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COMPTROLLER GENERAL OF THE UNITED STATES
WASHINGTON, D.C. 20541

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Dear Mr. Chairman:

This is in response to your request made during our meeting of August 9, 1971, that we furnish information on the policies and practices followed in establishing set-asides for small business in Government procurements of drugs.

To answer your request, we examined the policies, procedures, and criteria used by the Small Business Administration (SBA), the Veterans Administration (VA), and the Defense Supply Agency (DSA) for setting aside procurements of drugs for small business concerns. Our review was directed to VA and DSA because they procure most of the drugs bought directly by the Government.

STATUTORY AUTHORITY AND RELATED POLICIES

The statutory and regulatory authority under which the procurement programs of SBA are conducted includes:

1. Section 2(a) of the Small Business Act (15 U.S.C. 631) which, in general, states that it is the policy of the Congress that the Government shall assist the interests of small business to preserve free competitive enterprise and to ensure that a fair share of Government procurements is placed with small business concerns.
2. Section 8(a) of the act empowers SBA to contract directly with Government agencies for the purpose of letting subcontracts to small business firms.
3. Section 15 of the act provides that all or a part of any procurement shall be set aside for small business when SBA and the contracting agency jointly determine that such action would (a) be beneficial to the national productive capacity, (b) be in the interest of national defense programs, or (c) ensure that a fair share of Government procurements is made from small business.

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Unilateral set-asides for small business by the Department of Defense are made under authority of section 2304(a)(1) of Title 10, United States Code, and implementing regulations set forth in section I, part 7, of the Armed Services Procurement Regulation. Federal civilian executive agencies make unilateral set-asides in accordance with section 302(c)(1) of the Federal Property and Administrative Services Act of 1949, as amended [41 U.S.C. 252(c)(1)], and implementing regulations set forth in Federal Procurement Regulations, primarily subpart 1-1.7.

SBA National Directive 605-1 of April 8, 1968, requires that procurements of \$2,500 and more which have not been recommended for set-asides by either a small business specialist (employee of the contracting agency) or the contracting officer, or which have been recommended and then withdrawn, shall be screened by a SBA representative for possible small business set-asides action.

One hundred percent set-asides for small business are to be initiated on all procurements determined to be within the purview of Section 15 of the Small Business Act. However, SBA National Directive 605-1 states that one hundred percent set-asides shall not be initiated if any of the following conditions exists:

- "(1) The item is a proprietary item, ***
- "(2) There is the expectation of receiving insufficient small business competition to provide a reasonable price to the Government.
- "(3) The procurement is of a qualified product [item must pass specification test requirements and be on a list of qualified products prior to the procurement] unless ***none of the qualified large firms desire to participate.
- "(4) The item is on the Departments Planned Producers List unless *** none of the large business Planned Emergency Producers desire to participate.
- "(5) Item is being purchased for field test purposes following an R&D [Research and Development] contract.
- "(6) R&D procurements with small business competition insufficient to provide *** the best proposal.
- "(7) Construction procurements estimated at more than \$500,000."

Information obtained at the VA Marketing Center and at DSA's Defense Personnel Support Center, which procure about 70 percent of the drugs bought directly from suppliers by the Government, follows.

DEFENSE PERSONNEL SUPPORT CENTER PRACTICES

The Defense Personnel Support Center has formalized procedures to implement the small business procurement requirements for defense activities as set forth in the Armed Services Procurement Regulation. Also the Center has established a position of small business specialist, responsible for planning, implementing, and directing the small business and economic utilization programs.

Each year DSA sets small business goals for the Center by commodity grouping. For fiscal year 1971 the Center awarded 17 percent of the procurements in the medical commodity group--includes, in addition to drugs, many other medical federal supply classes, such as, surgical dressings, and instruments, dental, X-ray, hospital, optical, and laboratory instruments and equipment--to small concerns. A goal of 16 percent had been set by the parent organization, DSA. For fiscal years 1969 and 1970, the Center awarded 20 percent and 18 percent, respectively, of the medical commodity group procurements to small business, or slightly less than the goals of 22 percent and 21.5 percent set by DSA.

The purchase of drugs, biologicals, and chemicals by the Center represented over 50 percent of the total dollar value of procurements within the medical commodity group for fiscal years 1969 to 1971. Of this, less than 10 percent was procured from small business and the value of set asides for small business increased from about \$336,000 to about \$800,000. (See enclosure.) The percentage of awards to small business in the medical commodity group, other than drugs, biologicals, and chemicals, was about 30 percent for these years.

