innovative procurement methods.

In January 1978, the Administrator, OFPP, initiated the latest effort to establish a single system for the procurement of drugs 1/ as recommended by the Director, OMB, in June 1974. Under the guidance of OFPP's Deputy Assistant Administrator for Commercial Products, DOD, GSA, HEW, and VA began to develop and implement a DOD/VA Shared Procurement Program.

The group's approach called for developing multiple-use, requirements-type contracts for the joint use of the DOD and VA acquisition of common drugs. Implementation of the approach required the Secretary of Defense and the Administrator of Veterans Affairs to develop a cooperative arrangement by which the responsibility for central purchase of all medical items would be divided between the agencies. Provision for the joint development and use of requirements-type contracts and the establishment of item entry controls to preclude duplicate purchasing of new items were matters specifically required of the agencies by the Administrator, OFPP.

Recently, new responsibilities and increased authority have been given to the Administrator, OFPP. The Office of Federal Procurement Policy Act Amendments of 1979 (Public Law 96-83, enacted on Oct. 10, 1979) established, among other things, the requirement that the Administrator transmit to

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1/Medical devices in DOD and VA were also included in this effort. Our report discusses for the most part only matters related to drugs.

the Congress within 1 year a proposal for a uniform procurement system for all goods and services bought by the Government. This proposal must include a full description of the proposed system, projected costs and benefits, and short- and long-term plans for its implementation. The system would strive to have uniform policies, regulations, procedures, and forms for use by all Government agencies. Further, within 1 year of presentation of the proposal to the Congress, OFPP must propose recommended changes in legislation relating to procurement by executive agencies. If the Administrator, OFPP, believes it is necessary, he can propose a consolidated statutory base for procurement by the executive agencies. The Administrator, OFPP, must also submit at the earliest practicable date (but in no event later than the submission of the legislative recommendations mentioned above) a proposal for a management system to implement and enforce the uniform procurement system.

In addition, new subsections contained in this legislation provided the Administrator, OFPP, with the authority to issue policy directives with the concurrence of the Director, OMB, to promote the development and implementation of a uniform procurement system and the congressionally mandated policies set forth in this new legislation. Such policy directives must be followed by the executive agencies.

Included in this report as appendix II is the Office of Federal Procurement Policy Act Amendments of 1979.

CHAPTER 2

ACTION HAS BEEN INITIATED BUT MUCH REMAINS TO BE DONE TO ESTABLISH AN EFFECTIVE GOVERNMENT-WIDE DRUG PROCUREMENT SYSTEM

The DOD/VA Shared Procurement Program is the latest in a series of efforts that started in 1972 to improve the Government's purchase and supply management activities concerning medical items. Current plans initiated by direction of the Administrator, OFPP, in January 1978 do not call for the full implementation of this program until July 1982.

It appears that the DOD/VA Shared Procurement Program for drugs and medical devices has been a conscious and continuing effort by personnel in all affected agencies to establish an effective Government-wide medical materiel procurement system. Joint procurement contracts for certain single-source drugs have been awarded. Nevertheless, additional agency efforts are necessary to achieve the program's objectives.

RECENT DEVELOPMENTS ARE ENCOURAGING

As discussed in chapter 1, the Administrator, OFPP, in January 1978 accepted an approach proposed by the Interagency Medical and Nonperishable Subsistence Supply Management Committee for establishing a single system for the procurement of medical materiel. The approach called for developing contracts for the joint use of DOD and VA in the acquisition of common items. The Administrator, OFPP, requested that a cooperative arrangement be developed between the agencies so that all centrally procured medical items would be bought without duplication. The Administrator indicated that, regardless of the approach used, an aggressive and continuing program to eliminate the multiplicity of specifications and to improve Government specifications for medical items had to be implemented.

This approach was suggested by the Committee as a result of lessons learned from a pilot study started in July 1976 to implement the recommendations contained in the 1974 report to OMB to improve the Federal procurement and distribution systems for medical materiel items.

According to the Committee's report, purchase requests were exchanged so that DPSC could buy items for VA and VAMKC

could buy items for DOD. The actual operation, using existing procurement mechanisms and related policy, procedures, and documents, resulted in a mismatch in data processing applications and information management system requirements. The lack of uniform procedures essential for the effective control of total item management caused problems that resulted in extensive duplicative recordkeeping. It imposed a manual system (VA) upon an automated system (DOD).

Federal agency officials concluded that the pilot test clearly indicated that the procedures and techniques developed to accommodate the two divergent systems and sustain mission responsibilities were impractical. The Committee's report recommended that consideration be given to the development of contracts for the acquisition of common medical materiel items. Such contracts were to accommodate unique agency missions and requirements. However, according to agency officials who prepared the Committee report on the pilot test, the effort was successful in that it exposed traditional practices that were questionable. It improved DPSC/VAMKC relationships, opened up communications, and provided insight into each agency's operations. Although, strictly speaking, it failed to attain the principal objectives of the June 1974 OMB memorandum, it laid the foundation for the most recent effort to improve the management of these agencies' procurement and supply systems. OFPP's Deputy Assistant Administrator for Commercial Products was assigned oversight responsibility for establishing the single system for the procurement of medical items.

Immediately following the issuance of the January 1978 directive from the Administrator, OFPP, a DOD/VA Steering Group was established to monitor the development of an interagency agreement and to develop the required plans and milestones for implementation. The initial priority was to develop an interagency agreement.

In June 1978, an interagency agreement between DOD and VA was signed for establishing a system for purchasing medical items. The new system's objectives were to:

--Identify and eliminate any overlap and duplication between DOD and VA procurement systems.

--Provide responsible, effective, and economical procurement support to all Federal agencies (civil and military).

--Jointly develop and use multiple-use, requirements-type contracts in purchasing medical items.

--Jointly establish item-entry control procedures to insure that only one of the agencies purchase new items.

--Assume the purchasing/contracting responsibilities for medical items formerly exercised by GSA.

--Develop a program to simplify and eliminate the multiplicity of specifications.

To accomplish these objectives, DOD and VA officials agreed to:

1. Divide the purchasing responsibility, without duplication, for medical items.

2. Develop an item-entry control system to preclude duplicate purchasing of new items.

3. Establish procedures to review, simplify, and eliminate the multiplicity of specifications for medical items.

4. Form task groups to develop plans for implementing this agreement and a Joint Steering Group to furnish policy guidance to the task groups.

Task groups were established to develop detailed implementation plans and milestone dates. Actions necessary to implement this agreement were to be accomplished using existing staff resources.

On September 19, 1978, during a meeting of the members of the Interagency Medical and Nonperishable Subsistence Supply Management Committee, it was agreed that the medical portion of the Shared Procurement Program would be implemented in four phases and that the first contracts would be made in December 1978. Milestones for the four phases were considered and adopted. The four phases in their order of implementation were (1) single-source drugs, (2) single-source medical devices, (3) competitive drugs, and (4) competitive medical devices. The implementation periods agreed to for these four phases were as follows:

Phase I	December 1978 to January 1980
Phase II	June 1979 to June 1980
Phase III	September 1979 to September 1980
Phase IV	March 1980 to March 1981

Six committees were formed to implement the DOD/VA agreement. These committees' activities were also agreed upon at the September 19 meeting. A short statement of the objective of each committee is provided below.

--Committee on Reviewing DPSC and VA Contract Content. This committee is responsible for developing multiple-use, requirements-type contracts with standardized contract clauses developed for use by both DOD and VA in the acquisition of medical items.

--Committee on Candidate Items for Shared Procurement. This committee is responsible for selecting and recommending firms/item assignments for the Shared Procurement Program.

--Committee on Specifications. This committee is responsible for reviewing, evaluating, and developing one specification for items used by both agencies by applying ADCOP policy principles.

--Committee on Quality Assurance Support. This committee is responsible for developing a standard system for the approval of firms and acceptance of items for DOD and VA contracts.

--Committee on Item Entry and Item Commonality. This committee is responsible for applying the Federal cataloging system in (1) developing a single system of item entry and deletion of drug items and medical devices, (2) identifying common and potentially common items, and (3) modifying specified requirements of each medical materiel item as applicable.

--Committee on Systems Compatibility. This committee is responsible for the reviewing, evaluating, and developing of methods and procedures for DPSC/VAMKC compatibility for acquiring medical products.

In January 1979, DPSC and VAMKC sent solicitations to two drug manufacturers (McNeil Laboratories and Hoechst-Roussel, respectively) for certain single-source drugs to

formally initiate the contracting portion of Phase I of the DOD/VA Shared Procurement Program. Having only one agency, rather than two agencies negotiate with any one drug manufacturer for that manufacturer's single-source drugs stocked by the Government, made it possible to divide negotiation and contract administration responsibilities and eliminate the duplication which had previously existed.

However, these and several other subsequent solicitations issued under Phase I highlighted the differences which existed between the two agencies' supply systems. For example, certain identical items had:

--Different national stock numbers.

--Different units of issue (different quantities in inner and outer packages).

--Different quality assurance procedures for the inspection and acceptance of products.

--Different delivery dates (within 90 days after receipt of order for DPSC and within 10 days for VAMKC).

--Different shelf lives.

--Different labeling and marking on units of issue (DOD required national stock number on each unit of issue, but VA required only commercial labeling).

--Different warranty periods (1 year after receipt of item at depot for DOD and the entire length of the shelf life of the item for VA).

--Different exchange or credit clauses (none used by DOD because of the unique marking requirements).

Contracts were awarded by VAMKC in March 1979 to Hoechst-Roussel and by DPSC to McNeil Laboratories in April 1979 with many of these contract differences. Although one contract was used by both agencies to procure drugs from the same drug manufacturer, each contract contained separate and unique agency requirements for identical items. Other contracts we reviewed through August 1979 for single-source drugs under Phase I contained similar contract differences.

These different contract requirements for the same drug items demonstrated the lack of uniformity between the two drug supply systems. These differences were seen by the agencies as evidence of the substantial effort needed within the Government to develop a uniform drug procurement system. In effect, such differences, if continued, could have provided evidence, according to OFPP officials, that these agencies were reluctant to reconcile their differences and develop a uniform procurement system. In the long run, we believe such differences could have hindered or restricted the competitive procurement of drugs and medical devices by eliminating manufacturers who would choose not to compete under such conditions.

LIMITED PROGRESS TO DATE

In March 1979, the milestones established in September 1978 for implementation of the four phases of the DOD/VA Shared Procurement Program were modified. The revisions agreed to were:

Phase I	Extended to May 1980 (from Jan. 1980)
Phase II	Extended to October 1980 (from June 1980)
Phase III	Extended to January 1981 (from Sept. 1980)
Phase IV	Extended to July 1982 (from Mar. 1981)

DOD attributed the extension of time for each of the four phases to problems caused by differences in contract clauses, specification format, and inspection and acceptance criteria. The extension of the milestones also reflected the fact that additional staff resources would not be available to administer the program. VA cited delays caused by differences between Federal Procurement Regulations and the Defense Acquisition Regulation as the primary reason for delays. VA's specific areas of concern were related to different requirements between the two agencies for product labeling, source/destination quality assurance inspection and acceptance procedures, and packaging. These matters caused indepth reviews and analyses of each agency's contracting requirements.

DOD and VA have completed or are in the process of resolving differences concerning national stock numbers, shelf life, and warranties. Currently, different national stock numbers for the same item are being identified and eliminated. Shelf lives for the same items are being made uniform, to the extent possible, to reflect the commercial marketplace standard. As a general rule, the shelf life for both agencies will be not less than 36 months. Warranties will also be made uniform

to cover the entire shelf life of drug items. Also, DOD plans to initiate destination inspection and acceptance procedures for single source as well as multisource drugs to parallel the VA system.

VA believes differences in delivery dates do not impose a problem on either agency. DOD justifies the differences in delivery dates by citing, among other things, differences in mission requirements, national stock number requirements, and procedures for inspection and acceptance of materiel.

Differences in marking requirements continue to exist due to regulations. DPSC is required by Military Standard 129 to provide markings on all units of issue, intermediate packages, and shipping containers. Although DPSC permits commercial marking on units of issue, a national stock number is also required. VA permits commercial marking on units of issue and on the intermediate package in its contracts, but no national stock number is required. Although DOD's position is, in our opinion, counter to ADCOP policy, both the military medical services and DLA depots continue to support the need for a national stock number on the units of issue.

As a result of the national stock number marking on each unit of issue, DOD does not have any exchange or credit clause in its drug procurement contracts. DOD contractors are reluctant to accept this type of clause because of the difficulty encountered in attempting to sell, through commercial channels, materiel returned by DLA depots with a short shelf life and a national stock number marking. Consequently, DOD cannot return items to a manufacturer for exchange or credit before its shelf-life expiration. Therefore, the items must be discarded when the shelf life expires.

As of November 1, 1979, a total of 17 contracts had been awarded under Phase I, and 18 additional firms had been solicited by DPSC and VAMKC officials. The 17 contracts awarded totaled about $35.8 million, and the 18 additional firms solicited to date were expected to be awarded contracts totaling about $39.7 million. A breakout of these firms by contracting agency follows:

DOD

Firm	Dollar value
Ames	$ 2,104,550
Critikon	437,423
Lincoln Labs	299,985
McNeil Laboratories	3,681,514
Merck, Sharpe, and Dohme	5,850,341
West Chemical	71,000
	$12,444,813

VA

Baylor	$ 582,386
Breon	140,320
CIBA	850,182
Fleet	441,058
Giegy	600,273
Guardian	77,388
Hoechst-Roussel	4,118,412
Knoll	152,440
Penwalt	17,215
Roche Labs	12,844,318
Roche Products	3,584,441
	$23,408,433

Solicitations have been made by DPSC to Abbott; Ayerst; Endo; Hynson, Westcott and Dunning; Organon Pharmacy; Sandoz; and Travenol for contracts expected to total about $18.1 million. VAMKC has solicited Boehringer-Ingelheim, Pfizer, Ohio Medical, Roerig, Rorer, Schering, Searle and Co., Squibb, USV, Wallace, and Winthrop for contracts expected to total about $21.6 million.

No contracts have been awarded for any multisource (competitive) drugs or any single-source or multisource medical devices.

Significant cost savings anticipated as a result of joint drug procurements have not yet materialized under the DOD/VA Shared Procurement Program. At September 1979, DPSC had identified total actual savings of about $9,200 for certain drug items bought jointly, compared to previous acquisition costs. As of July 1979, VAMKC officials were unable to

identify any savings realized as a direct result of the Shared Procurement Program. We found that, in nearly all cases, DPSC and VAMKC were paying the same prices for common single-source drug items. However, these common items will be available at different prices from each supply system because of the difference (10.8 percent for DPSC versus 6 percent for VAMKC) in the markup or surcharge added to each agency's acquisition price.

The accomplishments to date of the six committees formed to implement the June 1978 DOD/VA agreement are primarily those related to single-source (Phase I) drugs. These committees will continue to function as required under Phases II, III, and IV.

The following discussion reflects the status of efforts, according to agency officials, to accomplish the objectives listed in the June 1978 interagency agreement.

Committee on Reviewing DPSC and VA Contract Content

--Reviewed and analyzed Federal Procurement Regulations and the Defense Acquisition Regulation to unify contract clauses to the extent possible.

Committee on Candidate Items for Shared Procurement

--A total of 72 single-source drug firms have been assigned to either DPSC or VAMKC for contract administration.

--Work is underway to complete solicitations of the other 37 firms under Phase I (to date 17 contracts have been awarded and an additional 18 solicitations have been issued).

--Single-source medical devices are being reviewed with the objective of making initial assignment of firms for Phase II.

Committee on Specifications

--Completed 186 procurement item descriptions covering a total of 412 single drug items (as of March 1980).

The efforts of this committee have been primarily concentrated on adopting a mutually agreeable format to accommodate both agencies' requirements. According to agency

officials, drug contract requirements for such things as disintegration, particle size, dissolution rate, and purity standards were removed several years ago to require nothing more for Government agencies than what is required for the general public. Therefore, the change in format itself will have no impact on increasing the competitive nature of medical items bought under the DOD/VA Shared Procurement Program. By adopting ADCOP policy, however, cost savings can be achieved by procuring a commercially available item through a commercial distribution network.

Committee on Quality Assurance Support

--Completed the review and identification of quality assurance requirements for both agencies.

--Recommended uniform standards more in line with those used by the Food and Drug Administration (FDA) for protecting the public.

--Reviewed the DOD and VA complaint reporting system in conjunction with DMMB and FDA.

Committee on Item Entry and Item Commonality

--Developed procedures for item entry control between DOD and VA.

--Completed the development of a glossary of terms and a list of metric equivalents.

--Continued process of reviewing and eliminating all dual national stock numbers for same item (as of November 1979, 26 national stock numbers have been eliminated).

Committee on Systems Compatibility

--Provided support to other committees in advisory role concerning system problems.

--Completed geographical distribution cost compatibility study which resulted in uniform charges to contractors.

--Evaluated cost to VA for Defense Contract Administration Services' support services under the shared procurement concept.

ADDITIONAL AGENCY EFFORTS NEEDED TO ACHIEVE FUTURE SUCCESS

Over the years, OFPP has issued written guidance to the other agencies to implement ADCOP policy. Since December 1977, this guidance has applied to the Shared Procurement Program. However, agencies have chosen to implement this guidance on a phase-by-phase basis rather than by immediately adopting the guidance in its entirety. Only the acquisition of items from common manufacturers has been pursued to date. No major consideration has been given to other important ADCOP policy principles, such as the use of commercial distribution systems and market research and analysis.

The slow pace in implementing the Shared Procurement Program should not be blamed upon the lack of available resources. Because the Shared Procurement Program is not a separate project from the implementation of ADCOP policy principles, it should not be considered to be in competition with the ADCOP efforts for priority assignment of available staff resources. Instead ADCOP policy is expected to be implemented, according to OFPP officials, throughout the Shared Procurement Program efforts because all the items are or should be commercial and are likely candidates for commercial distribution. However, DOD and VA officials view the situation differently from OFPP officials. As a result, the future progress of this program may be hindered.

In this regard, DOD believes additional staff resources are not available to achieve program objectives more quickly. Also, DOD believes that additional staff reductions at DPSC directed by overall governmental policy can have an adverse effect. In DOD's opinion, assigning personnel to task groups for implementing Shared Procurement Program objectives does not relieve them of their primary jobs. At the current rate of purchasing and technical activity in DPSC's Medical Directorate, DOD does not believe personnel can be diverted to the Shared Procurement Program without threatening mission performance.

Similarly, VA has stated resources are not available to implement the program at a more rapid rate. VA cites other OFPP-directed efforts (i.e., development of the Federal Acquisition Regulation, the National Supply System, and ADCOP) as factors which must be considered regarding the availability of additional resources being made to accelerate

the Shared Procurement Program beyond its current commitments. VA also cited its requirement to accomplish primary responsibilities before assignment of what it considers limited resources to other tasks.

To date, the agencies have concentrated on the relatively simple acquisition of single-source drugs needed by both DOD and VA. Written procedures to formalize the routines agreed upon during the acquisition of these items have been developed and are in the final approval process. Consequently, important procedures acceptable to both agencies which will serve as a foundation for subsequent improvements in the procurements of other medical materiel items should be available soon.

Full implementation of ADCOP policy to the Shared Procurement Program should cause the limited market research and analysis being conducted by the agencies to be expanded into looking at such things as FSS medical materiel supply schedules, non-Government medical materiel procurement, and commercial distribution networks. Market research is a vital, but as yet inadequately developed, element in implementing the new policy. Full-market research includes identifying user needs, determining the availability of commercial products of proven customer acceptance, and providing a basis for procurement decisionmaking. The importance of market research to the entire acquisition cycle indicates the need for organizational placement of the market research function that will complement the shift to buying commercial.

Currently, DOD and VA are dealing only with the acquisition phase of the entire array of supply activities. Therefore, efforts are concentrated on examining how each agency buys products from common manufacturers. Acquisition strategies need to be developed for all centrally managed medical items.

ADCOP policy stresses the application of market research and analysis techniques to develop an acquisition strategy that assures product market acceptability and promotes better procurement methodology through increased knowledge of the competitive commercial marketplace. The objective of market research and analysis is to eliminate uninformed buying caused by ineffective specifications, inadequate contracting approaches, and the inordinate use of Government distribution channels for commercial products, among other things. If properly applied, market research and analysis will eliminate

the current duplication and overlap of medical materiel between Federal Supply Schedules and DOD and VA central depot systems through developing appropriate acquisition strategies.

According to OFPP officials, the prospects for the future of the Shared Procurement Program are encouraging. These officials believe that, with the proper application of the ADCOP policy to the DOD/VA Shared Procurement Program, the potential for savings in administrative costs and acquisition prices are significant because of the work being done which will result in:

--Full, open and effective competition.

--Elimination of duplication in procurement.

--Unification of specifications.

--Use of commercial distribution networks.

--Use of uniform inspection and acceptance procedures.

--Establishment of item-entry controls to prevent duplicate item management.

--Establishment of an effective ongoing market research and analysis program for medical items.

Two important issues are discussed in the following chapters: chapter 3 deals with competition within the respective agencies' centralized wholesale drug procurement systems, and chapter 4 deals with the additional savings possible in agencies' drug procurements.

CHAPTER 3

CENTRALIZED WHOLESALE DRUG PROCUREMENT PROGRAMS

STRIVING TO INCREASE COMPETITION

To a large degree the number of drugs that can be bought competitively through the DOD and VA centralized wholesale drug procurement programs has been limited because of legislation and other factors that reflect other policy considerations. Action to increase competitive procurement of drugs has been initiated within DPSC and VAMKC.

