Chapter 5

Marketing, Procuring, and Supplying Devices

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The Veterans Administration (VA) both promotes and purchases medical devices, necessitating different kinds of VA programs. As part of its commitment to research, development, and evaluation of rehabilitative devices, the VA's Rehabilitation Research and Development Service (Rehabilitation R&D) works with private organizations in manufacturing and marketing products they have developed. The VA Marketing Center (VAMKC), in the VA Office of Procurement and Supply, on the other hand, determines the VA's need for commercially available devices and purchases and supplies these devices.

The VA activities related to prototype rehabilitative devices, which are discussed here first, by definition conclude at the marketing stage. VA activities related to commercially available devices (rehabilitative devices and equipment and supplies), which are described later, encompass marketing, procurement, and supply.

PROTOTYPE DEVICES

Technology transfer is generally one of the more difficult hurdles in developing and distributing rehabilitative devices. Chapter 3 touched on the VA's long absence of structured activities in this area. No VA system routinely ensures that successful new prototypes are transferred to clinical practice.

There are a number of significant obstacles to private industry's participation in this process as well *(65,109):*

- lack of adequate demographic data (or market statistics) about the technologies disabled people need;
- the commercial vulnerability of some ventures because of small, fragmented markets and high investment costs; and
- obstacles presented by the patent system, liability insurance requirements, and the third-party payment system.1

Figure 5 illustrates the generally complex dynamics and requirements of private sector efforts to bring research ideas, information, and products to the consumer.

One purpose of the Rehabilitation R&D Center's evaluation unit is to address the problem areas of marketing and finance, which it plans to do in at least two ways (154):

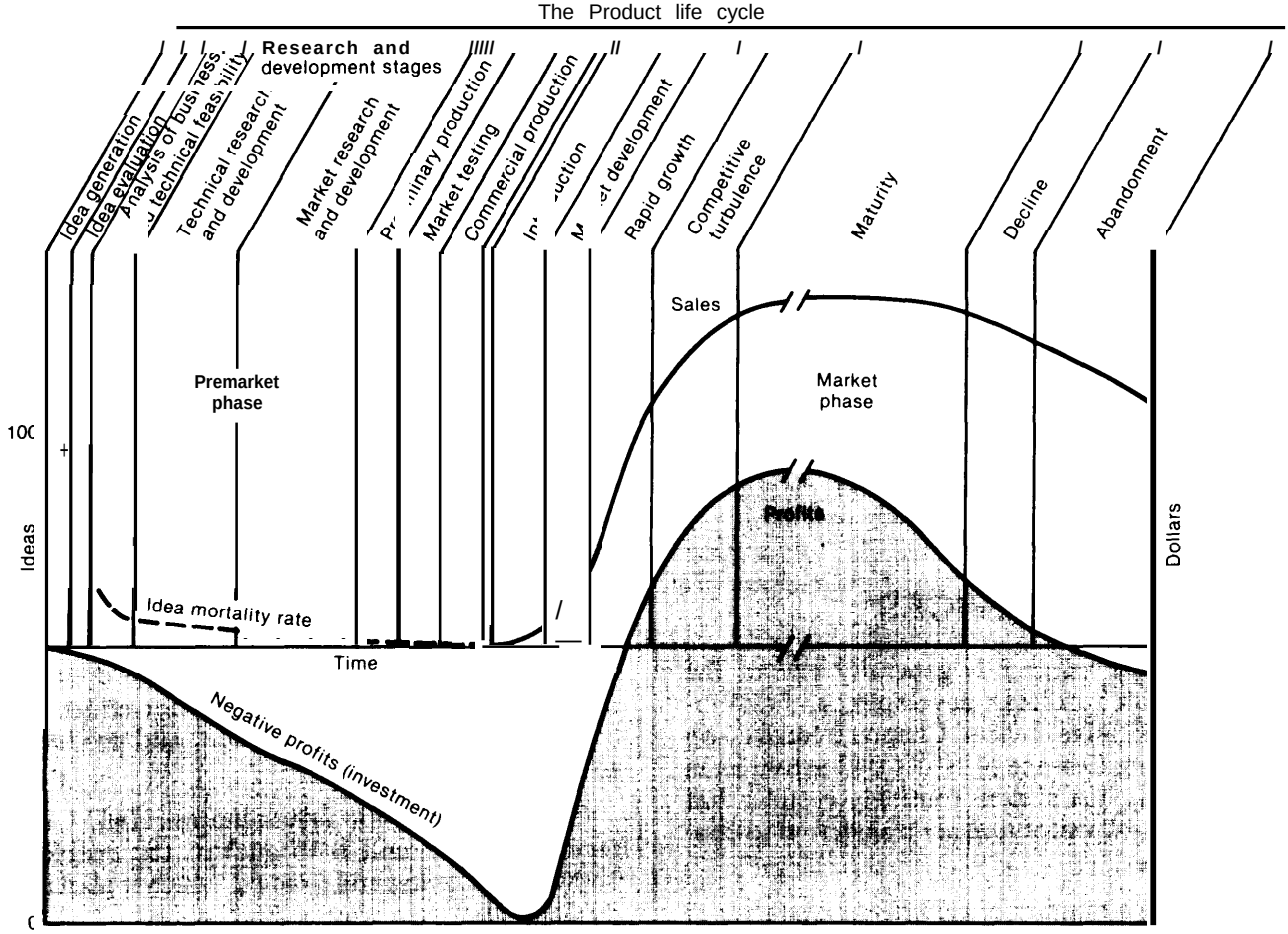
- by encouraging device development and innovation to meet disabled veterans specific needs, and
- by helping VA-supported researchers and appropriate industry representatives coordinate an interagency program with the Department of Commerce for commercializing prototype devices that the unit evaluates.