A purchase at the Center is initiated by a request prepared by the Division of Supply Operations. Upon receipt of the request, the contracting officer prepares a form which identifies the item and estimated quantity required and any known limitations toward making a partial, or total, set-aside for small business. These forms are reviewed by the Center's small business specialist who decides whether a small business set-aside should be made. These decisions are then reviewed by a representative of SBA who may appeal decisions not to make a set-aside, or withdrawals of set-asides to (1) the contracting officer, (2) the Commander of the Center, or (3) if necessary, the Commander, DSA, through SBA in Washington, D.C.

VETERANS ADMINISTRATION PRACTICES

Except in the area of construction services, VA has not issued instructions to implement the provisions of the Federal Procurement Regulations relating to small business set-asides. As of August 1971 VA had not designated anyone at the VA Marketing Center to be responsible for planning and implementing VA's small business programs.

Until about January 1970 an SBA representative was not assigned to review the activities of the VA Marketing Center from a small business viewpoint. Thus until that time set-asides for small business were of necessity initiated by the contracting officials.

For each of the 3 fiscal years 1969 through 1971, VA purchased over \$1 million worth of drugs and chemicals from small business firms. Most of these procurements resulted, however, from the small business firms meeting price competition under normal procurement practices. Contract awards totaling only \$11,400 in fiscal year 1969 and \$15,800 in fiscal year 1970 were attributable to set-asides for small business. See enclosure.

Beginning in fiscal year 1971, VA has actively participated in a program of procuring drugs from small business minority group enterprises. Initiated under section 8(a) of the Small Business Act (see page 1), this program involves VA contracting directly with SBA. In turn, SBA subcontracts with small business minority group enterprises. Under this program suppliers appear to have an advantage compared with suppliers under regular small business set-asides because prices negotiated by SBA with minority enterprises do not have to match the lowest price as under normal small business transactions. The minority group enterprise prices need only be considered reasonable. The SBA representative at the Defense Personnel Support Center informed us that the Support Center had not initiated a program for drug procurements under section 8(a) of the Small Business Act.

For fiscal year 1971 the VA Marketing Center reported purchases from minority group enterprises of about \$299,100. These purchases were reported as other agency contracts to small business, but not as small business set-asides.

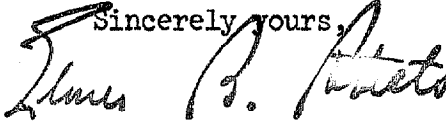
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During our review we identified the following factors which seem to contribute to the lack of small business participation in drug procurements compared with the participation in procurements of other commodities.

- The increasing number of drug products for which a new drug application--which is often costly to obtain--is being required by the Food and Drug Administration.
- The continuous reduction in the number of drug firms in the small business category due to acquisition by large concerns, or growth into the category of large business.
- The fact that most new drugs are developed and introduced into the market as proprietary or patented items by large business concerns.

We trust this information will serve the purpose of your request. We have not obtained written comments from VA or DSA on the matters discussed in this report.

We plan to make no further distribution of this report unless copies are specifically requested, and then we shall make distribution only after your agreement has been obtained or public announcement has been made by you concerning the contents of the report.

Sincerely yours,


Comptroller General
of the United States

Enclosure

The Honorable Gaylord Nelson
Chairman, Subcommittee on Monopoly
Select Committee on Small Business
United States Senate

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SET-ASIDES AND OTHER AWARDS TO SMALL BUSINESS BY DSA AND VA
IN FISCAL YEARS 1969-1971 FOR DRUGS, BIOLOGICALS, AND CHEMICALS

	Fiscal year 1969		Fiscal year 1970		Fiscal year 1971	
	DSA	VA	DSA	VA	DSA	VA
Set-asides	\$ 336,000	\$ 11,400	\$ 672,000	\$ 15,800	\$ 800,000	\$
Other awards (note a)	8,728,000	1,783,800	5,011,000	1,048,800	6,640,000	1,434,700 (note b)
TOTAL (small business)	<u>\$ 9,064,000</u>	<u>\$ 1,795,200</u>	<u>\$ 5,683,000</u>	<u>\$ 1,064,600</u>	<u>\$ 7,440,000</u>	<u>\$ 1,434,700</u>
TOTAL (drugs, biologicals, and chemicals)	<u>\$102,366,000</u>	<u>\$23,427,100</u>	<u>\$71,997,000</u>	<u>\$23,019,100</u>	<u>\$95,066,000</u>	<u>\$27,186,700</u>
Small business as percent of total	8.9	7.7	7.9	4.6	7.8	5.3

^aThese awards resulted, for the most part, from small business firms' meeting price competition under normal procurement procedures.

^bIncludes purchases of about \$299,100 from small business minority group enterprises. (See p. 4.)