CERTAIN BARRIERS LIMIT INCREASED COMPETITION

Legislative and other barriers preclude efforts to further increase the percentage of drugs bought competitively by DPSC and VAMKC. In fiscal year 1978, about $157 million of the approximately $209 million of drugs bought centrally by DPSC and VAMKC were purchased on a single-source basis. No overall statistical data were available concerning the specific reason(s) why nearly 75 percent of these centrally procured drugs were bought in this manner. In many cases, however, there was only one manufacturer of a drug.

The limited number of firms which participate in the Government's procurement of drugs is, to a great extent, beyond the immediate control of the agencies' drug procurement officials. In this regard, legislation which permits small business set-asides, patent protection, labor surplus set-asides, and preferential procurement of products produced by U.S. firms reflects other social and economic policies adopted by the Congress. However, there are other factors which contribute to the lack of a higher degree of competition in procuring drugs.

Legislative barriers

In addition to the policy of seeking the greatest possible degree of competition in Government procurement, the Congress has enacted several statutes which reflect other policy considerations. These statutes attempt to achieve certain social and economic goals through the procurement mechanism. Such legislation, in effect, provides favored treatment for certain contractors.

The following legislative barriers affect the competitive nature of Federal drug procurements as well as other goods and services bought by Federal agencies.

Small business

Possibly, the most extensive and complex social policy in Government procurement is to favor small business. The Small Business Act, as amended (15 U.S.C. 631 et seq.), states the policy of the Congress is that a fair proportion of Government procurement be placed with small business concerns. The Small Business Administration (SBA) created by that act assists small business in various ways and has issued regulations. For the purposes of Government procurement, SBA is empowered to carry out five principal functions: (1) to make a more detailed definition of a small business concern, (2) to determine the small business status of individual concerns, (3) to make joint determinations with procuring activities that a procurement or portion thereof should be set-aside for small business concerns, (4) to certify to Government procurement officials concerning matters of responsibility of small business concerns, and (5) to enter into contracts with the United States and to arrange for performance of those contracts through subcontracts with small business concerns.

SBA performs two interrelated functions insofar as small business-size standards are concerned. It is empowered by the Small Business Act to further define for procurements what constitutes a small business concern and upon request may certify that a particular concern is a small business. SBA considers a drug manufacturer with 750 employees or less to be a small business.

Eligibility for award of a Government contract as a small business concern is established by a procedure known as self-certification, whereby a firm certifies in its offer that it believes in good faith that it qualifies under the applicable size standards as a small business for the procurement. In the absence of a written protest from another bidder filed with the contracting officer or a question by the contracting officer, a concern which has certified itself as a small business is deemed to be a small business for the purpose of a particular procurement. In other words, the self-certification is usually accepted at face value.

The SBA regulations and those of the procuring agencies, in implementing the policy of the Congress of assuring a fair

proportion of contracts for small business, provide for total or partial set-asides at the unilateral discretion of the procuring agency or in consultation with SBA. When the decision is made to have a partial set-aside for small business, bids are solicited from all concerns, and award is made for the non-set-aside portion; negotiations are then conducted with small business concerns, which have submitted bids on the non-set-aside portion. The actual award price for the set-aside portion may not exceed the award price for the non-set-aside portion.

A total set-aside for small business is usually conducted as though the procurement were advertised; however, the procurement is restricted solely to small businesses on the basis of negotiation authority. The procurement agency, in determining to set-aside a procurement exclusively for small business, need have only a reasonable expectation that a sufficient number of bids (at least two under the Defense Acquisition Regulation) will be received so that the award will be made at a reasonable price.

Data we obtained from DPSC and the VA Central Office indicated that in fiscal year 1978 small business set-asides were used for about $1.7 million of DPSC's drug contracts awarded and about $2.1 million of VAMKC's drug contracts awarded.

Patents

A drug patent granted by the U.S. Patent Office gives an exclusive right for 17 years to manufacture and distribute a drug. Patents are recognized by the drug industry and others as necessary to encourage the intensive research and development that results in drug innovation. Patents may lead to more innovation in the development of new drugs but at higher prices, whereas less protection for innovation might dampen some research and development but result in lower drug prices.

Labor surplus

With the enactment of Public Law 95-89, the Congress provided for preferential treatment for businesses located in labor surplus areas. While the Department of Labor is responsible for determining the areas to be favored, the procurement agencies have the responsibility for administering the policy. In this regard, the Federal Procurement Regulations provide for both total and partial labor surplus set-asides so long as awards are made at fair and reasonable

prices. However, since every DOD appropriation act since 1954 has prohibited payment of price differentials for the purposes of relieving economic dislocations, the Defense Acquisition Regulation provides only for partial set-asides at prices no higher than those received under non-set-aside portions of individual procurements.

Procurement of domestic products

The procurement of domestic products has been preferred as a matter of congressional policy in appropriation acts since the 19th century. Annual DOD appropriation acts still commonly bar the use of the funds for the purchase of certain foreign items. The Buy American Act (41 U.S.C. 10a-10d), enacted as permanent legislation in 1933, imposes restrictions on the procurement of foreign supplies and construction materials. The act requires the procurement of domestic raw materials and supplies, or domestic manufactured materials and supplies, manufactured from domestic raw materials unless the head of the department determines domestic procurement to be inconsistent with public interest or the cost to be unreasonable.

The Buy American Act, as implemented and interpreted by Executive Order 10582, provides standards for preferential treatment of domestic supplies, not total exclusion of foreign products. The Executive order contains two key statements of policy. First, material is classified as foreign if the cost of the foreign products ("components") used constitutes 50 percent or more of the cost of the product. Second, 6 percent is established as the normal evaluation factor to be added to bids offering foreign products. Thus, for the purpose of bid evaluation, an amount equal to 6 percent of the foreign product bid will be added to that bid. This evaluation factor may be increased by the procuring agencies to 12 percent where the low domestic bid was submitted by a small business or labor surplus concern.

In addition, DOD contracting activities are required to comply with the DOD Balance of Payments Program requirements when buying from or through other Government agencies. DOD's application of a 50-percent evaluation factor in favor of domestic offers is exclusively a measure adopted to alleviate the impact of DOD expenditures on the country's balance of international payments.

Other barriers

There are several nonlegislative factors that restrict competition for Federal drug procurements. These factors are:

--The requirement of FDA approval of drug manufacturers.

--The designation of drugs as military unique or sole source by DOD.

--The failure of DOD and VA to solicit all sources of supply.

--The failure to implement all phases of the ADCOP Program.

These factors are discussed below.

Requirements for FDA approval of drug manufacturers

For Federal agencies to buy drugs from any company, FDA must assure DOD and VA that certain quality standards are met. According to FDA officials, the quality standards which FDA applies to drugs procured by the Government do not differ among the purchasing agencies and are the same standards FDA applies to the commercially distributed products.

DOD's procurement system provides for sending specific requests to FDA for preaward quality assurance evaluations of low bidders for each individual contact, when there has not been an FDA evaluation within the past year which found the low bidding firm acceptable. If there has been an acceptable evaluation within the past year and no other problems are known to have occurred affecting quality, DOD awards the contract without requesting an FDA preaward evaluation. DOD notifies FDA of these awards, so that, if a firm has developed a quality problem since the last evaluation that now makes it an unacceptable supplier, FDA can advise DOD and the contract can be terminated if necessary.

At VA's request, FDA provides VA an evaluation of the quality acceptability of individual suppliers. VA maintains a list of firms that FDA has advised are acceptable and awards contracts to them. FDA advises VA if any of the firms previously evaluated as acceptable become nonacceptable, so that VA will not unknowingly award a contract to such a firm.

Because of procedural differences which were inherent in each agency's procurement system, DOD previously required inspection and acceptance of the drug at the source of manufacture, whereas VA used destination inspection and acceptance exclusively. Therefore, FDA's postaward determination of

product acceptability was performed for DOD before shipment of the product to DOD's depots and for VA at destination before acceptance of the shipment at VA's depots. However, FDA has recently developed new procedures that reduce the amount of onsite acceptance activity performed for DOD. These new procedures are intended to bring about uniformity in DOD and VA postaward systems by adopting destination inspection and acceptance procedures.

In the case of DOD, FDA has provided another type of support. DOD drug contracts often have specific requirements for packaging, packing, preservation, and marking, as well as explicit expiration-date requirements. At the time that FDA is performing its inspection to assure the quality of drugs for DOD, it also verifies contractor conformance with these special requirements.

DOD-designated military unique or single-source drugs--DMMB identified 18 drug items as of April 1979 as being militarily unique. DMMB defines a military unique item as one manufactured, fabricated, assembled, or produced for military use and not commonly available in the commercial marketplace. Items requiring special packing and packaging to or for use in a military combat environment are included. However, special military requirements encompassing marking, labeling, and packaging (i.e., unit of issue and quantity) are excluded.

Also, DMMB officials provided us in April 1979 with a list of 15 additional drug items that had been designated by the Army, Navy, Air Force, or DMMB as being available from only one source because of bioequivalence or trade secret factors. Bioequivalence factors concern problems caused by substituting one drug for another. Trade secret factors concern the lack of a substitute drug because of the lack of information on certain brand name drugs.

Failure to solicit all possible sources of supply--We consulted several reference documents or publications that contained various sources of supply for drugs procured during the period covered by our review. In several cases, we identified additional sources which had not been solicited by DPSC or VAMKC officials.

In our review of 92 DPSC and VAMKC drug contracts, we identified 54 contracts which had been negotiated noncompetitively (i.e., only one offeror or only one manufacturer solicited). In 9 (4 in DPSC and 5 in VAMKC) of these 54

contracts, we identified additional sources which had not been solicited. In most cases there were numerous unsolicited sources of supply. In certain instances, these unsolicited sources had prices quoted in the 1979 "Redbook" 1/ which were below those paid by DPSC or VAMKC.

While certain prices paid by DPSC and VAMKC were substantially higher than the prices of many firms with price quotations in the "Redbook," it should be recognized that these firms may not submit bids on DOD and/or VA contracts or their products may not meet all agency requirements, including approval of the drug's safety and effectiveness by FDA.

The nine drug items and related solicitations, agency acquisition prices, and "Redbook" data are shown in the following table.

Item	Number of firms solicited	Number of firms not solicited (per GAO)	Latest agency acquisition price	Latest acquisition date	1979 Redbook acquisition prices
DPSC:					
Chlorpromazine hydrochloride tablets, 25 mg., 1000s	1	35	$ 24.83	1/31/79	8.35 to 28.80
Chlorpromazine hydrochloride tablets, 50 mg. 1000s	3	37	27.02	8/22/78	11.40 to 33.40
Fluocinolone acetonide cream, 0.025 percent, 15 gr.	2	1	0.945	4/24/79	3.13
Theophylline (130 mg.), ephedrine sulfate (25 mg.), hydroxyzine hydrochloride tablets (10 mg.), 500s	3	2	27.05	1/02/79	14.95 to 17.25
VAMKC:					
Cyclandelate capsules 200 mg., 100s	1	30	5.99	1/12/79	1.80 to 7.75
Hydralazine hydrochloride tablets, 25 mg., 1000s	1	35	14.39	3/16/79	6.50 to 42.30
Hydralazine hydrochloride tablets, 50 mg., 1000s	1	31	24.78	3/16/79	11.25 to 65.47
Nitrofurantoin capsules 50 mg., 1000s	1	3	57.15	3/20/79	57.00 to 72.40
Nitrofurantoin capsules 100 mg., 1000s	1	3	113.19	3/20/79	104.25 to 197.57

1/The "Drug Topic Redbook" is a pharmacist's detailed guide to drugstore products and commercial prices. It is published in January of each year by the Medical Economics Company of Oradell, New Jersey. The "Redbook" contains over 174,000 entries for products distributed through retail drug stores and hospital pharmacies. All the product and pricing information is supplied by the drug manufacturers.

Failure to implement all ADCOP policy principles--In addition to the three factors discussed above, there is the failure, discussed in the previous chapter, on the part of DOD and VA to implement all ADCOP policy principles--concerning the procurement and supply of drugs--which can adversely affect competition.

We have discussed ADCOP policy-related issues in the context of their impact upon implementation of the DOD/VA Shared Procurement Program in the previous chapter. In addition, our recent report, "Implementation of Federal Policy on Acquiring and Distributing Commercial Products Is Faltering Badly" (PSAD-80-13, Jan. 14, 1980), discusses this overall issue in much greater detail. It contains recommendations to assist executive agencies in implementing the commercial products policy on a Government-wide basis.

PROPER METHOD OF PROCUREMENT FOR DRUG ACQUISITION IS ESSENTIAL

In fiscal year 1978, 75 percent of DOD's and VA's combined procurement of drugs through the wholesale depot systems were purchased on a single-source (noncompetitively negotiated) basis. In most drug procurements, however, decisions are not made automatically and routinely to exclusively use either a formally advertised or negotiated method of procurement. Individual determinations based on the merits of each procurement action are considered. In all cases, competition is required to the maximum extent practicable in both formally advertised and negotiated contracting procedures involving more than one supplier.

Appendix III presents a general discussion of the advantages and disadvantages of each method of procurement. Included in this appendix are statistical data developed during our review of 92 selected drug contracts concerning formally advertised and negotiated methods of procurement as well as the reasons 54 of these contracts were noncompetitively negotiated.

Overall, both DOD and VA are close (on a dollar value basis) to the percentage cited by the Commission on Government Procurement for contracts awarded on a negotiated rather than a formally advertised basis. The Commission reported that 85 to 90 percent of the Federal Government's needs were satisfied through negotiated procurements. The following table presents the percentages we calculated for drug procurements at DPSC and VAMKC in fiscal year 1978.

	DPSC	VAMKC
Competitive:		
Formally advertised	11.4	17.3
Negotiated	18.7	.5
Noncompetitive:		
Negotiated	69.9	82.2
Total	100.0	100.0

It is important to recognize the data bases for the above statistics are different. DPSC maintains contract information on formally advertised versus negotiated, competitive versus noncompetitive, etc., only on the basis of actual individual procurements for more than $10,000 made against existing contracts. VAMKC maintains the same type of information. However, it is available only on the basis of contracts awarded and not on the basis of individual orders against existing contracts. Therefore, the DPSC percentages shown above are based on $110.8 million of individual purchases of more than $10,000 during the period. VAMKC's percentages are based on contracts awarded of $91.5 million in fiscal year 1978. During the same period, VAMKC bought $98.7 million of drugs from contracts that were in effect.

For the same 54 contracts mentioned above, we ascertained the extent of negotiations by DPSC and VAMKC officials.

In total, 12 of the 54 contracts had proposals submitted which, in the opinion of agency officials, required further discussions to agree on a suitable price. We did not question the officials' judgment concerning the decisions not to hold discussions on the other 42 proposals. Discussions on the 12 proposals resulted in total savings to the Government of about $52,800.

DPSC conducted discussions on 7 of the 33 noncompetitive contracts we reviewed. These 33 noncompetitively negotiated contracts totaled about $2.5 million. In 26 cases, the agency accepted the prices offered by the contracts as being fair and reasonable based upon its analysis of catalog and/or prior price histories for the drug items. Discussions took place on the other seven contracts. In three instances, DPSC was successful in negotiating a price reduction. These three instances resulted in total price reductions of about $12,800 on contracts totaling about $2 million.

DOD officials indicated to us that since their drug items are bought on a quarterly basis, acquisition prices are relatively stable from one purchase to the next. Besides price, the only other major negotiable items are delivery dates and specifications. In DOD's opinion, if these factors are unchanged from the previous acquisition and the offeror is the same, the conduct of discussion would appear to provide virtually no advantage.

VAMKC conducted discussions on 5 of the 21 noncompetitively negotiated contracts included in our sample. These 21 contracts were valued at about $1.95 million. For the five contracts for which discussions took place, VAMKC received price reductions of about $40,000. These five contracts were awarded for a total of about $445,000.

AGENCY EFFORTS INITIATED TO INCREASE COMPETITIVE PROCUREMENTS

Both DOD and VA have initiated efforts to increase the number of firms involved in drug procurements and correct certain other procurement-related weaknesses.

For example, we identified 55 drug items with an annual demand of $6.8 million in fiscal year 1978 that VAMKC was purchasing on a noncompetitive basis, although the items were available from other manufacturers. VAMKC officials had already initiated action to consider buying some of these drugs competitively. The other drugs, according to VAMKC officials, will be reviewed to determine if additional acceptable supply sources exist. Similar examples for several of the same drugs were identified during our inquiry on this matter with DPSC officials. These officials agreed that we had identified potential sources which they had not solicited.

The accomplishments of DOD and VA in bringing about improvements in the procurement and supply of drugs are evidenced in the progress made in implementing pertinent recommendations on this subject contained in previously issued reports. Our earlier report, "How to Improve the Procurement and Supply of Drugs in the Federal Government" (B-164031(2), Dec. 6, 1973), contained recommendations to promote Federal agency cooperation in procuring drugs. In April 1978 DLA issued an acquisition management review report, "A Review of Medical Materiel Management In DLA--Phase I." This report had been requested by the Director, DLA, to evaluate the efficiency and responsiveness

to the military departments of the medical materiel support system. The report review team was made up of not only DLA personnel but also personnel from VA, FDA, and the Army Procurement Research Office. The report discussed the current support operation to determine what improvements could be achieved within the present system.

A discussion of the agency actions taken in regard to selected pertinent recommendations contained in these reports are presented in appendix IV.

CHAPTER 4

ADDITIONAL SAVINGS POSSIBLE IN AGENCY PROCUREMENT OF DRUGS

Both DOD and VA health care facilities have the same options available to them for obtaining prescription drug products. These options--in the order of their expected use--are (1) the individual agency's own centralized wholesale depot system, (2) the FSS drug contracts, and (3) local drug wholesalers and retailers.

Our analyses of prices paid by DOD and VA through their respective wholesale depot systems for certain common prescription drug items indicated that lower prices could have been realized through greater cooperation and coordination among the Federal agencies. In addition, we found, in several instances, that (1) therapeutically equivalent drugs could be substituted for other drugs at a lower price, (2) prescription drugs were procured from a source that was not the lowest priced source, and (3) non-Federal buyers of prescription drugs purchased the same drug or its generic equivalent at a lower price than DPSC and/or VAMKC paid.

Although DOD and VA have established policies of using the most economical supply sources and buying all drugs on a generic rather than a brand name basis, the operation of the two separate supply systems, which until recently were virtually independent of each other, in our opinion, contributed to these situations described above.

Also, if DOD were to consider the total costs involved in the procurement of drugs and not merely the acquisition cost of the drug, it could buy--according to DLA's own cost model--many drugs currently stocked by DPSC directly from the manufacturer or locally at lower overall costs to the Government.

WHOLESALE DEPOT SYSTEMS

Using a list of 221 prescription drug items stocked by both DPSC and VAMKC, we identified 153 drug items that had identical national stock numbers. We obtained, with the assistance of DPSC and VAMKC officials, a procurement history for each of these 153 items for an 18-month period from October 1, 1977, to March 31, 1979. Ten drug items were eliminated from further analysis because either DPSC or VAMKC had not procured these items during the 18-month period.

Our selection of the 143 items was not intended to be a statistically valid sample for use in projecting the results of our analysis to the respective centralized wholesale drug depot inventories maintained within DOD and VA. Also, although the drug potency and package size are the same on the drugs reviewed, we recognize that other factors (i.e., packaging, packing, marking, shelf life, etc.) unique to one agency could affect the price paid by that agency for that drug. However, the cost implications of such factors are unknown because of the absence of cost and pricing data for the drugs.

On the basis of the last procurements for these 143 items during the 18-month period, DPSC paid the lower price for 52 items, VAMKC paid the lower price for 51 items, and DPSC and VAMKC paid the same price for 40 items.

On the basis of a weighted average price paid by the agencies over the entire 18-month period, DPSC paid the lower price on 67 items, VAMKC paid the lower price on 65 items, and the two Centers paid the same price on 11 items.

We did not attempt to ascertain the cost savings to the Government if the agency which paid the higher price during the entire period had paid the lower price because of some wide variances in the time frames involved in the procurements of the same items.

However, we determined the cost savings that were possible for the same drugs purchased by DPSC and VAMKC within 30 days of each other over the same 18-month period. This analysis showed that for 101 items, $759,923 in savings would have been realized by the Government, if both DOD and VA had received the lower of the two prices paid for these items. This total savings would have resulted by DPSC paying $497,114 less for the same items procured at the VAMKC price. Conversely, VAMKC could have saved $262,809 by procuring the same item at the DPSC price.

On an item-by-item basis, both agencies used the same method of procurement (formally advertised or negotiated) for 120 items during the entire 18-month period. For the other 23 items, the methods of procurement varied.

In the 23 instances where different methods of procurement were used, DPSC formally advertised for 3 items, competitively negotiated for 13 items, and negotiated noncompetitively for 7 items. However, VAMKC formally advertised for

20 drug items and negotiated noncompetitively for the other 3 drug items.

Matching the different methods of procurement on an item-by-item basis used by the agencies and comparing the weighted average price per unit for the entire period reviewed resulted in the following:

--For the two items for which DPSC had noncompetitively negotiated and VAMKC had formally advertised, there were significant price differences. In both instances, VAMKC received the most favorable price ($8.99 versus $18.25 for brompheniramine maleate, phenylephrine hydrochloride, and phenylpropanolamine hydrochloride tablets, 500s and $6.85 versus $31.02 for propantheline bromide tablets, 15 mg., 1000s).

--On three items for which DPSC formally advertised and VAMKC negotiated noncompetitively, DPSC received the lower prices per unit ($13.45 versus $16.66 for cloxacillin sodium capsules, 250 mg., 100s; $23.49 versus $26.20 for dextrose injection, 50 percent, 50 ml. (needle unit and needle), package of 10s; and $10.31 versus $15.42 for methocarbamol tablets, 500 mg., 500s).

--On five items (fluocinolone acetonide cream, 0.025 percent, 15 mg.; kanamycin sulfate injection, 0.33 gm. per ml., 3 ml.; minocycline hydrochloride capsules, 100 mg., 50s; selenium sulfide lotion, 2.5 percent, 4 oz.; and thyroid tablets, 64 mg., 100s) for which DPSC negotiated noncompetitively while VAMKC formally advertised, there was no significant price differential.

--On the other 13 items, DPSC competitively negotiated for all these items while VAMKC formally advertised for the same items. DPSC was able to receive the lower price for five items. VAMKC received the lower price in the eight other cases.

The results of our analysis of each of the 23 items are presented in appendix V.

FSS DRUG CONTRACTS

Drugs are bought by DOD, VA, and other Federal agencies' health care facilities through indefinite quantity requirement

FSS contracts. VAMKC's Marketing Division for Drugs and Chemicals is responsible for contracting with drug manufacturers for items which are carried on FSS's Federal Supply Schedules. This responsibility is performed concurrently with VAMKC's centralized drug procurement activities. Our limited review of the FSS schedules for drugs indicated that these items are not receiving adequate consideration in current agency efforts to procure drugs in the most cost-effective manner.

As of January 1978, VAMKC, in its continuing efforts to improve the Federal Supply Schedules for drugs and chemicals, adopted the use of two basic schedules. Schedule A lists drug items contracted for with various manufacturers with the lowest price listed first, and the other manufacturer(s) listed in ascending order based on price. In this manner, it provides the purchaser with the opportunity to compare prices without research through voluminous drug catalogs and price lists. At January 1979, there were 375 drug line items with a total reported Federal annual demand of about $18.2 million included in Schedule A.

Schedule B contains the list of drug manufacturers that are under contract to supply drugs. However, no individual manufacturer's products or prices are listed separately. It is up to supply personnel at the Federal health care facilities to order drugs from the various Schedule B manufacturers' catalogs. As of January 1979, 114,038 drug line items with a total reported Federal annual demand of about $136.9 million were included in Schedule B.

However, it is recognized by agency officials that there is overlap and duplication for many items carried in the (1) DOD and/or VA's centralized drug inventories and (2) the FSS drug schedules. As a result, identical drugs--manufactured by the same firms--are available at different prices. This situation needs to be resolved under ongoing DOD/VA Shared Procurement Program efforts to bring about increased efficiency, effectiveness, and economy.

As discussed in chapter 2, the Shared Procurement Program to date has dealt only with items stocked by both agencies. As a result, acquisition strategies do not reflect the availability of certain of these same items from FSS drug schedules. If drugs are to be procured in the most cost-effective manner, drug items should not be carried in both FSS drug schedules and Federal agencies' drug catalogs. Such practices are costly and do not reflect good management practices.

Federal facilities should be assured that the items they buy are at the lowest possible price from any Federal source. Such an assurance requires elimination of the duplication of items procured within the Federal sector.

LOCAL PURCHASES

The unavailability or unreliability of local drug procurement data within DOD and VA prevented a comprehensive evaluation of the need for these agencies' health care facilities to rely on supply sources other than their wholesale depot system. This issue is discussed in appendix IV. (See pp. 83 to 88.)

However, the Defense Audit Service (DAS) in its report (No. 79-081, dated May 7, 1979), entitled "Report on the Review of the DOD Medical Materiel Support Program," identified significant recurring savings possible by DOD facilities buying centrally stocked medical items (including drugs) rather than procuring the same item from a local supplier at a higher price.

DAS analyzed 279 purchases (costing $825,860) which were made in fiscal year 1977 at nine (four Army, four Navy, and one Air Force) health care facilities. DAS found that six facilities (three Army and three Navy) had made 38 local purchases valued at about $65,300 for items which were available at a lower price from DPSC. Thirty-three purchases, valued at about $32,400, were for drug items. Inadequate screening of supply catalogs, erroneous coding of items for local purchase, and other inaccuracies in the local supply records were cited as reasons for these improper purchases. Costs to DPSC for the items included in these 38 purchases could have been reduced by about $11,600. DAS projected savings of about $1.25 million to Army and Navy activities based upon (1) its belief that the conditions at the six facilities visited were typical and (2) the Army and Navy activities reported locally purchased medical items costing about $75 million in fiscal year 1977.

Two factors should be recognized concerning the projected savings of $1.25 million cited above. First, DAS did not consider the markup (currently 10.8 percent) that DPSC added to the acquisition price to arrive at the price quoted in the DPSC Federal Supply Catalog and that any individual health care facility purchasing the item must pay. A true savings comparison should have reflected the difference between the delivered prices for the same drug to the requesting facility.

Secondly, the calculated savings cited above are based upon reported local medical materiel. However, according to the DAS report, significant amounts of locally purchased medical materiel are not reported. Therefore, additional savings would be possible if these unreported local purchases were also considered.

SUBSTITUTION OF LOWER PRICED, THERAPEUTICALLY EQUIVALENT PRESCRIPTION DRUGS

The substitution of a lower priced, therapeutically equivalent prescription drug for another more costly prescription drug is one way in which Federal care providers can help control escalating health care costs. However, the substitution must occur without compromising the effectiveness of the substituted drug in treating a disease or illness.

All prescription drugs that fall into the multisource drug category are candidates for substitution. Such drugs can be marketed by a drug manufacturer with or without a brand name. Drugs manufactured without a brand name are referred to as generic drugs.

In January 1979, FDA issued a complete list of prescription drug products that it had approved for marketing. The FDA list, "Approved Drug Products With Proposed Therapeutic Equivalence Evaluation," was prepared to promote public education in the area of product selection, to foster containment of health costs, and to serve State health agencies in administering their laws relating to generic substitution. FDA believes that products considered therapeutically equivalent can be substituted with the assurance that the substituted product will produce the same therapeutic effect as the prescribed product.

The fundamental proposed policy governing this list is that FDA considers pharmaceutically equivalent drug products to be therapeutically equivalent providing they are approved for both safety and effectiveness, are manufactured in accordance with Current Good Manufacturing Practice Regulations, meet the same or equivalent standards and, in those instances where positive evidence of bioavailability is necessary, are shown to be bioequivalent to an appropriate standard. FDA believes this policy to be consistent with the prevailing opinion of experts and with general experience in the marketplace through the years.

The criteria for the therapeutic equivalence evaluation and the evaluations themselves as they appeared in the list were presented as FDA proposals rather than final agency determinations. FDA plans to release the comments received on its January 1979 proposed list and to follow up the release of comments with the issuance of its final list. FDA expects to update its list on a monthly basis after the final list is published. The substitution of therapeutic equivalent drugs for drugs currently stocked by DPSC and VAMKC and discussed in this chapter reflects FDA's position on these items at mid-September 1979.

The term "approved drug products" defined by FDA refers to those drug products manufactured or distributed under new drug applications (NDAs) or abbreviated new drug applications (ANDAs) approved by FDA under the provisions of section 505 of the Federal Food, Drug, and Cosmetic Act or in the case of antibiotics, under section 507 of the act. All drug products on FDA's list have been reviewed and approved for safety and effectiveness. FDA-approved drugs constitute about 75 percent and nonapproved drugs about 25 percent of the wholesale dollar value of prescription drugs in the United States.

Drug products are considered by FDA to be therapeutically equivalent if they contain the same active ingredients; are identical in strength, dosage form, and route of administration; and can be expected to give the same therapeutic effect when administered to the patient under the conditions specified in the labeling. The concept of therapeutic equivalence, as used in developing the list, applies only to products containing the same active ingredients and does not encompass a comparison of pharmaceutical alternatives or two different active ingredients used for the same disease.

FDA believes an evaluation of therapeutic equivalence is scientific judgment based upon evidence, while generic substitution is a social and economic policy intended to minimize the cost of drugs at the consumer level. FDA proposes to consider products to be therapeutically equivalent even though they may differ in certain other characteristics (e.g., color, flavor, packaging, expiration time, and minor aspects of labeling). When such differences are important in the care of a particular patient, it is appropriate for prescribing physicians to require that a particular brand be dispensed as a medical necessity.

In analyzing the 153 common DPSC/VAMKC drug items, we found that 58 items were single source (i.e., no therapeutic

equivalent substitute); 52 items were considered by FDA to have therapeutically equivalent substitutes; 7 items were classified by FDA as not being able to be recommended as being therapeutically equivalent to any other pharmaceutically equivalent products; and 36 items 1/ were not included in FDA's January 1979 draft list of approved drug products.

We concentrated on those 52 drug items contained in the FDA January 1979 list to ascertain supply sources which were therapeutically equivalent for those drugs needed by DPSC, VAMKC, or both. After identifying the (1) FDA-approved source(s) of supply and (2) items classified as being therapeutically equivalent, we used the 1979 "Redbook" as a basis for determining the commercially available prices quoted by the supply source(s). For comparison purposes we used the lowest price of those FDA-approved manufacturers quoted in the "Redbook" to determine potential savings. However, we recognize that not all such FDA-approved manufacturers may choose to bid or have the capacity to manufacture the quantities needed to comply with DOD and VA drug procurement contracts. In total, the agencies' procurement of the lower priced substitutes on the last procurements before March 31, 1979, would have resulted in savings to the Government of about $85,000.

DPSC and VAMKC had procured four drug items (bethanechol chloride tablets, 10 mg., 100s; chlorpromazine hydrochloride tablets, 25 mg. and 50 mg., 1000s; and hydralazine hydrochloride tablets, 25 mg., 100s) at costs exceeding the costs of therapeutically equivalent drugs listed in the 1979 "Redbook." In total, DPSC and VAMKC could have saved about $62,500 by procuring generic drugs which had the therapeutic equivalency of the brand name or generic drugs most recently bought (as of March 31, 1979) by the agencies. This information is summarized in appendix VI. In fiscal year 1978, DPSC spent $533,553 and VAMKC spent an additional $336,817 for these four drugs.

1/The Federal Food, Drug, and Cosmetic Act permits certain drugs to be legally marketed without fully approved FDA drug applications under certain circumstances. Such drugs consist primarily of (1) drugs marketed before 1938 that are not subject to the premarket clearance procedure of the law and (2) drug products marketed between 1938 and 1962, which were approved for safety but not effectiveness. This latter category of drugs are being reviewed under the administrative procedure of the Drug Efficacy Study Implementation process.

Three additional drug items (chlordiazepoxide hydrochloride capsules, USP, 5 mg., 500s; methocarbamol tablets, NF, 500 mg., 500s; and propantheline bromide tablets, USP, 15 mg., 1000s) could have been bought by DPSC or VAMKC at a savings to the Government of about $22,800 for the most recent procurement of these items before March 31, 1979. This information is summarized in appendix VII. In fiscal year 1978, VAMKC spent $180,585 for chlordiazepoxide hydrochloride capsules, 5 mg., 500s and methocarbamol tablets, 500 mg., 500s. During the same period, DPSC spent $66,441 for propantheline bromide tablets, 15 mg., 1000s.

The policies of DOD and VA in regard to the substitution of lower priced, therapeutically equivalent drugs for higher priced drugs currently stocked and distributed by DPSC and VAMKC are similar.

DOD's overall policy is to procure drugs to the standards prescribed by the "U.S. Pharmacopeia," 1/ and the "National Formulary," 2/ and those issued by FDA. Therefore, whenever a generic product can be acquired from a lower bidder in full compliance with FDA regulatory requirements and the low bidder is able to satisfy other terms of the solicitation, the low bidder will be awarded the contract. DOD policy has always required procurement of drugs on a generic basis except those designated by DOD for limited source acquisition due to bioinequivalency or where the manufacturer will not provide technical information for preparing a purchase description. DOD currently has 15 drugs designated for limited source acquisition.

According to the Deputy Assistant Secretary of Defense (Supply, Maintenance, and Services), final publication of FDA's "Approved Drug Products With Proposed Therapeutic Equivalence Evaluation" will not eliminate DOD's limited source procurement policy. As a matter of fact, this official believes the number of drugs designated for limited source acquisition within DOD will have to be expanded because FDA is considering the establishment of bioequivalency

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1/A book containing a list of products used in medicine, with descriptions, chemical tests for determining identity and purity, and formulas for certain mixtures of these substances.

2/A book of standards for certain drugs and preparations that are not included in the "U.S. Pharmacopeia."

standards for more drugs and in the process has determined that even more dosage formulations are not interchangeable.

In reference to the FDA proposed list, VA's Chief Medical Director told us that it is VA's policy to provide a particular drug based on the most economical method of supply, which will be the lowest published price available. As single-source drugs become available on the commercial market, action is initiated to secure the drug competitively. Deviation from the standard procedure must be therapeutically justified and submitted to the Office of the Chief Medical Director through the VA Central Office's Executive Committee on Therapeutic Agents for approval.

LOWER PRICES PAID BY NON-FEDERAL HEALTH CARE ORGANIZATIONS

To compare Federal drug acquisition prices at the wholesale depot level with those paid by other public and private health care providers, we obtained acquisition prices for several non-Federal health care organizations. These organizations were a health maintenance organization, a large hospital management company which, among other things, contracts on a group purchase basis with pharmaceutical suppliers and manufacturers for its affiliated hospitals, and the New York City Health and Hospitals Corporation.

The three non-Federal organizations bought 18 of the 143 items (see p. 34) that DPSC and VAMKC bought in the 18-month period covered by our review. One or more of the non-Federal organizations (and in two cases all three non-Federal organizations) paid lower prices than DPSC or VAMKC.

A schedule of the most recent acquisition prices per unit (as of March 31, 1979) paid by DPSC, VAMKC, and the three non-Federal drug procurers for the 18 drug items common to all five organizations and the manufacturers of the drugs is presented in appendix VIII. The eight items in which DPSC and/or VAMKC paid a higher price than one or more of the non-Federal health care organizations are numbered 4, 6, 8, 11, 13, 15, 16, and 17 in this appendix.

The prices cited in the appendix reflect acquisition costs for each of the five organizations. In the cases of DPSC and VAMKC, there is a markup or surcharge added to the prices shown for delivery to DOD and VA hospitals. Currently, DPSC's surcharge is 10.8 percent, and VAMKC's is 6 percent. However, the acquisition prices for all three non-Federal

organizations are, in reality, the prices paid by the organizations' health care units, because these items are delivered to the requestors directly from the suppliers at the prices cited. There is no additional markup or surcharge; therefore, the price differences between the drugs are more pronounced than they first appear.

CONSIDERATION OF TOTAL COSTS IN PROCUREMENT OF DRUGS

In its 1972 report, the Commission on Government Procurement stated that the practice throughout the Government for procuring commercial products was to focus on the price paid for the item rather than on the total costs of procuring, stocking, and distributing the item. The result, according to the Commission, was that the Government had failed to develop the total costs of fulfilling its needs.

Failure to give consideration to all costs could result in a stronger preference for central stockage and issuance of drugs than may be justified. Generally, total costs should include the price of the product, procurement personnel costs, warehousing, distribution, obsolescence, and other costs arising through use and consumption. DOD and VA have recently given increased consideration to this overall concept in issues involving drug supply decisions. However, DOD must give more attention to this matter.

Within DOD, DLA has developed a total support cost mathematical model to evaluate the alternative methods of inventory management. The DLA model includes the market price paid for 1 year's supply of each item in its supply plus an allocated share of the cost of the support system needed to order, acquire, and deliver the item to the user. It includes both funded (budgetary) and unfunded (opportunity) costs. In essence it identifies the total costs to the Government for an item by including the price of the item, administrative management variable costs and overhead costs, inventory holding costs, and transportation costs. The model was furnished to the Assistant Secretary of Defense (Manpower, Reserve Affairs and Logistics) for review and approval in December 1978. A computerized economic model which provides for an evaluation of changes in unit price was made available to DPSC and other DLA supply centers in February 1980. The contracting officer has the responsibility of determining the most economical method of acquisition. DAS is verifying the model's input cost data.

At our request, DLA's Office of Operations Research and Economic Analyis identified the most cost-effective method of supply (i.e., centralized DPSC depot stockage or direct delivery of goods from manufacturer) for 152 items which were, at the time of our request, centrally stocked by DPSC and VAMKC. Because of incomplete data for certain items, the cost model was run against 146 DPSC drug items. This analysis was based upon the costs associated with these items being acquired on an individual item-by-item basis by DPSC rather than being procured in groups according to drug manufacturer. DLA's analysis, completed in July 1979, indicated that 79 items (54.1 percent) should be direct delivered by the manufacturer and 67 items (45.9 percent) should continue to be depot stocked. Quantifiable savings were not specifically requested by us, and therefore, the completed analysis did not contain these data.

We did not assess the assumptions or cost factors contained in the DLA cost model or evaluate its effectiveness as a decisionmaking tool. We assumed that the assumptions and cost factors were reasonable. Also, we assumed that only the 175 1/ DPSC-stocked drug items (as of June 1979) needed for war or contingency purposes which cannot be satisfied by relying on industrial capability in the civilian sector will continue to be centrally stocked regardless of the total support costs. Therefore, there remains a substantial number of eligible DPSC drug items which could possibly use the commercial distribution system instead of the DOD depots, if the costs identified with each method of acquisition so indicate.

Information provided to us in September 1979 through DPSC indicated that 1,166 drug items had been considered for eligibility to be run on the DLA computer model. Of these

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1/As of September 30, 1979, DPSC had identified 867 items in Federal Stock Class 6505 which were possible candidates--subject to their commercial availability--for stockage in DPSC because of the military services' requirements for these items for other war reserve materiel. These items did not include the services' prepositioned war reserve materiel requirements. As of March 1980, DPSC personnel had reviewed the commercial availability of approximately 100 of the 867 items. Based on their review of these items and recognizing that the 100 items were not selected on a random sample basis, DPSC estimates that approximately 350 items rather than the 175 items cited in our report will have to be stocked by DPSC.

items, 897 had been excluded from further consideration as being eligible for acquisition from sources other than the DOD depot system. One hundred sixty-two of these exclusions were for supply reasons (for example, too much stock on hand), and the other 735 exclusions were for technical reasons (for example, the existence of military and/or Federal specifications for items). There were also 51 items of stock that were considered to be commingled mobilization stock (commingled mobilization stock is materiel being held by both the military departments and the DOD depots).

We do not subscribe to DOD's rationale for excluding most of these items from being eligible for acquisition from sources other than the DOD depot supply system. For example, most of the military and Federal drug specifications could be eliminated without any adverse impact and, in reality, should be eliminated to comply with ADCOP policy. Nevertheless, DOD in 1979, after excluding the 897 national stock numbers for supply and technical reasons and the additional 51 stock numbers because of their need in case of mobilization, did identify 218 items which were, according to its own criteria, eligible for consideration for alternative means of acquisition.

A DLA official told us in September 1979 that these 218 items had not been run through the DLA cost model, but that the 218 items' frequency of order and annual demand on an item-by-item basis indicated that contracts requiring vendor delivery of these items directly to the user facility were the most economical procurement method for these drugs. A subsequent analysis by DLA revealed that 65 of these 218 items were most cost effectively acquired through the DOD wholesale depot system. In any event, DPSC was not in a position as of March 1980 to utilize an admittedly less costly means of acquisition for the remaining 153 items. According to DLA officials, DPSC does not have a fully automated direct delivery method of supply support to take advantage of this alternative means of acquisition. In addition, there may also be a lack of vendor response due to the type of contracting method employed or the level of contractor support it requires.

In regard to the VA Supply System, VA Central Office officials told us that total costs of procuring, storing, and issuing drugs under centralized procurement and its relative cost effectiveness had been determined before arriving at a decision to buy and stock drug items. According to these officials, the savings resulting from centralized purchasing

and stockage is 36 percent when compared to local procurement costs under FSS contracts.

In our report to the Congress, "Uniformed Procurement Decisions For Commercial Products Are Costly" (PSAD-77-170, Oct. 26, 1977), we concluded that even though VA did not include all possible full cost elements in its procurement and supply decisions, its method was sufficiently accurate to support reasonable decisions.

At the time of our current review, VA was concluding a study to identify and incorporate certain additional costs into its calculations. The drug share of these additional indirect costs was calculated to be about $4.1 million which would require an additional markup on depot drug items of 4.7 percent. However, while VA's investment costs may be used in determining the method of supply, these costs are not directly incurred by VA and are, therefore, not included in the present markup (6 percent) because VA recovers only its direct costs. VA includes in its minimum savings criteria for centralized drug stockage such indirect costs as investment costs and depreciation. In this way, VA believes that it does not have an unfair competitive advantage over potential commercial suppliers (manufacturers and distributors) of drugs to individual VA hospitals in its decisions concerning whether to centrally stock or locally procure a drug.

CHAPTER 5

CONCLUSIONS, RECOMMENDATIONS, AND AGENCY COMMENTS

CONCLUSIONS

The Federal Government has attempted for nearly two decades to improve its management of medical materiel (drugs and medical devices) by establishing a single system for the procurement and supply of such items. To date, DOD, VA, and more recently OFPP have had only limited success in their efforts to establish a Government-wide system.

The latest effort--the DOD/VA Shared Procurement Program--to establish such a Government-wide system was begun in January 1978 and proposed agency efforts to accomplish this task were approved by OFPP in September 1978. The Shared Procurement Program is to be implemented as part of the executive branch's efforts to institute ADCOP policy guidance. ADCOP-related initiatives were begun by OFPP to implement the Federal Government policy, adopted in May 1976, to recognize the need for a shift in the Government's fundamental philosophy for procuring commercial products. As a result, the Government's policy has been to (1) purchase commercial off-the-shelf products, when such products will adequately serve the Government's needs, and (2) use commercial distribution channels for supplying commercial products to its users.

Initial efforts under the Shared Procurement Program for single-source drugs reflected the individual needs of the respective agencies' supply systems. In most cases, the individual supply systems' requirements (i.e., stock numbers, shelf lives, marking and labeling, unit of issue, warranty, and inspection and acceptance of products) for the same manufacturer's products were different. In our opinion, the differences in DOD and VA procurement systems were, for the most part, highlighted rather than reconciled in the initial joint requirements-type contracts issued for single-source drugs. Only recently have these issues begun to be resolved to DOD's and VA's mutual satisfaction.

The issue of DOD's need for a national stock number on each unit of issue of a drug item remains the major impediment under the Shared Procurement Program to achieving commonality with VA on contract requirements. We believe DOD's position is counter to ADCOP policy. However, it has the support of

the military medical services and DLA depots. Nevertheless, it contributes significantly to DOD's inability to return drug items to manufacturers for exchange or credit before their shelf-life expiration. We believe requiring national stock numbers on things, such as each bottle and tube, is unnecessary and costly.

In addition, the agencies' efforts to reach a mutually agreeable and uniform expiration dating requirement for drugs merit closer attention. As a general rule, the shelf life will be not less than 36 months. (Before this arrangement, VA's shelf-life requirement was for not less than 18 months.) However, several recent DPSC drug procurements brought to our attention in DOD's comments on this report (see pp. 101 to 104) demonstrate both the lower prices being paid and new suppliers becoming involved in DPSC procurement actions as an apparent direct result of DOD's waiver, at the request of suppliers, of its normal shelf-life requirement.

In our opinion, any DOD/VA Shared Procurement Program solicitation should reflect the actual minimum requirement for shelf life established by considering the users' minimum needs on an item-by-item basis rather than a subjectively established longer shelf-life requirement than may be necessary. DOD's own experiences appear to demonstrate the benefits of waiving the standard shelf-life requirement of not less than 36 months. We believe the lessons learned by DOD on this matter should be adopted in the Shared Procurement Program. To assure competition to the maximum practical extent, decisions on the minimum acceptable shelf-life requirement should be made at the time the initial solicitation is made. It may be unreasonable to expect requests from potential suppliers for waivers of this requirement which may or may not be approved.

Steps have recently been taken by DOD and VA to implement the lessons learned from their experiences under Phase I of the Shared Procurement Program into the daily routine of Federal medical materiel procurement. Standard operating procedures have been developed and are in the final approval process. This effort should assist the agencies in their efforts to build a foundation toward full development and implementation of the uniform procurement system required by the Office of Federal Procurement Policy Amendments of 1979 (Public Law 96-83).

However, agency efforts to date have focused only on the acquisition phase of the ADCOP Program. Little effort has

been expended under the Shared Procurement Program to address other ADCOP-related issues concerning medical materiel that we believe should be considered. For example, the recognized overlap and duplication between the FSS schedules and DOD and VA central stock programs, non-Government procurement of medical materiel, and commercial distribution networks are issues which have not been fully addressed or considered. In regard to drugs available through FSS contracts, VA--through its delegated authority from GSA--in cooperation with DOD personnel should identify and eliminate from FSS those items which are procured more cost effectively through DOD or VA depots. Simultaneous consideration of all these matters would improve the agencies' market research and analysis efforts. Also, better acquisition strategies for federally managed items would result.

Repeated failures to establish a single system for the procurement of medical materiel and recent congressional policies contained in Public Law 96-83 dictate, in our opinion, that this commodity area be given a higher priority by OFPP for implementing a uniform procurement system for medical materiel specifically that adopts all ADCOP-related guidance issued to date by OFPP. OFPP should use its newly acquired legislative authority to assure that ADCOP policy principles are fully adopted and implemented in all phases of the Government's procurement and supply of medical materiel. Otherwise, the most recent efforts started about 2-1/2 years ago to implement a single Government-wide medical materiel procurement system will bring about only superficial rather than the substantive changes anticipated.

In our opinion, the principal reason for the slow pace involved in implementing a single system for the supply of medical materiel is the existing differences in philosophies, procedures, and techniques in the various Federal supply management systems. Such differences are based on different methods being employed to accomplish different missions. Also, efforts to implement a new system are viewed as something that must be done in addition to the normal business rather than in place of it. As a consequence, a lack of resources has been cited as a major reason for delays or why progress cannot be achieved faster.

To address the procurement weaknesses described in this report requires a renewed effort on the part of OFPP, DOD, and VA officials who have, in good faith, attempted since January 1978 to implement a single Government-wide system. We believe that the ultimate success in fully implementing the DOD/VA Shared Procurement Program and other related OFPP-directed

efforts will hinge on the ability of the existing supply management systems to increase their efforts. We do not underestimate the task needed to simultaneously change from two divergent systems to one uniform system while continuing to provide service as required to users of each system. However, we believe such increased efforts are required by the recently enacted Public Law 96-83.

There has been, and continues to be, a lack of reliable or compatible local drug procurement acquisition price data generated for agency management use. VA has attempted to address this issue by developing reports which contain such prices. However, certain VA officials' opinions of the data, and the accuracy of such data reported by the VA hospitals we visited raise serious questions about its reliability. DOD's failure to establish procedures to collect and review acquisition price data for locally procured drugs has resulted in a situation wherein it is not possible for DOD to determine--on an acquisition-by-acquisition price, item-by-item basis--if more economical procurements could have been made. Different reporting systems and inconsistent reporting practices exist within the three military departments. We believe that a comprehensive evaluation of the need for the Federal hospitals' reliance on supply sources other than the central procurement system is not possible without the benefit of accurate local (including FSS) drug procurement data. Such data should be used with other total system costs in formulating acquisition strategies.

The central depot systems of DOD and VA should be used only when it is the most cost-effective method of procurement for medical materiel. In this regard, the total system costs and not merely the acquisition costs of the items should be used in determining the preferred means of procurement. In DOD, a need may exist to centrally stock drug items irrespective of total costs because overall national security requirements cannot be totally supplied by relying upon the Nation's industrial capability.

Nevertheless, DOD's failure to take into consideration the total costs in the procurement of drugs may have resulted in policy determinations to centrally stock certain items which might be obtained more cost effectively through other means. Over half of the 146 DOD items we examined using the DLA cost model were found to be more economically obtainable by having the items delivered directly from the drug manufacturer to the user under various types of contracts. In addition, DPSC does not have a fully automated direct delivery

method of supply support at this time. Also, there may be a lack of vendor response due to the contracting method DOD uses or the level of support it requires. The DLA cost model has been recently completed, released for use at DLA supply centers, and is undergoing further validation and study. In this regard, we believe DOD's cost model should not include quantified factors to accommodate highly subjective issues involved in DOD's worldwide logistics network. (See p. 97.)

VAMKC, however, even when it took its total (direct and indirect) costs into consideration found that all of the same 146 items should be stocked centrally. Apparently, the VA supply system is less costly to operate than DOD's.

The number of drugs that can be bought competitively has been limited because of legislation which reflects other policy considerations. For example, the Buy American Act (41 U.S.C. 10a-10d) provides preferential treatment to domestic drugs, the Small Business Act, as amended (15 U.S.C. 631 et seq.), requires that a fair proportion of Government procurement be placed exclusively with small businesses, Public Law 95-89 provides for preferential treatment of contractors in areas of high unemployment or underemployment, and patent legislation grants an exclusive right for 17 years to manufacture and distribute a drug. These factors, or "barriers" in the broad sense, decrease the level of competition which might otherwise be possible if such restrictions did not exist.

In instances involving legislative barriers, as well as military unique drugs, single drug manufacturers, or the failure of drug manufacturers to meet FDA's quality standards, a decreased level of competition or in some cases its elimination is necessary. However, both DPSC and VAMKC have not in some instances solicited all possible sources of supply for drugs. Solicitation of additional sources of supply, along with full implementation of ADCOP policy principles, could increase the chances of increasing the competition for drugs purchased by the agencies and perhaps result in lower overall costs.

As a first step toward assigning Federal agency responsibility and accountability for item management, we believe a need exists to develop a single uniform Federal supply catalog for all drug, biological, and chemical reagent items. Such a single supply catalog would highlight product and price differences between the two major supply systems and

the FSS supply schedules. It not only would help industry and other interested parties by assigning Federal agency responsibility and accountability for item management but also would assist Federal efforts to lower health care costs by presenting in one document the full range of manufacturers and prices for the same drug.

We believe that the full economies inherent in VA's medical supply system are not being realized. It seems to us that items which are common to both DOD and VA's centralized wholesale depot systems should be handled by the agency which incurs the least costs to acquire, stock, and distribute such items. Such a transfer of responsibility to VA for all common drug items would appear to complement the policies of the Congress contained in the Office of Federal Procurement Policy Act Amendments of 1979 to promote economy, efficiency, and effectiveness in the procurement of goods and services.

Care must be taken not to equate the primary methods of procurement (formally advertised and negotiated) with varying degrees of competition. In both methods, competition is required to the maximum extent practical. In this regard, the Commission on Government Procurement has reported that 85 to 90 percent of the Government needs are satisfied using negotiated rather than formally advertised means of procurement.

Improvements in the current manner in which each agency procures its drugs are possible. Based on our review of prices paid at various levels for the same drugs, lower prices are available than those paid by one agency or both. Improvements in the overall procurement mechanisms should increase competition and, if jointly implemented under the DOD/VA Shared Procurement Program, should result in substantial savings to both agencies in drug acquisition costs as well as administrative costs. DPSC and VAMKC have already initiated action that should result in increased competition for drugs bought by these agencies.

RECOMMENDATIONS TO OMB

We recommend that the Director, OMB, direct the Administrator, OFPP, to:

--Give higher priority to medical materiel-related issues.

--Use the authority provided in the Office of Federal Procurement Policy Act Amendments of 1979 to the

maximum possible extent to fully implement the objectives of the DOD/VA Shared Procurement Program for medical materiel.

--Institute actions necessary to assure that all OFPP-directed guidance on the implementation of the ADCOP policy principles is fully considered and implemented by agency personnel throughout all Government medical materiel procurement activities.

--Direct the appropriate Federal agencies to develop a single uniform Federal supply catalog for all drug, biological, and chemical reagent items.

--Initiate a study to explore the feasibility of transferring to VA the responsibility for procuring, stocking, and distributing all drugs (except those needed for war or contingency purposes) that are common to the DOD and VA centralized wholesale depot systems.

RECOMMENDATIONS TO DOD AND VA

We recommend that the Secretary of Defense and the Administrator of Veterans Affairs:

--Establish an effective market research and analysis program for drugs and medical devices in accordance with the specific requirements of the Administrator, OFPP.

--Use FDA's expertise in identifying therapeutically equivalent drugs and substitute, to the maximum possible extent, any lower priced therapeutically equivalent drug for a higher priced drug currently procured by either or both of the respective agencies' centralized wholesale drug supply systems.

RECOMMENDATIONS TO DOD

We recommend that the Secretary of Defense:

--Instruct DOD supply personnel to (1) adopt a total cost methodology for use by DPSC personnel in management decisions concerning all current and proposed drug items to be centrally procured, stocked, and distributed and (2) eliminate from DPSC's wholesale depot system management control items which can be more cost effectively supplied through alternative methods.

--Reassess the need for placement of the national stock number on each unit of issue in light of ADCOP policy principles, its effect to date on achieving commonality for the items procured under the DOD/VA Shared Procurement Program, and the inability to exchange or receive credit for drug items returned to suppliers with national stock number markings.

RECOMMENDATIONS TO VA

We recommend that the Administrator of Veterans Affairs instruct VA Marketing Center officials in cooperation with other Federal officials involved in ongoing DOD/VA Shared Procurement Program efforts to

--identify duplicative drug items (procured and distributed through the Federal depot systems and Federal Supply Schedules) in efforts to adopt a suitable single acquisition strategy to satisfy all Federal users and

--eliminate those items identified above from availability through the Federal Supply Schedules if such means of supply are not the most cost effective.

AGENCY COMMENTS AND OUR EVALUATION

OFPP, DOD, VA, and HEW provided written comments on our report. (See apps. IX, X, XI, and XII, respectively.) A discussion of their major comments and our evaluation follow.

OFPP comments

The Administrator, OFPP, in commenting on our draft report, emphasized the immense task involved in establishing a single Government-wide medical procurement system. She stated that the implementation of ADCOP policy represents a fundamental change in the Government's procurement practices, and changes of this type are, at best, difficult and time consuming. Furthermore, OFPP believes that implementation of ADCOP policy principles in the DOD/VA Shared Procurement Program requires the internal realignment and adjustment of some agencies' resources, the development of new operating procedures, and the training of personnel. These changes must be accomplished by the agencies while concurrently performing their operational requirements.

We agree with the Administrator's comments. However, Federal agencies have historically resisted making these types of changes. To the agencies' credit, standard operating procedures for the DOD/VA Shared Procurement Program have recently been developed and are in the final approval process. Further, a training program is being developed through the Federal Acquisition Institute, which will help agency personnel better understand ADCOP techniques which apply to drugs.

In addition to these actions, we believe there is a need for OFPP to play an active role in specifically expressing policy guidance to the affected agencies as well as to monitor their efforts to carry out this guidance.

OFPP was concerned that our report did not recognize the progress made by DOD and VA in their shared drug procurement activities. Similar concerns were also expressed by DOD and VA in their comments on our draft report. Specific examples of accomplishment cited by the Administrator in her March 25, 1980, letter were (1) over $60 million in annual volume of drugs currently under contract with another $100 million expected to be under contract by the end of fiscal year 1980, (2) the settlement of differences in contract clauses, and (3) specifications unification.

We do not underestimate the magnitude of the accomplishments made to date by agency personnel. Mutual respect and understanding of each agency's supply management concerns by DOD and VA officials at all levels have been necessary to make such progress. Our draft report contained the most recent accomplishments by the agencies at the time our data collection and analysis efforts were completed. With the primary exceptions of more contracts issued and more specifications made uniform, the status and direction of the Shared Procurement Program have not changed. In our opinion, the progress made in the Shared Procurement Program should be judged on the procedures implemented in the day-to-day operations of the respective supply systems. Such changes have a recurring benefit to both an individual agency and the Government as a whole. Overall, we agree that a Government-wide system is beginning to take shape, but we believe that much remains to be considered and accomplished.

OFPP took issue with our recommendation to give higher priority to the medical materiel commodity area to assure full implementation of the congressional policies contained in the Office of Federal Procurement Policy Act Amendments

of 1979. OFPP stated that it had consistently assigned high priority to ADCOP policy implementation and that the management of medical procurement was an integral part of that assignment.

Our recommendation was based on the following rationale. First, the June 4, 1974, OMB memorandum establishing the objective of creating a single Government-wide medical procurement system was presented in the context of its interrelationship with the need for simultaneously improving the agencies' supply management activities. Secondly, the Office of Federal Procurement Policy Act Amendments of 1979 complemented OMB's earlier position by defining "procurement" to mean all stages of the acquisition process, beginning with determining a need through the Government's actual supply of property and services. In addition, this legislation required the Administrator, OFPP to develop a uniform procurement system which would, to the extent considered appropriate and with regard to the agencies' program activities, include uniform policies, regulations, procedures, and forms. Legislatively mandated time frames were also provided for OFPP's completion of these tasks.

OFPP has allowed the agencies to concentrate primarily on acquiring medical materiel which is needed by the DOD and VA centralized wholesale depots. Nothing substantive in the DOD/VA Shared Procurement Program has been required by OFPP in, for example, the areas of market research and analysis and the use of commercial distribution networks. Therefore, we believe that, unless the Administrator, OFPP, gives a higher priority to the medical materiel commodity area to address highly relevant but as yet unconsidered issues, the changes proposed by the Administrator to the Congress to implement the recent statutory requirements concerning a uniform procurement system as it relates to this particular commodity will not be accomplished soon.

OFPP agreed with our recommendation to develop a single uniform Federal supply catalog for all drugs, biologicals, and reagent chemicals which are centrally managed. OFPP plans to pursue this effort. It believes the development and adoption of a single catalog should improve responsiveness to the user and provide an overall visibility for all items centrally managed.

OFPP gave a qualified endorsement to our draft report recommendations that VA, because of its lower operating costs, assume responsibility for procuring, stocking, and

distributing all drugs (except those needed for war or contingency purposes) that are common to the DOD and VA centralized wholesale depot systems. OFPP reserved judgment until facts regarding mission impact analysis, cost benefits, user satisfaction and feasibility could be developed. It believes that any Government-unique products which are currently stocked should be converted to commercial products as ADCOP policy principles are implemented. In this manner, DOD and VA will be given the opportunity to rely less on Government depot distribution and more on acceptable commercial distribution. As a result, OFPP believes our draft report recommendation was premature.

We understand OFPP's concern regarding this recommendation. Further study is warranted. The overall question of proper administration of medical distribution activities appears to be a logical progression of issues to be considered in the near future by OFPP and agency officials. It is a major topic in the two basic documents cited by OFPP in its comments which govern the establishment of a single Government-wide medical procurement system. As a result of OFPP's concerns, as well as DOD and VA's on this matter, we have modified our proposed recommendation to the Director, OMB. We believe that the Administrator, OFPP, should initiate a study to explore the impact of other factors relative to assigning VA the responsibility of procuring, stocking, and distributing all drugs, with certain exceptions, that are common to the DOD and VA centralized wholesale depot systems. In our opinion, OFPP should serve as the catalyst for this study.

DOD comments

In commenting on the draft of this report, the Principal Deputy Assistant Secretary of Defense (Manpower, Reserve Affairs, and Logistics) said that the report fairly portrayed the difficulties associated with the progress being made in the areas of shared procurement and the use of commercial products. However, DOD was concerned that the report failed to give recognition to DOD's mission and to distinguish between the very different missions of DOD and VA.

DOD stated that it must stand ready to assure the operating forces of a viable worldwide support structure in wartime as well as peacetime, no matter where the forces may be located. This means that DOD supplies a wide array of items to respond to the needs of numerous large and small users. DOD must be ready in peacetime to meet a tremendous surge in demand, without notice, to support wartime needs.

DOD supplies overseas customers that normally would be supplied from retail distributors if the users were in the United States. War reserve items are also bought and stocked. As a result of these unique factors, DOD believes different staffing requirements in its wholesale depot system, different packaging and marking requirements, and different stockage requirements are necessary. DOD admits that these factors result in higher operating costs for DOD than are required by the VA medical supply system to meet VA's mission needs.

Our review of DOD's, as well as VA's, procurement of drugs was undertaken with a basic understanding of and appreciation for the missions of each agency. A statement of DOD's mission in relation to the procurement of drugs through its wholesale depot system has been added to the report.

Progress has been made recently by DOD in collaboration with VA to gain uniformity on issues which had previously been considered nonnegotiable by DOD because of their apparent adverse impact on DOD's mission. We believe that DOD supply officials in consultation with other executive branch supply officials and industry representatives should continue to strive to meet DOD's mission needs by relying to the maximum possible extent on commercial products and commercial distribution networks for medical materiel.

DOD pointed out that, while the adoption of ADCOP policy principles is moving forward, perhaps more slowly than desired, there have been positive results. Unique specifications that formerly hindered DOD's reliance on commercial distribution systems are being replaced. However, DOD cautioned that it must be sure that the commercial sector can respond to war readiness, overseas support, and unit of issue requirements before the depot stockage of items can be relinquished. DLA officials have previously agreed that no additional legislative authority to rely on the commercial distribution system in times of national emergency is necessary. Therefore, we believe that DOD should pursue the procurement and production of drugs needed to fulfill emergency requirements and maintain an adequate mobilization production base by reliance on the commercial marketplace.

When drug items are considered for acquisition on an item-by-item basis from the commercial marketplace, only DOD's minimum needs for each commercial drug item should be solicited from commercial sources. An expanded market

research and analysis program would provide, for consideration of DOD's users, the total array of available commercial items. Because only about 1 percent of DOD's centrally stocked drug items are militarily unique, the decision to rely on the commercial distribution systems will not be decided on the drug product itself, but on the total costs involved in acquiring the items needed by DOD users and certain DOD ancillary requirements. These ancillary requirements are, for the most part, cited by DOD as being necessary to satisfy the overseas support needs. Drugs bought by stateside DOD health care facilities from local drug suppliers and/or through FSS drug contacts do not have the special requirements of, for example, packaging, marking, or a uniform expiration dating period. The lack of such requirements has no apparent detrimental effect on these facilities' war readiness position. Therefore, it may be possible to develop measures to overcome those requirements needed to satisfy DOD's overseas support needs.

DOD did not believe that we fully accepted the resource constraints with which it has to work. DOD considered unjustified our report's conclusion that the slow pace in implementation of the Shared Procurement Program cannot be blamed upon the lack of available resources. DOD pointed out that people had been taken away from their regular duties to resolve different contract clauses, item specifications, and quality assurance procedures. In DOD's view, progress was being made in phasing in shared procurement procedures while continuing its day-to-day support of customers.

Our report's criticism of the pace in which the ADCOP policy principles were being implemented into the Shared Procurement Program was not meant to lessen the degree of effort expended or accomplishments made to date by relatively few agency personnel, particularly since September 1978. Further, in our report, we recognized the need for day-to-day support of customers and pointed out certain important issues which had not been addressed or fully considered. For example, issues, such as market research and development, commercial distribution networks, and total cost methodology, have not been adequately considered.

DOD provided comments on the recommendations we made to the Director, OMB.

DOD stated that the first three recommendations regarding (1) establishing a higher priority within OFPP for issues involving medical materiel, (2) increased use of existing

legislative authority to fully implement the objectives of the DOD/VA Shared Procurement Program, and (3) immediate implementation of the ADCOP policy principles would not result in faster progress because progress is governed by the realities of missions and resources. Although we cannot guarantee faster progress, we believe that, unless OFPP implements these recommendations, the result will be an incomplete effort by agency personnel to address all necessary issues concerning the development of a uniform procurement system for medical materiel within the statutorily established time frames. (See p. 8.)

The two remaining recommendations to OMB on which DOD provided comments addressed the (1) development of a single uniform Federal catalog for drugs, biologicals, and chemical reagents and (2) transfer from DOD to VA the responsibility of procuring, stocking, and distributing all common drugs, except those needed for war or contingency purposes, that are centrally managed and stocked by each supply system.

DOD does not believe that a special effort to develop a catalog is necessary since, over time, price uniformity will be achieved through the Shared Procurement Program. We believe that price uniformity should not be anticipated under Shared Procurement Program efforts. Unless the policies of DOD and VA are changed significantly, catalog prices for the same drug will be different within each respective supply system. Differences in the markups between supply systems will continue to account for differences in catalog prices.

A single drug catalog would provide all Federal users with a document that highlighted product differences as well as Federal agency responsibility and accountability for drug item management. Lower drug purchase costs should result by the presentation in one document of the full range of manufacturers' products and their prices.

DOD disagreed with our recommendation to transfer to VA the responsibility of procuring, stocking, and distributing certain drug items common to each agency. DOD said that it was not supported by an analysis of VA's capability to provide peacetime support. In DOD's opinion, such an analysis must consider local procurement items not available overseas, differences in DOD and VA units of issue, and the total number of customers being handled. In addition, DOD stated that it must be recognized that war readiness would require VA to be ready to respond to DOD's readiness requirements. As stated earlier by DOD in discussing the unique factors involved in

fulfilling its mission, this is a costly process. DOD believes VA's costs would be driven up and any savings generated by such an arrangement would be eliminated.

Our work showed that there is a significant difference in prices paid by individual DOD and VA health care facilities for common items bought for identical prices under the Shared Procurement Program. These differences occur because of unequal surcharges and markups imposed by the two agencies. The differences become greater if all DOD's direct costs are taken into consideration. Therefore, the reasonable issue to be pursued, under the direction of OFPP (and in cooperation with DOD and VA) is whether both agencies should continue to procure, stock, and distribute the same items. We understand that acceptance and implementation of this recommendation does not hinge solely on the issue of cost. As mentioned previously in our evaluation of OFPP's comments on our report, further study on this matter by OFPP and the affected agencies is warranted.

Obviously, the ability of VA to provide needed support would be essential. The Administrator of Veterans Affairs in commenting on this recommendation stated that VA's supply system is designed for its own needs and any alteration of the balance between the integrated operation of its wholesale and retail components could adversely affect the efficiency of the whole VA supply system. VA does not believe the adoption of this recommendation would adversely affect its system, but VA does not know if this is true of DOD's system.

In commenting on our recommendation to establish an effective market research and analysis program for drugs and medical devices, DOD stated that, since market research has not been specifically defined, establishing it as a uniform practice in the acquisition process is difficult and incorporating it in training curriculums and organizational functional descriptions against which personnel can be recruited and assigned is even more difficult. DOD believes it conducts market research with the resources it has. This effort involves determining users' needs and finding commercial products and supplies to fill those needs. DOD believes that its market research efforts will expand as DOD proceeds further into the preparation and use of commercial product descriptions in place of formal specifications.

Our recommendation to implement a more effective market research and analysis program was made in the context that

such activities would be in accordance with the requirements of the Administrator, OFPP. In our opinion, OFPP needs to give the agencies more specific guidance regarding the procedures and practices to be followed in implementing such a program. We believe that OFPP would consider many of the topics discussed in our report appropriate for the agencies to pursue in their expanded market research and analysis programs. Historically, any formalized DPSC market research and analysis for medical materiel has commanded the lowest priority of any commodities managed by DPSC. Furthermore, we understand that DPSC's Office of Market Research and Analysis is in the process of being eliminated.

We believe that the application of planned and coordinated market research and analysis techniques to DOD's medical materiel requirements is required for this commodity and all other DPSC-managed commodities. DOD's market research activities in the medical materiel area could be enhanced by a closer working relationship with OFPP staff to determine, in specific terms, the overall requirements for an effective program.

DOD agreed with our recommendation that it utilize FDA's expertise to identify therapeutically equivalent drugs and substitute such drugs for other higher priced drugs currently procured. DOD stated that this has been its policy and that continued efforts will be made to improve its application of this policy.

We made two other recommendations to DOD: The first was that DOD (1) adopt a total cost methodology for making stocking decisions and (2) eliminate those items from DOD depot stockage which are not found to be most cost effectively obtained in this manner. The second recommended that DOD reassess the need for a national stock number on each unit of issue.

DOD believes that the total cost methodology for making stocking decisions which we recommended has been adopted by the development of its Commercial Item Support Program (CISP) cost model. This cost model was used in our determination of the most economical acquisition method for 146 DPSC managed and stocked drug items discussed on page 47 of this report. As noted in the report, we did not assess the assumptions or cost factors contained in the DLA cost model or evaluate its effectiveness as a decisionmaking tool.

However, DOD's statement that its application has been hindered because of the difficulty in quantifying subjective areas, such as war readiness considerations, unit of issue requirements, and overseas support needs, concerns us. These are issues which do not lend themselves to quantitative analysis. They involve questions for which there are no apparent definitive answers and factors requiring public policy determinations. These issues need to be considered in light of whether they outweigh the potential cost differentials shown in a total cost-effectiveness analysis. Also, DPSC must devise a method to permit direct delivery from commercial sources of DPSC-managed medical materiel items which are shown to be more cost effectively supplied by means other than the DPSC depots.

DOD was concerned that we recommended a reassessment of its need for a national stock number on each unit of issue. DOD believes that a national stock number is necessary to avoid mixups that can occur when stock handlers unfamiliar with different medical terminology are processing such items. In DOD's opinion, a national stock number on each unit of issue is absolutely essential for effective identification and processing of materiel through its supply system. As DOD pointed out, all major supply systems rely on number identification systems; many also depend on uniform packaging. DOD believes these two elements are especially critical in automated systems like those used in its worldwide defense logistics network.

Our recommendation was directed to drugs only. We remain unconvinced that a national stock number on such things as every drug bottle and tube is needed. The VA drug supply system relies on national stock numbers as the basis for its number identification system to control its logistics system. However, VA permits commercial marking on units of issue and its intermediate packages; no national stock number is required. One tangible benefit of this method of operation is that VA can, through its exchange or credit contract clause with a drug manufacturer, return items to the manufacturer when an item's shelf life is about to expire. DOD drug contractors are reluctant to accept this type of clause in their contracts because of the difficulty encountered in attempting to sell, through commercial channels, drug materiel returned with national stock number markings.

VA comments

In commenting on our recommendation to establish an effective market research and analysis program, the Administrator of Veterans Affairs stated that VA would like to have a market research and analysis program for drugs and medical devices as sophisticated as the one described by OFPP. Unfortunately, a stylized market analysis using the concepts and having the scope required is not possible with VA's current resources. In VA's opinion, its current market research and decisionmaking process protects the interest of the taxpayer and complies with ADCOP policy. However, VA's market research will be expanded along the lines suggested and to the extent resources permit.

VA presently uses FDA's expertise to identify and substitute therapeutically equivalent, lower priced drugs for a higher priced drug currently procured and stocked by VAMKC. Use of therapeutically equivalent drugs is contingent on meeting the requirements of VA's professional medical staff. Procuring items other than those required by the physicians would generate dormant inventories which would be uneconomical. As stated in our report, VA's policy is to provide a particular drug at the lowest published price using the most economical method of supply. As sole/single-source drugs become available on the commercial market, action is initiated to buy the drug competitively. Deviations from standard procedure must be therapeutically justified and submitted to the Office of the Chief Medical Director through the Executive Committee on Therapeutic Agents, Central Office, for approval. We believe, however, that VA medical supply personnel should routinely inform VA's medical professional staffs that there are lower priced, FDA-recognized drugs available which are therapeutically equivalent to higher priced drugs currently being used.

In commenting on our recommendation that VAMKC officials (1) identify duplicative drug items procured through Federal depots and the Federal Supply Schedule drug contracts and (2) eliminate those items from availability from all but the most cost-effective source, VA stated that it currently reviews and analyzes such items to determine the most cost-effective method of procurement and supply. We made our recommendation to VA primarily because it was a major participant in the DOD/VA Shared Procurement Program and, in addition, had been delegated the responsibility by GSA for buying drugs for all civil agencies. However, the assistance of DPSC personnel in implementing this recommendation would be essential.

Our primary objective in making this recommendation was the elimination of identical items from all but one Federal supply source. In this regard, identical items stocked only by DPSC and available through FSS drug contracts should be removed from availability from FSS because DPSC must have a lower price than that available from FSS in order to stock the item and DPSC, in its normal course of business, provides drugs in small quantities to minor users. Therefore, minor users within the Federal sector could presumably be supplied by DPSC without any apparent difficulty. On the other hand, identical drugs procured and stocked only by VAMKC and available through FSS drug contracts should continue to be available from both sources only if VA can demonstrate that such items provide the needed flexibility to major and minor users to support their demand. Likewise, Shared Procurement Program efforts initiated to adopt a suitable single acquisition strategy should take into consideration whether a specific drug needed by the professional medical staff of one or both major agencies (as well as other Federal users) should be available in every possible quantity. The question which should be asked is, is it economical to procure and stock in Federal depots and/or have available through FSS drug contracts every current quantity (i.e., 50s, 100s, 500s, 1000s, and unit dose)?

VA stated that it will continue its efforts to assess the FSS drug schedules to insure that items included are cost effective and in the best interest of all users.

In commenting on our recommendation that VA take over responsibility for procuring, stocking, and distributing all items common to VA and DOD, VA stressed caution in implementing the recommendation. VA stated that its acquisition process is an integrated operation of wholesale and retail activities. The system is closely monitored with a primary objective of achieving a balance between these activities which will provide supplies to the customer at the most economical cost. VA's system is designed for its own needs and any alteration of the balance between the wholesale and retail components could adversely affect the VA system. Adoption of this recommendation would not adversely affect the VA system, but VA does not know if this is true of DOD. Consolidation into a single agency should be considered only if it is the most efficient and economical solution. In VA's opinion, various shared procurement activities, such as item assignment, unification of specifications, elimination of duplicate stock numbers, item commonality, and unification of quality assurance requirements, should be completed before this recommendation is considered.

As stated previously in commenting on OFPP's and DOD's concerns about this recommendation, we believe further study is necessary, and we have modified our recommendation.

HEW comments

In commenting on our draft report, HEW's Acting Inspector General stated that references to its programs were accurate and current.

While we made no recommendations to the Secretary of HEW, HEW expressed concern that our recommendation that the Secretary of DOD and the Administrator of Veterans Affairs implement an effective market research and analysis program contained language which might be interpreted as our advocating the establishment of a medical materiel quality assurance program in each agency.

Such agency actions were not intended. We have clarified our recommendation to avoid any misunderstanding of our intent. In addition, we strongly support ongoing efforts by OFPP, DOD, and VA in collaboration with FDA to reach agreement on a uniform quality assurance program for medical devices to be administered solely by FDA personnel.

CHAPTER 6

SCOPE OF REVIEW

We limited our review primarily to prescription drugs used by DOD and VA health care facilities. However, it was necessary during our inquiry into the status of the DOD/VA Shared Procurement Program to consider the issue of medical devices because of the interrelationship that drugs and medical devices have in this program.

Information developed during our review was obtained by:

--Randomly selecting and reviewing 92 drug procurement contract files at DPSC and VAMKC.

--Developing procurement history data on selected prescription drug items common to DOD and VA.

--Comparing acquisition price data for drugs procured by DPSC, VAMKC, and three non-Federal health care organizations.

--Sending several letters of inquiry to agency officials concerning various aspects of the DOD/VA Shared Procurement Program.

--Holding discussions with agency officials.

We obtained information from and spoke to officials at the following organizations:

OMB:
Office of Federal Procurement Policy, Washington, D.C.

DOD:
Deputy Assistant Secretary of Defense for Supply Maintenance and Service, Washington, D.C.
Defense Logistics Agency:
Headquarters, Cameron Station, Alexandria, Virginia
Defense Personnel Support Center, Philadelphia, Pennsylvania
Defense Medical Materiel Board, Ft. Detrick, Maryland
Department of the Army:
Office of the Surgeon General, Washington, D.C.
Walson Army Hospital, Fort Dix, New Jersey

Department of the Navy:
Office of the Surgeon General, Washington, D.C.
Great Lakes Regional Medical Center, Great Lakes, Illinois
Philadelphia Naval Regional Medical Center, Philadelphia, Pennsylvania
Department of the Air Force:
Office of the Surgeon General, Washington, D.C.

FDA:
Headquarters, Rockville, Maryland

SBA:
Headquarters, Washington, D.C.

VA:
Supply Service, Department of Medicine and Surgery, Washington, D.C.
VA Marketing Center, Hines, Illinois
Veterans Administration Hospital, Downey, Illinois
Veterans Administration Hospital, Hines, Illinois

Other:
New York City Health and Hospitals Corporation, New York, New York

We also obtained pricing data from two other non-Federal health care organizations. These organizations honored our request for detailed price information with the understanding that their identities would not be associated with the data in any public disclosure. Non-Federal health care organization A is a health maintenance organization, and non-Federal health care organization B is a large hospital management organization which, among other things, contracts with pharmaceutical suppliers and manufacturers on a group purchase basis.

APPENDIX I

United States Senate

COMMITTEE ON THE JUDICIARY
SUBCOMMITTEE ON ANTITRUST AND MONOPOLY
WASHINGTON, D.C. 20510

January 19, 1979

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

Dear Mr. Comptroller General

The Senate Committee on the Judiciary is presently engaged in an inquiry into the pricing practices of the prescription drug industry. In this connection we are requesting the assistance of the General Accounting Office relative to the purchasing practices used by the Department of Defense and the Veterans Administration in their centralized buying program, as well as local purchasing by the agencies' hospitals. It has been estimated that roughly half of each agency's total disbursements for drugs is divided between centralized and local procurement.

Specifically, we are interested in the following:

1. A sampling of prices paid for selected major drug items purchased under the two programs, and an evaluation of the need for the substantial reliance upon other than central procurement by the agency's hospitals.

2. The explanation for the limited number of drug firms participating in offers for sale, either under formal bidding or the negotiation procedures used in centralized procurement.

3. The precise character of the negotiation procedures employed and the kinds of issues involved and the types of firms contacted.

4. The specific barriers which preclude smaller firms from qualifying as accepted sellers, i.e. product specifications, testing data, packaging requirements, patent monopolies and so forth.

5. The reasons for the limited use of formal bidding procedures, as compared with negotiation (10% by DOD, 15% by VA), and the explanation for why current Red Book price quotations of smaller firms to pharmacists for small volume purchases are frequently substantially lower than the agencies' negotiated prices for high volume purchases of the same drugs.

APPENDIX I

6. The present status of the OMB-approved program for the establishment of a single system for the procurement of drugs by DOD and the VA. The proposal contemplates that purchases will be divided between the two agencies without duplication, i.e., a specific drug used by both agencies will be purchased by one agency under an agreed division of labor. (See Memorandum, "Improving the Purchase and Supply Management of Medical Items and Nonperishable Substances" issued by the Office of Federal Procurement qolicy, OMB, January 19, 1978.) Since most major drug firms market a wide array of drugs, both agencies will continue separate negotiation with the same companies but on different items. An appraisal of this program would be helpful.

I hope to hear from you soon on this matter. The staff of the Committee stands ready to assist you in designing your inquiry pursuant to this request, and in providing any information you may need regarding our interests.

Sincerely,

Edward M. Kennedy
Chairman
Committee on the Judiciary

APPENDIX II

PUBLIC LAW 96-83—OCT. 10, 1979

OFFICE OF FEDERAL PROCUREMENT POLICY ACT AMENDMENTS OF 1979

59-139 O - 79 (87)

Public Law 96-83
96th Congress

An Act

Oct. 10, 1979
[S. 756]

To amend the Office of Federal Procurement Policy Act, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

Office of Federal Procurement Policy Act Amendments of 1979.
41 USC 401 note.

SHORT TITLE; REFERENCE

SECTION 1. (a) This Act may be cited as the "Office of Federal Procurement Policy Act Amendments of 1979".

41 USC 401 note.

(b) As used in this Act, the term "the Act" means the Office of Federal Procurement Policy Act.

DECLARATION OF POLICY

SEC. 2. Strike Section 2 of the Act (41 U.S.C. 401) and insert in lieu thereof the following:

"DECLARATION OF POLICY

"SEC. 2. It is declared to be the policy of Congress to promote economy, efficiency, and effectiveness in the procurement of property and services by and for the executive branch of the Federal Government by—

"(1) promoting the use of full and open competition in the procurement of products and services;

"(2) establishing policies, procedures, and practices which will require the Government to acquire property and services of the requisite quality and within the time needed at the lowest reasonable cost;

"(3) improving the quality, efficiency, economy, and performance of Government procurement organizations and personnel, and eliminating fraud and waste in the procurement process;

"(4) avoiding or eliminating unnecessary overlapping or duplication of procurement and related activities;

"(5) avoiding or eliminating unnecessary or redundant requirements placed on contractor and Federal procurement officials;

"(6) identifying gaps, omissions, or inconsistencies in procurement laws, regulations, and directives and in other laws, regulations, and directives, relating to or affecting procurement;

"(7) achieving greater uniformity and simplicity, whenever appropriate, in procurement procedures;

"(8) otherwise promoting economy, efficiency, and effectiveness in Government procurement organizations and operation;

"(9) coordinating procurement policies and programs of the several departments and agencies;

"(10) minimizing possible disruptive effects of Government procurement on particular industries, areas, or occupations;

"(11) improving understanding of Government procurement laws and policies within the Government and by organizations and individuals doing business with the Government; and

"(12) promoting fair dealing and equitable relationships among the parties in Government contracting.".

DEFINITION

SEC. 3. Section 4 of the Act (41 U.S.C. 404) is amended by inserting "(a)" immediately after "SEC. 4." and by inserting at the end of such section the following new subsection: 41 USC 403.

"(b) As used in this Act, the term 'procurement' includes all stages of the acquisition process, beginning with the process for determining a need for property and services through to the Federal Government's disposition of such property and services.".

AUTHORITY AND FUNCTIONS

SEC. 4. (a) Section 6(a) of the Act (41 U.S.C. 405(a)) is amended to read as follows:

"SEC. 6. (a) The Administrator shall provide overall leadership in the development and implementation of procurement policies and the coordination of programs to improve the quality and performance of procurement personnel. The Administrator shall develop for submission under section 8(a) a uniform procurement system which shall, to the extent he considers appropriate and with due regard to the program activities of the executive agencies, include uniform policies, regulations, procedures, and forms to be followed by executive agencies— Uniform procurement system. 41 USC 407.

"(1) in the procurement of—

"(A) property other than real property in being;

"(B) services, including research and development; and

"(C) construction, alteration, repair, or maintenance of real property; and

"(2) in providing for procurement by recipients of Federal grants or assistance of items specified in clauses (1)(A), (1)(B), and (1)(C) of this subsection, to the extent required for performance of Federal grant or assistance programs.".

(b) Section 6(c) of the Act (41 U.S.C. 405(c)) is amended to read as follows:

"(c) The Administrator shall develop and propose a central management system consisting of the Office of Management and Budget, the General Services Administration, and procurement offices in executive agencies to implement and enforce the uniform procurement system described in subsection (a) of this section.". Central management system.

(c) Section 6(d) of the Act (41 U.S.C. 405(d)) is amended to read as follows:

"(d) The functions of the Administrator shall include—

"(1) reviewing the recommendations of the Commission on Government Procurement to determine those recommendations that should be completed, amended, or rejected, and to propose the priority and schedules for completing the remaining recommendations;

"(2) developing a system of simplified and uniform procurement policies, regulations, procedures, and forms;

"(3) establishing criteria and procedures for an effective and timely method of soliciting the viewpoints of interested parties in the development of procurement policies, regulations, procedures, and forms;

"(4) promoting and conducting research in procurement policies, regulations, procedures, and forms, through the Federal Acquisition Institute, which shall be located within the Office and directed by the Administrator;

"(5) establish, through the Federal Procurement Data Center, which shall be located in the General Services Administration

and acting as executive agent for the Administrator, a computer-based information system for collecting, developing, and disseminating procurement data which takes into account the needs of the Congress, the executive branch, and the private sector;

"(6) recommending and promoting, through the Federal Acquisition Institute, programs of the Office of Personnel Management and executive agencies for recruitment, training, career development, and performance evaluation of procurement personnel;

41 USC 407

"(7) developing, for inclusion in the uniform procurement system to be submitted under section 8(a), standard contracts and contract language in order to reduce the Government's cost of procuring goods and services as well as the private sector's cost of doing business with the Government; and

"(8) providing leadership and coordination in the formulation of executive branch positions on legislation relating to procurement.".

(d) Section 6(e) of the Act (41 U.S.C. 405(e)) is amended to read as follows:

Consultation with executive agencies.

"(e) In the development and implementation of the uniform procurement system the Administrator shall consult with the executive agencies affected, including the Small Business Administration and other executive agencies promulgating policies, regulations, procedures and forms affecting procurement. To the extent feasible, the Administrator may designate an executive agency or agencies, establish interagency committees, or otherwise use agency representatives or personnel to solicit the views and the agreement, so far as possible, of executive agencies affected on significant changes in policies, regulations, procedures and forms.".

(e) Section 6 of the Act (41 U.S.C. 405) is further amended by inserting at the end thereof the following new subsections:

"(h)(1) Until the effective date of legislation implementing a uniform procurement system, the Administrator may, with the concurrence of the Director of the Office of Management and Budget, issue policy directives, in accordance with existing law, for the purpose of promoting the development and implementation of the uniform procurement system or for the purpose of promoting the policies set forth in paragraphs (1) through (8) of section 2 of this Act. Such policy directives shall be followed by executive agencies.

"(2) Any policy directives issued pursuant to paragraph (1) may require executive agencies to issue implementing regulations which shall be in accord with the criteria and standards set forth in such policy directives.

Regulations, denial or rescission of promulgation.

"(i) Until the effective date of legislation implementing a uniform procurement system, the Director of the Office of Management and Budget shall deny or rescind the promulgation of any final rule or regulation of any executive agency relating to procurement if the Director determines that such rule or regulation is inconsistent with the policies set forth in paragraphs (1) through (8) of section 2 of this Act or is inconsistent with any policy directives issued pursuant to subsection (h).

"(j) Nothing in this Act shall be construed—

40 USC 471 note.

"(1) to impair or affect the authorities or responsibilities conferred by the Federal Property and Administrative Services Act of 1949 with respect to the procurement of automatic data processing and telecommunications equipment and services or of real property; or

"(2) to limit the current authorities and responsibilities of the Director of the Office of Management and Budget.".

RESPONSIVENESS TO CONGRESS

SEC. 5. (a) Section 8(a) of the Act (41 U.S.C. 407(a)) is amended to read as follows:

"SEC. 8. (a)(1) The Administrator shall keep the Congress and its duly authorized committees fully and currently informed of the major activities of the Office of Federal Procurement Policy, and shall submit a report thereon to the House of Representatives and the Senate annually and at such other times as may be necessary for this purpose. Report to Congress.

"(2) At the earliest practicable date, but in no event later than one year after the date of enactment of the Office of Federal Procurement Policy Act Amendments of 1979, the Administrator shall transmit to the House of Representatives and the Senate his proposal for a uniform procurement system. Such proposal shall include a full description of the proposed system, projected costs and benefits of the system as proposed, and short- and long-term plans for implementation of the system, including schedules for implementation. At the same time, the Administrator shall transmit a report on the recommendations of the Commission on Government Procurement specified in section 6(d)(1) of this Act. Uniform procurement system proposal, transmittal to Congress.

"(3) At the earliest practicable date, but in no event later than one year after presentation of the proposal described in paragraph (2) of this subsection, the Administrator shall propose to the House of Representatives and the Senate recommended changes in legislation relating to procurement by executive agencies. If the Administrator deems it necessary, these recommendations shall include a proposal for a consolidated statutory base for procurement by executive agencies. Executive agencies' procurement proposal, transmittal to Congress.

"(4) At the earliest practicable date, but in no event later than the submission of the legislative recommendations described in paragraph (3) of this subsection, the Administrator shall present a proposal for a management system described in section 6(c) to implement and enforce the uniform procurement system.". Management system proposal.

(b) Section 8 of the Act (41 U.S.C. 407) is further amended—

(1) by striking out "any major policy or regulation prescribed under section 6(a)" in subsection (b) and inserting in lieu thereof "any policy prescribed under section 6(h)"; 41 USC 405.

(2) by striking "or regulation" each place it appears in such subsection; and

(3) by striking out "any major policy or regulation" in subsection (c) and inserting in lieu thereof "any policy".

EFFECT ON EXISTING REGULATIONS

SEC. 6. Section 10 of the Act (41 U.S.C. 409) is amended to read as follows:

"EFFECT ON EXISTING REGULATIONS

"SEC. 10. Procurement policies, regulations, procedures, or forms in effect as of the date of enactment of the Office of Federal Procurement Policy Act Amendments of 1979 shall continue in effect, as modified from time to time by the issuing offices on their own initiative or in response to policy directives issued under section 6(h) until repealed, amended, or superseded pursuant to the adoption of the uniform procurement system described in section 6 of this Act.". 41 USC 405.

AUTHORIZATION OF APPROPRIATIONS

SEC. 7. Section 11 of the Act (41 U.S.C. 410) is amended—

(1) by striking out the first sentence and inserting in lieu thereof the following: "There are authorized to be appropriated to carry out the provisions of this Act, and for no other purpose, $4,000,000 for the fiscal year ending September 30, 1980, and for each of the three succeeding fiscal years; and one-third of the funds appropriated for any such fiscal year shall be made available to the Federal Acquisition Institute for the performance of its functions under this Act."; and

(2) by striking out "Government Operations" in the second sentence and inserting in lieu thereof "Governmental Affairs".

DELEGATION

SEC. 8. Section 12(a) of the Act (41 U.S.C. 411(a)) is amended by striking out "direction of Federal procurement policy and to prescribe policies and regulations to carry out that policy" and by inserting in lieu thereof "leadership in the development of Federal procurement policy".

ACCESS TO INFORMATION

SEC. 9. Section 14(b) of the Act (41 U.S.C. 412(b)) is amended by striking out "establishing" and inserting in lieu thereof "developing".

CONFORMING AMENDMENTS

SEC. 10. (a) Sections 201(a)(1), 201(c), and 206(a)(4) of the Federal Property and Administrative Services Act of 1949 (40 U.S.C. 481(a)(1), 481(c), 487(a)(4)) are each amended by striking out "subject to regulations" and inserting in lieu thereof "subject to policy directives".

(b) Section 602(c) of the Federal Property and Administrative Services Act of 1949 (40 U.S.C. 474(c)) is amended by striking out "except as otherwise provided by the Office of Federal Procurement Policy Act, and".

41 USC 401 note.

EFFECT ON OTHER LAW

41 USC 405a note.

SEC. 11. The provisions of the Act as amended by this Act shall supersede the provisions of section 222 of the Act of October 24, 1978, entitled "An Act to amend the Small Business Act and the Small Business Investment Act of 1958" (41 U.S.C. 405a) to the extent they are inconsistent therewith.

92 Stat. 1771.

EFFECTIVE DATE

41 USC 401 note.

SEC. 12. Except to the extent otherwise provided therein, the amendments made by this Act shall take effect on October 1, 1979.

Approved October 10, 1979.

LEGISLATIVE HISTORY:

HOUSE REPORT No. 96-178 accompanying H.R. 3763 (Comm. on Government Operations).

SENATE REPORT No. 96-144 (Comm. on Governmental Affairs).

CONGRESSIONAL RECORD, Vol. 125 (1979):

May 21, considered and passed Senate.

Sept. 10, H.R. 3763 considered and passed House; passage vacated and S. 756, amended, passed in lieu.

Sept. 27, Senate concurred in House amendments with amendments.

Sept. 28, House agreed to Senate amendments.

WEEKLY COMPILATION OF PRESIDENTIAL DOCUMENTS, Vol. 15, No. 41:

Oct. 10, Presidential statement.

○

GENERAL COMMENTS ON FEDERAL METHODS OF PROCUREMENT:

FORMALLY ADVERTISED AND NEGOTIATED
(including statistical information developed relative to Federal drug procurements)

The Federal Government's drug procurements are accomplished by either of two methods: by formal advertisement or negotiation.

Formal advertised bidding consists of four steps:

--The issuance of an invitation for bids which contains specifications describing the actual minimum needs of the Government.

--The submission of sealed bids.

--A public opening of the sealed bids at a specified time and place.

--The award of a contract to the lowest responsible bidder whose bid conforms in all material respects to the requirements of the invitation for bids.

Negotiation, however, does not involve a rigid set of formalized procedural steps and may be defined to include all methods of procurement other than formal advertising. However, care should be taken not to equate competition with only formally advertised contracting since negotiation is required to be competitive to the maximum extent practical. The process of negotiation usually entails discussions between the Government and the prospective contractor after the receipt of initial proposals along with the submission of revised proposals, in contrast to the "one shot" procedure which characterizes formal advertisement.

The underlying reasons prompting the adoption of formal advertising for bids as the preferred procedure in Federal procurement have been stated numerous times. In this regard, formal advertising is to restrict the use of appropriation funds to acquire actual Government needs, to secure such needs at the lowest cost, and to guard against such things as injustice, favoritism, collusion, and graft in transacting public business.

APPENDIX III

Although formal advertising is the traditional mode of Government procurement, many exceptions to advertising have been provided by statutes which permit negotiation in specified instances. Moreover, however, desirable advertised competitive bidding may be as a procedure in securing advantageous contracts for the Government, procurement by negotiation has assumed an increasingly larger role in recent years. By far the greater portion of procurement expenditures is now effected under negotiated contracts. The Commission on Government Procurement reported that, in terms of contract award dollars, 85 to 90 percent of the Federal Government's needs are satisfied through negotiated procurements.

Currently, the principal authorities to negotiate contracts are listed as exceptions to the advertising requirements of the Armed Services Procurement Act of 1947 (10 U.S.C. 2301-2314) and the Federal Property and Administrative Services Act of 1949 (41 U.S.C. 251-260). The former statute provides 17 exceptions to the advertising requirement, and the latter act contains essentially all but two of those exceptions. However, it should be noted that 10 U.S.C. 2304(a), by its language, and Federal Procurement Regulations, implementing 41 U.S.C. 252, require that formal advertising be used if "feasible and practicable under the existing conditions and circumstances," even where one of the exceptions may apply.

A prerequisite to negotiation is the ascertainment that advertising is not feasible and practicable. Additionally, several of the specific exceptions warranting negotiation require high level determinations to be used as the basis for negotiation. As amended by Public Law 87-653, enacted on September 10, 1962, the Armed Services Procurement Act of 1947 requires written determinations and findings as a prerequisite to negotiation under certain statutory exceptions (10 U.S.C. 2310).

The purchase or contracting for medicines or medical supplies is one of the exceptions to 10 U.S.C. 2304 and 41 U.S.C. 252 permitting negotiations.

Our analysis of the 92 selected DPSC and VAMKC prescription drug contract files disclosed the following statistical information for the respective procurement systems.

Method of procurement	Number of contracts	Percent	Contract dollar value	Percent
DPSC:				
Competitive:				
Advertised	11	20	$ 367,365	11
Negotiated	11	20	588,688	17
Total competitive	22	40	956,053	28
Noncompetitive:				
Negotiated	33	60	2,506,266	72
Total (DPSC)	55	100	3,462,319	100
VAMKC:				
Competitive:				
Advertised	16	43	864,968	31
Noncompetitive:				
Negotiated	21	57	1,943,381	69
Total (VAMKC)	37	100	2,808,349	100
Grand total (DPSC and VAMKC)	92		$6,270,668	

The reasons for the 54 (33 DPSC and 21 VAMKC) contracts in our sample of 92 contracts being noncompetitively negotiated are disclosed on the next page.

A fundamental concept of Government procurement is that competition assures a fair and reasonable price. However, where negotiation is authorized, certain restrictions upon the competitive process are usually present. To compensate for these inherent restrictions on competition, the procurement agencies have developed guidelines for contracting officers to use in determining whether a negotiated proposal is fair and reasonable. Therefore, the Defense Acquisition Regulation requires some form of price or cost analysis for every negotiated procurement action. Federal Procurement Regulations state that such analysis "should" be made in

Reasons for noncompetitive procurements	Number of contracts		Percent		Amount		Percent	
	DPSC	VAMKC	DPSC	VAMKC	DPSC	VAMKC	DPSC	VAMKC
Patents and/or licenses	15	12	46	57	$1,322,478	$1,455,955	53	75
Single source (only manufacturer)	14	4	42	19	947,005	250,202	38	13
Only one FDA-approved supplier	2	-	6	-	200,530	-	8	-
FDA rejected low bidder	1	-	3	-	26,577	-	1	-
Emergency procurement	1	-	3	-	9,677	-	(a)	-
Brand name preferred	-	b/ 5	-	24	-	237,323	-	12
	c/33	21	100	100	$2,506,267	$1,943,480	100	100

a/Less than 1.

b/Other drug manufacturers with lower priced products have been identified, and VAMKC officials have initiated action to solicit these other manufacturers.

c/On 14 of these 33 contracts, DPSC solicited two or more firms. In fact, in 3 of the 14 at least eight firms were solicited. However, only one responsive bid was received by DPSC for each of these 33 contracts.

APPENDIX III

connection with each negotiated procurement. Under both regulations, the method and degree of such analysis depends on the particular circumstances.

Price analysis is performed in all cases where cost and pricing data are not required. Price analysis is defined in the regulations as the process of examining and evaluating a prospective price without evaluating the separate cost elements or proposed profit of the prospective supplier. Price analysis may be performed by comparing the submitted price quotations with each other, with prior quotations and contract prices for the same or similar items, and with published competitive price lists or published market prices.

STATUS OF IMPLEMENTATION BY DOD AND VA OF SELECTED DRUG PROCUREMENT-RELATED RECOMMENDATIONS CONTAINED IN PREVIOUSLY ISSUED REPORTS

In our December 6, 1973, report, "How To Improve The Procurement and Supply of Drugs In the Federal Government," we made recommendations to the Director, OMB; the Secretary of Defense; the Secretary of Health, Education, and Welfare; and the Administrator of Veterans Affairs to promote Federal agency cooperation in procuring drugs.

These agencies have made progress in implementing certain of our recommendations. For example, the Administrator, OFPP, is attempting to develop, in cooperation with DOD, VA, HEW, and GSA, policies and procedures to provide greater coordination and cooperation among Federal agencies in buying drugs as well as medical devices. The DOD/VA agreement signed in June 1978 (see p. 11) for shared procurement of medical materiel is evidence of the agencies' commitment to continue working on many of the same types of deficiencies disclosed in our 1973 report and other coordinated procurement matters that should improve the Government's procurement and supply of drugs.

Since June 1978, certain single-source items have been combined under the DOD/VA Shared Procurement Program to try to take advantage of the savings possible through bulk procurements under requirements-type contracts with drug manufacturers. Under this arrangement, each agency is supposed to be aware of the other's annual estimated requirements and the prices of the items under contracts. Task groups have been established to divide purchasing responsibility without duplication, develop an item-entry control system to avoid duplicate purchasing of new items, develop a uniform quality assurance procedure for approval of firms and acceptance of material, and establish procedures for eliminating the multiplicity of specifications for drugs. The status of the efforts conducted to date under this agreement are discussed in chapter 2.

After the issuance of our report, OFPP issued its ADCOP policy designed to increase the purchasing of off-the-shelf commercial products. One of the objectives was to eliminate unnecessary Government specifications for commercial products and/or adopt non-Government specifications.

In keeping with OFPP policy, VA's preparation of specifications for all drugs as well as chemicals has been discontinued and deleted as of February 1979. Likewise, DOD has started to "scrub down" its Federal and military specifications to eliminate any unnecessary requirements. Procurement Item Descriptions (PIDs) are currently being developed by DOD and VA under the shared procurement concept for use by both agencies in procuring medical materiel. A PID is a brief description of an item tailored to commercially available items.

DOD Directive 5000.37, dated September 29, 1978, established a DOD policy to insure that drugs, among other things, will be obtained centrally whenever savings would result. This directive officially established OFPP's ADCOP policy within DOD. Before the establishment of this directive, two separate but related programs to implement OFPP's directive had been initiated, namely the Commercial Commodity Acquisition Program (CCAP) and the Commercial Item Support Plan (CISP). CCAP is primarily a research and engineering initiative to increase the acquisition of defense materiel requirements from the commercial marketplace, without the use of Federal or military specifications. CISP is primarily concerned with providing planning and direction for the management and procurement of commercial items, and to provide the maximum feasible use of the commercial distribution channels. Under CISP, the total cost (inventory investment, holding, distribution, overhead, and acquisition cost) rather than merely the acquisition cost is to be used in determining the method of management and procurement of commercial items. A DLA cost model has been developed for use in determining the optimum method of management. By using the model, DOD hopes to insure that drugs will be obtained centrally whenever savings would result.

The responsibility for all quality assurance activities for medical materiel has been transferred to FDA. In July 1975 and January 1976 VA and DOD, respectively, signed interagency agreements with HEW for FDA to assume the responsibility for providing quality assurance for drugs. Negotiations are presently underway for FDA to assume quality assurance responsibilities for all medical devices bought through DPSC and VAMKC. According to agency officials, differences in the DOD and VA procurement systems have historically necessitated differences in the procedures employed by FDA to assure the quality of drugs bought by each agency. However, the same standard of quality is used for Government and non-Government purchases, according to FDA's Associate Commissioner

for Regulatory Affairs. As pointed out earlier in this report, efforts are underway to adopt the destination inspection and acceptance procedures for drugs for both DOD and VA use.

Recommendations contained in our earlier report concerning the need for accurate reporting of local drug purchases by the agencies' medical facilities have not been implemented. Our efforts to analyze local drug purchases by Federal facilities were hindered by the unavailability or unreliability of such data within DOD and VA.

In June 1979, we were informed by the Surgeons General of the Army, Navy, and Air Force that comprehensive hospital-by-hospital lists of drugs purchased from local suppliers was not available. The DAS report (No. 79-081, May 7, 1979) on DOD's medical materiel support programs addressed this issue. DAS found that the data collected on medical materiel by the three military departments are transmitted to the U.S. Army Medical Materiel Agency for consolidation into the DMMB's Tri-Service Local Purchase Report. However, information on the facilities' purchase of the items which are bought locally but stocked by DPSC is not reported by the military departments to DMMB.

DAS found different reporting systems and inconsistent reporting practices for local procurement at the health care activities visited. As a consequence, two military departments reported medical items on the basis of procurement data, one reported medical items on the basis of issue data, and all three had different dollar-value criteria. In contrast to the Navy and Air Force, the Army did not require its health care activities to report data on standard items authorized for local purchases.

DAS found that four Navy health care activities included in its review did not properly report local purchases of consumable medical and dental items that had centrally managed identification numbers. During fiscal year 1977, these Navy activities obtained medical items costing $5.5 million through local purchase. However, only $600,000 of the $5.5 million was reported. At another four Army medical activities, DAS found local purchases of about $19.8 million but only $3 million had been reported.

Even though the reporting of the military departments' facilities differ, DMMB uses the data provided by the departments to evaluate nonstandard medical materiel for inclusion as standard items in the DOD supply distribution system. For

an item to be considered for standardization by DMMB, demands must amount to $10,000 annually and at least 12 activities must report the use of the item. In turn, DPSC evaluates the candidate items proposed by DMMB to determine if the criteria for central procurement and stockage are met. Unfortunately, such a system does not provide for comparisons for drug items bought locally by DOD activities which are available through DPSC. According to the DAS report, DPSC, by not establishing procedures to collect and review such data, has not been able to determine if a drug item could be purchased more economically through central procurement. Recommendations were made in the DAS report to correct these problems.

In regard to VA's reporting of local drug procurement data, serious questions exist about the reliability of the data submitted by the individual VA hospitals. VA has attempted to prepare computer summarized data for managing its drug procurement program. However, our discussions with VA Central Office and VAMKC officials concerning the accuracy and reliability of the local procurement data indicate an overall lack of confidence in the information reported from the individual hospitals through VAMKC to the VA Central Office.

In our visits to two VA hospitals, we found evidence of the inaccurate local drug procurement data reported by these facilities. Officials at the Hines VA hospital told us that local drug purchases by that facility were "insignificant." However, the VA quarterly reports generated to reflect the sources of supply by dollar value in fiscal year 1978 for that facility showed that 29 percent of the drugs procured came from local sources. Similarly, officials at the Downey VA hospital estimated their local drug purchases to be about 1 percent. The same quarterly reports mentioned above for the Downey VA hospital indicated that about 11 percent of the drugs were procured locally. In both these instances, the primary cause of incorrect local purchase data being reported was that local purchases were reported as FSS contract purchases and vice versa.

In April 1978, DLA issued a report, "A Review of Medical Materiel Management DLA--Phase I." This report had been requested by the Director, DLA, to evaluate the efficiency and responsiveness to the military departments of the medical materiel support system. It discussed an evaluation of the current support operation to determine what improvements could be achieved within the present system. The report contained

63 broad recommendations, many of which contained multiple suggestions to improve the current system. In all the DLA report contained 98 specific recommendations.

At June 1979, corrective action had been initiated or was being initiated for 73 of the 81 recommendations which required DPSC action. These recommendations, if fully and effectively implemented, should increase competition in DPSC's procurement of drugs. For example, DPSC officials have agreed to:

--Arrange to obtain from other agencies purchasing medical materiel the names of firms supplying their requirements.

--Reexamine workload priorities in the Office of Market Research and Analysis with the objectives of making the expertise available to support medical procurement planning and operation.

--Announce its annual medical materiel procurement forecast in the Commerce Business Daily.

--Fill the vacant Small Business Advisor position in order to provide adequate program coverage.

--Invite small businesses and SBA to jointly review medical specifications and purchase descriptions to identify factors that restrict small business participation.

--Maximize efforts to secure effective competition by intensifying efforts to encourage generic drug suppliers to bid on solicitations and monitoring repetitive single-source procurements on a regular basis to revalidate and document the reasons for the absence of competition.

--Purchase all medical items competitively or convincingly document the procurement file to indicate why this is not possible.

--Adequately document noncompetitive procurement actions, assure that the contracting officer documents the file to describe the actions taken to avoid the need for noncompetitive or limited competition in the future, and when appropriate structure selected solicitations to permit offers of alternative products.

--Make arrangements with VA to (1) obtain price history records on any medical item that is centrally procured by that agency, (2) exchange copies of contracts for major procurements at time of award, (3) obtain current pricing information from VA when a comparative price analysis is being performed, and (4) exchange supplier information for possible identification of new sources.

--Coordinate with VA the preparation of specifications/purchase descriptions for medical materiel and prepare Federal rather than military specifications/purchase descriptions to the maximum practical extent.

--Increase the use of commercial packaging whenever practical.

--Review its procedures for processing waivers or review specifications for nonessential requirements.

APPENDIX V

SCHEDULE OF 23 DRUGS IDENTIFIED AS HAVING DIFFERENT

METHODS OF PROCUREMENT FOR PERIOD OCTOBER 1, 1977, TO MARCH 31, 1979

FROM 143 COMMON STOCK ITEMS REVIEWED BY GAO

Item name and description	Method of procurement		Weighted average price and average quantity procured October 1, 1977, to March 31, 1979			
			DOD		VA	
	DOD	VA	Price	Quantity	Price	Quantity
1. Amitriptyline hydrochloride tablets, 25 mg., 1000s (6505-00-724-6358)	Negotiated (competitive)	Advertised	$14.64	4,416	$12.52	1,539
2. Ampicillin capsules, 250 mg., 100s (unit dose) (6505-00-117-8741)	Negotiated (competitive)	Advertised	5.33	1,095	4.83	1,212
3. Ampicillin capsules, 500 mg., 100s (unit dose) (6505-00-117-8743)	Negotiated (competitive)	Advertised	8.50	568	7.82	976
4. Bethanechol chloride tablets, 100s scored, uncoated, 10 mg. (6505-00-616-7856)	Negotiated (competitive)	Advertised	3.20	12,560	1.89	8,028
5. Brompheniramine maleate, (12 mg.) phenylephrine hydrochloride, (15 mg.) and phenylpropanolamine hydrochloride (15 mg.) tablets, 500s (6505-00-890-1891)	Negotiated (noncompetitive)	Advertised	18.25	28,754	8.99	5,688
6. Cloxacillin sodium capsules, 250 mg., 100s (6505-00-853-8608)	Advertised	Negotiated (noncompetitive)	13.45	4,855	16.66	1,210
7. Cyanocobalamin injection, 1000 mg., per ml., 10 ml. (6505-00-687-4049)	Negotiated (competitive)	Advertised	.42	12,000	0.32	33,600
8. Dextrose injection, 50 percent, 50 ml. (needle unit and needle) 10s (6505-00-139-4460)	Advertised	Negotiated (noncompetitive)	23.49	1,038	26.20	720
9. Ephedrine sulfate capsules, 25 mg., 500s (6505-00-117-4912)	Negotiated (competitive)	Advertised	3.60	2,016	3.75	960
10. Erythromycin tablets, 250 mg., 100s (6505-00-662-9790)	Negotiated (competitive)	Advertised	3.57	46,650	3.67	31,656
11. Fluocinolone acetonide cream, 0.025 percent, 15 gm. (6505-00-985-7710)	Negotiated (noncompetitive)	Advertised	.88	25,612	0.95	10,176
12. Fluocinolone acetonide cream, 0.025 percent, 425 gm. (6505-00-905-9041)	Negotiated (competitive)	Advertised	13.73	664	12.25	628
13. Hydrocortisone cream, 1 percent, 1 lb. (6505-00-926-2096)	Negotiated (competitive)	Advertised	6.03	885	7.00	1,720
14. Isoproterenol hydrochloride inhalation, 0.5 percent, (1:200), 10 ml. (6505-00-299-9661)	Negotiated (competitive)	Advertised	.67	9,360	1.03	3,708
15. Kanamycin sulfate injection, .33 gm. per ml., 3 ml. (6505-00-660-1676)	Negotiated (noncompetitive)	Advertised	8.42	13,220	9.00	7,920
16. Meprobamate tablets, 400 mg., 500s (6505-00-550-8464)	Negotiated (competitive)	Advertised	4.30	3,000	3.10	12,258
17. Methocarbamol tablets, 500 mg., 500s (6505-00-660-1601)	Advertised	Negotiated (noncompetitive)	10.31	4,880	15.42	1,957
18. Minocycline hydrochloride capsules, 100 mg., 50s (6505-00-003-5112)	Negotiated (noncompetitive)	Advertised	13.91	34,531	14.00	2,160
19. Phenazopyridine hydrocloride tablets, 100 mg., 1000s (6505-00-582-5344)	Negotiated (competitive)	Advertised	19.31	2,095	13.44	1,008
20. Propantheline bromide tablets, 15 mg., 1000s (6505-00-584-0398)	Negotiated (noncompetitive)	Advertised	31.02	832	6.85	3,840
21. Selenium sulfide lotion, 2.5 percent, 4 oz. (6505-00-299-8671)	Negotiated (noncompetitive)	Advertised	.60	188,676	.63	53,136
22. Sulfasalazine tablets, 0.5 gm., 500s (6505-00-754-2797)	Negotiated (competitive)	Advertised	11.50	2,420	11.69	3,450
23. Thyroid tablets, 64 mg., 100s (6505-00-153-9745)	Negotiated (noncompetitive)	Advertised	.39	116,718	.43	8,208

PRESCRIPTION DRUGS PURCHASED BY DPSC AND VAMKC AT PRICES IN EXCESS OF THERAPEUTICALLY EQUIVALENT DRUGS AT COMMERCIAL PRICES QUOTED IN "REDBOOK" 1979

Item	Agency	Date of purchase	Quantity	Actual procurement			Alternative procurement			Potential savings
				Vendor	Brand	Unit price	Vendor	Brand	Unit price	
Bethanechol chloride tablets, NF, 10 mg., 100s										
	DPSC	9/11/78	12,560	Glenwood	Myotonachol	$ 3.20	Danbury	Generic	$ 1.92	$16,076.80
	VAMKC	2/05/79	7,416	Glenwood	Myotonachol	3.25	Danbury	Generic	1.92	9,863.28
Chlorpromazine hydrochloride tablets 25 mg., 1000s										
	DPSC	1/26/79	313	Smith, Kline, and French	Thorazine	24.53	Purepac	Generic	10.31	4,544.76
	VAMKC	3/14/79	305	Smith, Kline, and French	Thorazine	a/15.85	Purepac	Generic	10.31	1,689.70
Chlorpromazine hydrochloride tablets 50 mg., 1000s										
	DPSC	10/19/78	264	Smith, Kline, and French	Thorazine	27.02	Purepac	Generic	14.44	3,321.12
	VAMKC	3/14/79	500	Smith, Kline, and French	Thorazine	b/18.31	Purepac	Generic	14.44	1,935.00
Hydralazine hydrochloride tablets, USP, 25 mg., 1000s										
	DPSC	9/28/78	11,712	Lemmon	Generic	9.94	Zenith	Generic	9.47	5,504.64
	VAMKC	3/16/79	3,968	Ciba	Apresoline	14.39	Zenith	Generic	9.47	19,522.56
										$62,457.86

a/VAMKC procured another generic drug, which is therapeutically equivalent to Thorazine 25 mg., 1000s, from Zenith Laboratories in July 1978 at an acquistion cost per unit of $4.65.

b/VAMKC procured another generic drug, which is therapeutically equivalent to Thorazine 50 mg., 1000s from Zenith Laboratories at an price per unit of $6.53.

APPENDIX VI

PRESCRIPTION DRUGS PURCHASED BY DPSC OR VAMKC
AT PRICES IN EXCESS OF THERAPEUTICALLY EQUIVALENT
DRUGS AT COMMERCIAL PRICES QUOTED IN "REDBOOK" 1979

Item	Agency	Date of purchase	Quantity	Actual procurement			Alternative procurement			Potential savings
				Vendor	Brand	Unit price	Vendor	Brand	Unit price	
Chlordiazepoxide hydrochloride capsules, USP 5mg., 500s										
	VAMKC	3/09/79	912	Roche	a/Librium	$12.00	Rachelle	a/Chlordiazachel	$ 5.43	$ 5,991.84
Methocarbamol tablets, NF. 500 mg., 5002										
	VAMKC	3/20/79	402	A. H. Robins	Robaxin	12.95	Bolar	Generic	12.00	381.90
Propantheline bromide tablets, USP. 15 mg., 1000s										
	DPSC	2/02/79	960	Searle	Pro-Banthine	26.75	Bolar	Generic	9.60	16,464.00
										$22,837.74

a/A generic drug which is therapeutically equivalent to Librium and Chlordiazachel is procured by DPSC under the DOD's CISP/CCAP Program for direct delivery by the manufacturer (Purepac) to DOD health care facilities at a price at $3.79 per unit.

APPENDIX VII

APPENDIX VIII

SCHEDULE OF MOST RECENT ACQUISITION PRICES PER UNIT PAID

BY DPSC, VAMKC, AND THREE NON-FEDERAL DRUG PROCURERS FOR

18 SELECTED PRESCRIPTION DRUG ITEMS AS OF MARCH 31, 1979

AND THE MANUFACTURER OF THE DRUG PROCURED BY EACH ORGANIZATION

Item name and description	Federal agencies		Non-Federal organization		
	DPSC	VAMKC	Health and Hospital Corporation of New York City	Health organization A	Health organization B
1. Amitriptyline hydrochloride tablets, USP 25 mg., 1000s	$13.99 (Roche)	$13.30 (Warner Chiliott)	$17.30 (Roche)	$40.00 (Squibb)	$29.92 (Roche)
2. Ampicillin sodium, sterile USP, powder, 50 mg.	0.36 (Bristol)	0.31 (Bristol)	0.38 (Bristol)	0.37 (Lederle)	0.40 (Wyeth)
3. Amplicllin sodium, sterile UPS, powder, 1000 mg.	0.53 (Bristol)	0.44 (Bristol)	0.56 (Bristol)	1.30 (Wyeth)	0.58 (Wyeth)
4. Chlordiazepoxide hydrochloride capsules, USP 5 mg., 500s	4.90 (Smith, Kline, French)	12.00 (Roche)	3.25 (Pharmachem)	4.42 (Squibb)	6.95 (Parke Davis)
5. Chlordiazepoxide hydrochloride capsules, USP 25 mg., 500s	5.75 (Barr)	4.69 (Mylan)	6.00 (Pharmachem)	68.10 (Roche)	14.95 (Parke Davis)
6. Chlorpeniramine maleate tablets, 4 mg., 1000s	1.68 (Panray)	2.34 (Lannett)	2.50 (Pharmachem)	1.50 (Tablicaps)	3.19 (Lederle)
7. Cloxicillin sodium capsules, USP, 250 mg., 100s	12.68 (Bristol)	14.60 (Bristol)	19.00 (Beecham)	26.82 (Wyeth)	22.00 (Bristol)
8. Cyanocabalamin injection, USP 1000 micrograms per ml. 10 ml.	0.45 (Elkins-Sinn)	0.32 (Carter-Glogau)	0.31 (Torrigan Labs)	0.56 (Dell)	0.53 (Inverex)
9. Dexamethasone sodium phosphate injection, USP 4 mg., per ml., 5 ml. rubber capped vial	0.80 (Carter-Glogau)	0.85 (Maurry Biol)	1.21 (Merck, Sharp and Dohme)	5.09 (Merck, Sharp and Dohme)	2.50 (Merck, Sharp and Dohme)
10. Diazepam injection USP, 5 mg. per ml. 2 ml, 10s	6.24 (Roche)	6.24 (Roche)	9.26 (Roche)	12.76 (Roche)	8.51 (Roche)
11. Diphenhydramine hydrochloride capsules, USP, 50 mg., 1000s	6.72 (Parke Davis)	5.15 (West-Ward)	6.39 (Parke Davis)	9.88 (Lederle)	8.50 (Lederle)
12. Hydrochlorothiazide tablets, USP 50 mg., 1000s	3.25 (Bolar)	3.25 (Camall)	3.52 (Remo)	8.50 (Abbott)	10.84 (Lederle)
13. Hydoxyzine hydrochloride tablets NF, 25mg., 500s	44.19 (Roerig)	44.19 (Roerig)	31.46 (Roerig)	57.96 (Roerig)	52.22 (Roerig)
14. Isosorbide dinitrate tablets 10 mg., 500s	3.40 (Ives)	1.63 (West-Ward)	5.40 (Ives)	48.18 (Ives)	6.99 (Lederle)
15. Meprobamate tablets USP., 400 mg., 500s	4.30 (Halsey)	3.34 (Coastal)	3.10 (Halsey)	12.36 (Wyeth)	3.23 (Lederle)
16. Methocarbamol tablets, NF, 500 mg., 500s	9.50 (Generic Labs)	12.95 (A.H. Robins)	13.50 (Pharmachem)	10.00 (not available)	15.57 (Lederle)
17. Propantheline bromide tablets, USP, 15 mg., 1000s	26.75 (Searle)	6.85 (Philips Roxane)	6.85 (Bolar)	7.54 (Danbury)	10.74 (Lederle)
18. Sulfisoxazole tablets 500 mg., 1000s	7.21 (Roche)	7.21 (Roche)	8.25 (Roche)	17.50 (Lederle)	14.00 (Parke Davis)

APPENDIX IX

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

OFFICE OF FEDERAL
PROCUREMENT POLICY

March 25, 1980

Mr. Gregory J. Ahart
Director, Human Resources Division
General Accounting Office
Washington, D.C. 20548

Dear Mr. Ahart:

This is in response to your letter of February 19, 1980 regarding the General Accounting Office draft report, "Efforts to Implement a Single Federal Drug Procurement System Can Be Improved and Expedited" (HRD 80-59).

As noted in the draft report, the effort to establish a single government-wide medical procurement system is governed by two basic documents; i.e., OMB memorandum of June 4, 1974, subject: Procurement and distribution of medical and nonperishable subsistence supplies; and OFPP memorandum of December 27, 1977, subject: Implementation of Policy on Acquisition and Distribution of Commercial Products (ADCoP). The ADCoP policy is correctly identified as the basis for DOD and VA to develop a government-wide medical acquisition and distribution system to satisfy users' needs with acceptable commercial products supplied directly from commercial distribution channels.

As noted in the draft report, this is indeed an immense task. The report of the Comptroller General dated January 14, 1980, entitled "Implementation of Federal Policy on Acquiring and Distributing Commercial Products is Faltering Badly" (PSAD 80-13) describes the problems encountered. The OFPP insert to this report, dated October 16, 1979, stated in part that "ADCoP represents a fundamental change in the Government's procurement practices, and changes of this type are at best difficult and time consuming. The proper implementation of ADCoP requires the internal realignment and adjustment of some agencies' resources, the development of new operating procedures, and the training of personnel. The agencies must, of course, accomplish these changes while concurrently performing their operational requirements." These requirements are also appropriate to the medical shared procurement responsibilities of DOD and VA.

We are encouraged by recent developments in DOD/VA drug procurement. Over $60M in annual volume of drugs are now under contract with another $100M anticipated by the end of FY 80. Settlement of differences in contract clauses and specification unification are proceeding more rapidly. Standard operating procedures, recently developed, are in the final approval phase. The government-wide system is beginning to take shape,

although much remains to be done. We believe that this progress made by DOD and VA should be recognized.

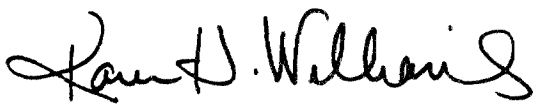
In consideration of your recommendation on ADCoP priority, OFPP has consistently assigned high priority to ADCoP policy implementation. Improving the management of medical procurement is an integral part of the assignment. To facilitate implementation, the OFPP, in cooperation with the agencies, is developing additional policy and guidance materials which will emphasize the routines for purchasing and distributing commercial products. A training program is also being developed through the Federal Acquisition Institute which will help agency personnel to a better understanding of ADCoP techniques which also apply to medical products.

The concept of a single uniform Federal supply catalog for all drugs, biologicals, and reagent chemicals that are managed centrally is worthwhile. OFPP will pursue this approach with DOD and VA as the single government-wide system emerges. Its development and adoption should improve responsiveness to the user and provide an overall visibility of all items managed centrally.

As to the recommendation that VA be responsible for procuring, stocking and distributing all drugs, with certain war contingency exceptions, we reserve judgment on the logic of directing this move until facts are presented regarding mission impact analysis, cost benefits, user satisfaction and feasibility. As the ADCoP policy is implemented, government-unique products which now are stocked should be converted to commercial products. This will give DOD and VA the opportunity to rely less on government depot distribution and more on acceptable commercial distribution. Therefore, while not totally ruling out your approach, we believe pursuit of the recommendation is premature.

Thank you for the opportunity to comment, keeping us informed as you developed your report, and your continued support of the policy on the acquisition and distribution of commercial products.

Sincerely,



Karen Hastie Williams
Administrator

ASSISTANT SECRETARY OF DEFENSE

WASHINGTON D.C. 20301

MANPOWER SR
RESERVE AFFAIRS
AND LOGISTICS

18 APR 1980

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

Dear Mr. Ahart:

Your draft report, "Efforts to Implement a Single Federal Drug Procurement System Can be Improved and Expedited" (Code 101016)(OSD Case #5385), has been reviewed. Mr. Baine, Mr. Yohey, and other members of your office have been cooperative in accepting recommended editorial changes and clarifications. We believe that the report fairly portrays the difficulties attendant to progress in the areas of shared procurement and the use of commercial products. However, as stated in the meetings, we find substantive issues in the report that give us cause for concern.

The report fails to give any recognition to the mission of the Department of Defense (DoD) and to distinguish between the very different missions of the Veterans Administration (VA) and DoD. And yet the report proceeds to make a series of conclusions and recommendations which cannot legitimately be made without adequate consideration of DoD and VA mission differences in the delivery of health care materiel support. DoD must stand ready to assure the operating forces of a viable worldwide support structure in wartime as well as peacetime, no matter where the forces may be located or how occupied. This means that we have to supply a wide array of items to respond to the needs of numerous large and small users. We have to be ready in peacetime to meet a tremendous surge in demand, without notice, to support wartime needs. We have to supply items for overseas customers that normally would be supplied from retail distributors if the customers were in the United States, and we have to buy and hold war reserve items. These factors inevitably lead to different manning requirements in our wholesale systems. They lead to different packaging and marking requirements, different stockage requirements, and they result in higher operating costs for DoD than are required by the VA medical supply system to meet their mission needs.

The report is also critical that too much attention is being spent on technicalities of shared procurement at the expense of matters related to the commercial products policy. While the Acquisition and Distribution of Commercial Products (ADCOP) Program is moving forward, perhaps

more slowly than desired, there have been positive results. Commercial Item Descriptions are being prepared and are replacing the unique specifications that hindered DoD's reliance on commercial distribution systems. Two major medical commodities, X-Ray film and dental alloys, are direct vendor delivery items with more to come. However, we must be sure that the commercial sector can respond to our war readiness, overseas support and unit of issue requirements before we relinquish the stocks from our system.

While the report acknowledges the problems attendant to shared procurement, it does not fully accept the resource constraints with which we have had to work. Subjective judgements are made on resource application without any support. We believe the report's conclusion that the "the slow pace of implementation cannot be blamed upon the lack of available resources" is unjustified. We have taken people away from their regular duties to participate on seven committees for shared procurement. They have made progress in bringing order out of differing contract clauses, item specifications, quality assurance support and so forth. This is being done in the face of different procurement regulations and operating conditions between DoD and VA. We cannot emphasize too strongly that we must continue day-to-day support to our customers while we phase-in shared procurement.

We believe that the first three recommendations to the Office of Management and Budget (OMB) regarding priorities and increased use of existing legislative authority for shared procurement and immediate implementation of ADCOP will not materially speed up the solution to our problems. They will not result in faster progress because progress is governed by the realities of missions and resources.

Two other recommendations are made to OMB. The first calls for the development of a new Federal supply catalog for medical items to preclude having the same item in DoD, VA and GSA catalogs under different prices. We do not believe that a special effort to develop such a catalog is necessary since, over time, uniformity will be achieved through the shared procurement program.

The second recommendation calls for DoD to transfer to VA the responsibility of procuring, stocking and distributing all common drugs except those needed for war or contingency purposes. We object to the recommendation. It is not supported by an analysis of VA's capability to provide peacetime support. Such an analysis must consider local procurement items not available overseas, differences in DoD and VA units of issue, and the total number of customers being handled. In addition, it must be recognized that war readiness extends beyond war reserve items, which means that VA would have to be ready to respond to our readiness requirements. As stated earlier, this is a costly process and undoubtedly would drive up VA's costs and wipe out any savings envisioned by GAO.

Two recommendations are made to DoD and VA. The first calls for establishing a market research and analysis program. We do not understand what GAO has in mind. Since the function of market research has not been specifically defined, it is difficult to establish it as a uniform practice in the acquisition process and even more difficult to incorporate it in training curricula and organizational functional descriptions against which personnel can be recruited and assigned. We already do what we consider to be market research with the resources we have. This involves determining users' needs and finding commercial products and commercial suppliers to fill those needs. As we proceed further in the preparation and use of commercial product descriptions in place of formal specifications, market research attendant to that effort will obviously expand. Based upon the lack of a formal definition of market research, it is not clear from the report what is required for DoD to improve.

The other recommendation is that lower priced, therapeutically equivalent drugs be used. This has been our policy and we will continue to search for ways to improve its application.

Two recommendations are made to DoD. The first is that we adopt a total cost methodology for making stocking decisions. We have done this in the Commercial Item Support Program (CISP) cost model. Its application has been hindered because of the difficulty in quantifying subjective areas such as war readiness considerations, unit of issue requirements and overseas support. We plan to continue our attempts to produce a useful and reliable cost model.

The report also recommends that we reassess the need for a National Stock Number (NSN) on each unit of issue. The report does not explain why such a reassessment is necessary. We have long held that the NSN is necessary to avoid mixups that can occur when stock handlers unfamiliar with difficult medical terminology are processing such items. The NSN is absolutely essential for effective identification and processing of materiel through the supply system. All major supply systems, to our knowledge, rely on number identification systems. Many also depend on uniform packaging. These two elements are especially critical in automated systems, like those used in the worldwide Defense logistics network. They permit accurate communication, planning and cohesive management of heavy volumes of materiel through the logistics system (transportation, supply, maintenance, procurement, and quality control) in a cost effective manner.

In addition to these comments, we have enclosed specific page-by-page comments to clarify or correct minor points.

We request that our views be incorporated in the final report, and appreciate the opportunity to comment.

Sincerely,

Enclosure
As stated

Richard Dennis
Principal Deputy Assistant
Secretary of Defense (MRA&L)

APPENDIX XI

each newly standardized item, and are again reviewed at the time items are replenished. We believe our market research and decisionmaking processes protect the interest of the taxpayer and comply with the Acquisition and Distribution of Commercial Products Policy. We will expand our market research along the lines suggested and to the extent resources permit.

> --utilize the expertise possessed by the FDA in regard to identifying therapeutically equivalent drugs and substitute, to the maximum possible extent, any lower priced therapeutically equivalent drug for a higher priced drug currently procured by the respective agencies' centralized wholesale drug supply systems.

The primary mission of the VA drug procurement activity is to support the requirements of the professional staff. Items procured and/or stocked are those which the medical staff has specifically requested through prescriptions or by other means. Procuring items other than those required by the physicians would generate dormant inventories which would be uneconomical. The policy of the VA is predicated on providing a particular drug at the lowest published price and using the most economical method of supply. As sole/single source drugs become available on the commercial market, action is initiated to buy the drug competitively. Deviation from standard procedure must be therapeutically justified and submitted to the Office of the Chief Medical Director through the Executive Committee on Therapeutic Agents, Central Office, for approval.

GAO also recommends that I instruct VA Marketing Center officials, in cooperation with other Federal officials involved in ongoing DoD/VA Shared Procurement Program efforts, to concurrently

> --identify duplicative drug items (procured and distributed through either or both the Federal depot systems and Federal Supply Schedules) in efforts to adopt a suitable single acquisition strategy to satisfy all Federal users, and
>
> --eliminate those items from availability through the Federal Supply Schedules if such means of procurement and supply are not the most cost effective.

Items carried in the depot system and the Federal Supply Schedules (FSS) are reviewed and analyzed on an ongoing basis to determine the most cost-effective method of procurement and supply. The demands of all users are carefully considered to insure that suitable and cost-effective means are available for supporting all users, regardless of size or location. In some instances, it has been determined that like items will be carried on the FSS and in the depot system to provide major and minor users with flexible means for supporting their demands. Experience shows that the minor user's demands are better supported through the FSS while the demands of major users are better supported through the depot system. The VA will continue to assess the FSS to insure that items included are cost effective and are in the best interest of all users.

2. Introduction.

a. Page 2, paragraph 1.

DoD Comment: There is no mention of the DoD national security mission and impact on the medical materiel support system or its cost. There is no mention of mobilization items, overseas dependent items, refrigerated items, field kits, or heavy items which increase DoD overhead which impacts VA either only minimally or not at all. There is no mention that DLA depots will issue to overseas activities and ships single quantities of items based on their demand frequency and, in the case of ships, their physical storage constraints.

3. Chapter 2.

a. Page 15, paragraph 2, line 4.

DoD Comment: We do not agree that a reorientation of agency efforts is necessary to achieve the objectives of DoD/VA Shared Procurement program. The statement on full implementation of the program from January 1978 to July 1982 needs to be clarified in that the program is a phased program. As such it was expected to take the designated amount of time, from the signing of the agreement through all phases (single-source drugs, single-source devices, competitive drugs and competitive devices) until the last renewal contract is initiated in the last phase. Nothwithstanding the agreement date of 2 June 1978 the original plan was not approved by OFPP until 19 September 1978. We are currently proceeding on the approved phased implementation schedule as revised.

b. Page 17, paragraph 1, line 4,
Page 22, paragraphs 1 and 2.

DoD Comment: The GAO comment regarding results of the DoD/VA pilot test, i.e., "was successful in that it exposed traditional habits that were questionable." is not supported in the draft report.

If the purpose for citing differences is to achieve a standardized contract format for both agencies, then it will ultimately be necessary to force one agency to also change its SUPPLY operations, or moreover, relinquish their supply operations to the gaining agency. The mission of any procurement function is to support the supply function in response to customer demand. Changing the method or responsibility of acquisition will not, in itself, change the requirements for differing units of issue, quality assurance, longer potency periods, and different markings on the labels. Although the report indicates efforts undertaken to resolve these differences, it must be understood that total uniformity can never be achieved because of mission differences.

c. Page 31, paragraph 2.

DoD Comment: DoD recognized the need to capture the lessons learned in Shared Procurement to date, and the need to formalize the procedures developed in the initial implementation in the appropriate DPSC manuals. This task was fully contemplated to be a part of the implementation process. Procedures were not formalized initially for all actions since experience had to be obtained in how best to operate in the interchange of information and requirements. Procedures have been prepared for item entry and item commonality and are being followed. Proposed procedures for interchange of procurement information between the Defense Personnel Support Center (DPSC) and the Veterans Administration Marketing Center (VAMKC) are currently being reviewed for approval.

d. Page 57, paragraph 1.

DoD Comments: The significant price differences indicated are warranted for the following reasons:

(1) Brompheniramine Maleate, Phenylephrine HCL, and Phenylpropanolamine HCL Tablets, 500's:

DPSC Price	$18.25
VA Price	$ 8.99

Although multiple firms have been solicited on previous procurements (item history dates back to July 1964) only A.H. Robbins has responded. DPSC has paid $18.53 for this item (from Robbins) since August 1975 (3 separate requirements contracts). The VA currently has a requirements contract with Inwood Laboratories, Inc. at a unit price of $8.00/BT. Inwood Labs has responded to the most current DPSC solicitation with a unit price quotation of $8.00; however, the firm requested a deviation from one aspect of the essential characteristics specified, i.e., the requirement for a "cored repeat action" tablet. This deviation has been suspended pending results of the evaluation. Inwood extended their acceptance period to 31 March 1980.

(2) Chlorpheniramine Maleate Tabs, 8 mg., 1000's:

DPSC Price	$26.51
VA Price	$ 5.97

DPSC specifically requires an 8 mg. "TIMED RELEASE" tablet packaged in 1000's which is not a USP item. The VA, on the other hand, buys an 8 mg. "REPEAT ACTION" tablet which is a USP item, i. e., not modified. Further investigation by the GAO would have revealed this significant (and vital) difference, thus providing basis for the cost differential, identical DoD and VA Stock Numbers notwithstanding. Although

as many as 42 firms have been solicited for this item, only Schering Corp., has ever offered a priced response, dating back to December 1959.

e. Page 74a and 75, paragraph 1.

DoD Comment: The DLA model is an economic model which is applied to items after screening for military exclusion, commercial availability and other stockage considerations. Page 74 of the report is slightly inaccurate. The models were furnished to ASD(MRA&L) in December 1978 and subsequently furnished to DLA supply centers. Initially they were used as a guide to suggest least cost management methods based upon an item's dollar sales and frequency of requisitions. Major differences in unit price were initially difficult to evaluate. A more computerized mode, the one we used for GAO, was made available to DLA centers on 4 February 1980. This model does provide for evaluation of changes in unit price. Section 2, part 4, of the Defense Acquisition Regulation (DAR) leaves to the contracting officer the responsibility for the final decision. The DAS is still in processes of reviewing the input cost data.

f. Page 76, paragraph 2, line 2.

DoD Comment: The Draft report states that all 218 items' frequency of order and annual demand on an item-by-item basis indicated that contracts requiring direct vendor deliveries are the most economical acquisition method. DLA analysis of the data reveals the least cost method of support to be depot management for 65 or the 218 items. DPSC is not in a position at this time to utilize a fully automated direct delivery method of supply support.

g. Page 83a, paragraph 1.

DoD Comment: This paragraph should be revised to consider those items which will be stocked for national security reasons and not subject to the total cost model. In addition the paragraph should indicate that the total cost model has only recently been completed and released for use, and is still subject to validation and study of certain key elements.

h. Page 85, paragraph 1.

DoD Comment: DoD does not agree that the requirement for NSN is counter to ADCOP. ADCOP does permit a commercial product to be modified with some Government peculiar addition. The labeling of the NSN on unit of issue is such a requirement.

i. Page 121, paragraph 1-4.

DoD Comment: In regard to the four items listed, the following applies:

(1) Bethanechol Chloride Tabs, NF, 10 mg., 100's:

APPENDIX X

DPSC has acquired this item competitively since September 1965. Merck Sharp and Dohme received every award until Glenwood Labs successfully competed in January 1976. Prices have ranged from $7.38 in 1965 to $3.25 in 1979. The most recent solicitation was responded to by Bolar Pharm. Co., Inc. with a price of $1.20 and they were consequently awarded the contract. The generic firm indicated by the GAO as marketing a therapeutically equivalent item (Danbury) has never responded to a DPSC solicitation.

(2) Chlorpromazine HCL Tablets, 25 mg., 100's:

and

(3) Chlorpormazine HCL Tablets, 50 mg., 100's:

Purepac has never submitted a priced response for these items. Other firms which have been solicited in the past are Barr Labs, Zenith, Rochelle, USV, Smith Kline and French, MBH Chemicals, Cord, and Western Research. Since 1975, only Smith Kline and French has responded to DPSC solicitations, which have all, with a single exception, been small buys. DAR does not require solicitation of more than three sources in such cases.

(4) Hydralazine HCL Tablets, 25 mg., 1000's:

Zenith Labs, although solicited on prior acquisitions, has never responded. Firms currently on DPSC's bidder List, other than Zenith, are Ciba, Elkins-Sinn, Lemmon, M. D. Pharmaceutical, ICN, The Vitarine Co., Zenith Labs, and Lederle. As a result of the latest solicitation, an annual requirements contract was awarded to Lederle Labs at a unit price of $7.98 which is substantially lower than that represented by GAO as being the lowest available therapeutically equivalent drug (Zenith).

(5) Propantheline Bromide Tablets, USP. 15 mg., 1,000's:

At the time of the acquisition indicated for DPSC (2/5/79), Searle was the only firm holding an approved NDA with the dating required by DPSC. Since that time, the dating restriction has been revised to 24 months and an award was made to a new supplier, Philips Roxanne, at a much lower price than that indicated for Bolar in the Appendix.

j. Page 123-24, paragraphs, 4, 6, 8, 11, 13, 15, and 17.

DoD Comment: In regard to the items listed the following applies:

(1) Chlordiazepoxide HCL, Caps, 25 mg., 500's:

DPSC acquires this item competitively among prospective sources such as Zenith, Generics, Lederle, Smith Kline and French, Ormont, Roche, and Parke-Davis. Pharmachem, the indicated source for Health and

Hospital Corp. of NYC is not listed in the Redbook, the FDA Approved Drug Products List, or the Physician's Desk Reference. E. R. Squibb, supplier to "Health Organization A" is not approved by the FDA for the item and is therefore ineligible for award of a government contract.

(2) Chlorpheniramine Maleate Tabs, 4 mg., 1000's:

DPSC acquires this item on the basis of 100% Small Business Set Aside. Competition is obtained from Panray, Barr Labs, Anabolic, Generic Pharm, Bolar, Zenith, Gotham Pharm, Halsey, and Lemmon. The price obtained, $1.68, is considered to be fair and reasonable considering DPSC's dating and labeling requirements.

(3) Cyancabalamin Injection:

DPSC acquires this item on a competitive basis. Currently, Elkins-Sinn is the only firm responding that can satisfy 36-month dating.

(4) Diphenhydramine HCL Caps, 50 mg., 1000's:

The price differential between $6.72 (DPSC) and $6.39 (Health and Hospital Corp. of NYC) is felt to be reasonable based on DPSC's dating and labeling requirements. The commercial item marketed by Parke-Davis can normally support 18-24 months whereas DPSC requires 36-months (or not later than 33 at time of delivery).

(5) Hydroxyzine HCL Tabs, 25 mg., 500's:

Quantities and transportation requirements of the Health and Hospital Corp. of NYC are unknown and therefore cannot be compared to DPSC in attempting to justify the price difference. DPSC requires multiple destination shipments throughout the U.S.. Roerig Division is located in New York City and therefore may consider transportation costs only in DPSC and VA acquisitions. (See GAO note 1 below.)

(6) Meprobamate Tablets, 400 mg., 500's:

This is a highly competitive item and price is affected by the quantities being acquired. When larger quantities were obtained on prior contracts, much lower prices were realized; for example, 37,008 bottles were purchased at a unit cost of $2.35. The $4.30 price for 3000 bottles cannot be compared to the $3.10 price of Health and Hospital Corp. of NYC unless quantities are considered. Additionally, Halsey Drug Co. is located in Brooklyn, NY, thereby possibly eliminating transportation elements from the $3.10 price. (See GAO note 2 below.)

GAO note:

1. DPSC paid $44.19 each for 5,716 bottles on Feb. 1, 1979. The quantities bought by the Health and Hospital Corporation of New York City were not available.

2. DPSC paid $4.30 each for 3,000 bottles on Feb. 1, 1979. For the period Jan. 1, 1978, through June 30, 1979, the Health and Hospital Corporation of New York City contracted for 1,200 bottles at $3.10 each.

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(7) Propantheline Bromide Tabs, 15 mg., 1000's:

The $26.75 price paid to Searle was when that firm was the only source holding an approved NDA and could fulfill the dating require-- ments of DPSC, even though 12 firms were solicited for the requirement. Since then, the dating requirement has been reduced to 24 months and competition has been obtained with a resultant contract awarded to Philips Roxanne.

APPENDIX XI

Office of the
Administrator
of Veterans Affairs

Washington, D.C. 20420

Veterans
Administration

MARCH 28 1980

Mr. Gregory J. Ahart
Director, Human Resources Division
U. S. General Accounting Office
Washington, DC 20548

Dear Mr. Ahart:

We are pleased to furnish our comments on your February 19, 1980 draft report, "Efforts to Implement a Single Federal Drug Procurement System Can Be Improved and Expedited." This report states that for nearly two decades the Federal Government has attempted to establish a single system for the procurement and supply of drugs and medical devices. The General Accounting Office (GAO) found that only recently has the Office of Federal Procurement Policy (OFPP), the Department of Defense (DoD), and the Veterans Administration (VA) made progress in establishing and implementing a single Federal drug procurement system. The recommendations made by GAO are designed to assist all affected agencies to fully implement congressional policies contained in the OFPP Act Amendments of 1979 and the Executive Branch's Acquisition and Distribution of Commercial Products policy. We will address the recommendations made to this Agency as they appear in the report.

GAO recommends that the Secretary of Defense and I:

> --establish an effective market research and analysis program for drugs and medical devices in accordance with the requirements of the Administrator, OFPP, to fully ascertain and analyze the range and quality of available commercial products (including prices paid by non-Federal organizations for these products), to determine whether such products meet the respective agencies' needs, and to identify any cost-effective market practices in procuring, stocking, and distributing such products which could be adopted for Government use, and

The VA would like to have a market research and analysis program for drugs and medical devices as sophisticated as the one described by the OFPP. Unfortunately, a stylized market analysis using the concepts and having the scope required is not possible with our current resources. However, the VA has a market research and analysis program consisting of a continuous review of each item currently in the central system. Items are removed when they cannot be economically maintained and new items are not added to the central distribution system unless economical to do so.

The feasibility of using commercial products and commercial distribution is incorporated in our ongoing review of item management. As items are introduced into the system, they are reviewed to determine if they should be procured locally, centrally with commercial distribution, or centrally with government distribution. Findings are documented in the case of

APPENDIX XI

each newly standardized item, and are again reviewed at the time items are replenished. We believe our market research and decisionmaking processes protect the interest of the taxpayer and comply with the Acquisition and Distribution of Commercial Products Policy. We will expand our market research along the lines suggested and to the extent resources permit.

> --utilize the expertise possessed by the FDA in regard to identifying therapeutically equivalent drugs and substitute, to the maximum possible extent, any lower priced therapeutically equivalent drug for a higher priced drug currently procured by the respective agencies' centralized wholesale drug supply systems.

The primary mission of the VA drug procurement activity is to support the requirements of the professional staff. Items procured and/or stocked are those which the medical staff has specifically requested through prescriptions or by other means. Procuring items other than those required by the physicians would generate dormant inventories which would be uneconomical. The policy of the VA is predicated on providing a particular drug at the lowest published price and using the most economical method of supply. As sole/single source drugs become available on the commercial market, action is initiated to buy the drug competitively. Deviation from standard procedure must be therapeutically justified and submitted to the Office of the Chief Medical Director through the Executive Committee on Therapeutic Agents, Central Office, for approval.

GAO also recommends that I instruct VA Marketing Center officials, in cooperation with other Federal officials involved in ongoing DoD/VA Shared Procurement Program efforts, to concurrently

> --identify duplicative drug items (procured and distributed through either or both the Federal depot systems and Federal Supply Schedules) in efforts to adopt a suitable single acquisition strategy to satisfy all Federal users, and
>
> --eliminate those items from availability through the Federal Supply Schedules if such means of procurement and supply are not the most cost effective.

Items carried in the depot system and the Federal Supply Schedules (FSS) are reviewed and analyzed on an ongoing basis to determine the most cost-effective method of procurement and supply. The demands of all users are carefully considered to insure that suitable and cost-effective means are available for supporting all users, regardless of size or location. In some instances, it has been determined that like items will be carried on the FSS and in the depot system to provide major and minor users with flexible means for supporting their demands. Experience shows that the minor user's demands are better supported through the FSS while the demands of major users are better supported through the depot system. The VA will continue to assess the FSS to insure that items included are cost effective and are in the best interest of all users.

APPENDIX XI

We would also like to comment on the recommendation that the Director, Office of Management and Budget, direct the Administrator, OFPP, to

> --transfer to the VA the responsibility of procuring, stocking, and distributing all drugs (except those needed for war or contingency purposes) which are common to the DoD and VA centralized wholesale depot systems.

The VA acquisition process is an integrated operation of wholesale and retail activities. The system is closely monitored with a primary objective of achieving a balance between these activities which will provide supplies to the customer at the most economical cost. Our system is so designed for our own needs and any alteration of the balance between the wholesale and retail components could adversely impact on the efficiency of the whole system. Adoption of this recommendation would not adversely affect the VA system, but we do not know if this is true of DoD. It is a factor to be considered before accepting this recommendation. Consolidation into a single agency should only be considered if it is the most efficient and economical solution, and the report does not establish this point. It is also our opinion that this recommendation is untimely and could prove counter-productive to the continued progress of the Shared Procurement Program.

While reviewing this report we noted that much of the data concerning the status of the Shared Procurement Program is not current and does not accurately reflect the progress made to date.

Various shared procurement activities, such as item assignment, unification of specifications, elimination of duplicate stock numbers, item commonality, and unification of quality assurance requirements, should be completed before this recommendation is considered. We believe the completion of shared activities would result in much higher benefits to the taxpayer.

We appreciate the opportunity to review and comment on this report.

Sincerely,

MAX CLELAND
Administrator

APPENDIX XII

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

REFER TO:

OFFICE OF THE INSPECTOR GENERAL

MAR 20 1980

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

Dear Mr. Ahart:

The Secretary asked that I respond to your request for our comments on your draft report entitled, "Efforts To Implement A Single Federal Drug Procurement System Can Be Improved And Expedited." The enclosed comments represent the tentative position of the Department and are subject to reevaluation when the final version of this report is received.

We appreciate the opportunity to comment on this draft report before its publication.

Sincerely yours,

For Richard B. Lowe III
Acting Inspector General

Enclosure

APPENDIX XII

COMMENTS OF THE DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE ON THE GENERAL ACCOUNTING OFFICE'S DRAFT REPORT ENTITLED "EFFORTS TO IMPLEMENT A SINGLE FEDERAL DRUG PROCUREMENT SYSTEM CAN BE IMPROVED AND EXPEDITED"

The report largely concerns the Department of Defense and the Veterans Administration. References to Department of Health, Education, and Welfare programs are accurate and current. While there are no recommendations to the Secretary of HEW, we are somewhat concerned about the wording of the recommendation to the Secretary of Defense and the Administrator of Veteran Affairs (page 89) which suggests that these agencies "ascertain . . . quality of available commercial products (drugs and medical devices)." As the report discusses, efforts were undertaken in 1974 to establish a single system for Government-wide management of medical supplies, with the Food and Drug Administration (FDA) having the responsibility for drug quality assurance. We are concerned that the quality assurance aspects of Federal drug procurement may once again become fragmented if this recommendation is interpreted literally and implemented. Some clarification is needed to indicate that drug quality will be determined by the FDA and this information provided to government purchasers as required.

(101016)

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