The VA Administrator signed an interagency agreement with the Department of Commerce in May 1983, and the VA planned to reimburse the Department for up to $125,000 in fiscal year 1983 for its expertise in marketing and commercializing technology.

The VA is also considering a specific program with the Department of Commerce like the Na-

'A further problem, discussed in ch. 4, results from the VA's being both a large market for many devices and an arbiter of performance and design standards. To a large extent the VA can thus determine which technologies enter the market. If the VA uses specifications and standards developed for existing technologies, it may impede the emergence of innovative devices.

Figure 5.—The Innovation Process



SOURCE: J. E. Muthard, "Putting Rehabilitation Knowledge to Use," Rehabilitation Monograph No. 11 (Gainesville, FL: University of Florida Rehabilitation Research Institute, 19S0), as cited In (109).

tional Science Foundation's Small Business Innovation Research Program. Funding of up to $20,000 would be provided to small businesses to "demonstrate the_feasibility of a new concept." When feasibility studies have been done, the program may support a limited number of more substantial proposals to carry new concepts through prototype testing and evaluation. The program would be directed at established, specific needs of disabled veterans (154).

Another purpose of the evaluation unit is to improve the link between the VA's R&D and industry by several means (154):

- monitoring the progress of all Rehabilitation R&D projects on devices;
- staying informed of any links Rehabilitation R&D projects have with industry, and encouraging industrial interest where there is none;

- developing information on U.S. and foreign industry that relates to disabled veterans, and accessing data stored in VA banks and in ABLEDATA;[2] and
- coordinating the Rehabilitation R&D interagency agreement with the Department of Commerce in market surveys, locating capitalization funds, and stimulating the commercialization of R&D prototype devices based on its evaluation program.

The Rehabilitation R&D Center's evaluation unit can substantially increase, centralize, and improve Rehabilitation R&D's role in marketing and financing, though until now efforts have been piecemeal. The Rehabilitation R&D Center at Palo Alto, for example, has retained an in-house marketing specialist since December 1982. The Palo Alto Center is now working with about 30 companies in developing devices.

Nevertheless, the evaluation unit does not necessarily solve all problems of technology transfer. The Palo Alto group ran into difficulties because of Public Law 96-517, concerning patent rights to inventions developed by nonprofit institutions using Government funds. The VA will not implement the law for several months, although other Federal agencies that fund R&D already have. In the interim, Stanford University (whose engineers work with the VA at Palo Alto) has been unable to file a patent application to protect its intellectual property rights on at least one prototype device.[3] Instead, Stanford has requested that the engineer-inventors participate in VA patent evaluation and application filing and has encouraged the VA to conduct its investigation of the device "with due speed, so that the publication ban will not post before a patent filing decision is made" *(53,76).*

[2] ABLEDATA is a new computer information system funded by the National Institute of Handicapped Research as a service of the National Rehabilitation Information Center based at Catholic University, Washington, DC. ABLEDATA combines manufacturers' data and updated information on local availability of products, names of manufacturers, locations of distributors, product descriptions, costs, and results of any relevant evaluations. The data bank is accessible to information brokers at locations around the country, and the brokers are accessible to rehabilitation centers, individuals, or anyone who needs the information. The Prosthetic Technology Evaluation Committee (discussed in ch. 4) also plans to share information routinely with ABLEDATA (109).

[3] A recently named property right distinct from patents, copyrights, trademarks, and trade secrets is "tangible research property." For example, in March 1982 Stanford University developed a special policy on tangible research property to protect its ownership of "tangible (or corporeal) items produced in the course of research projects, " including "biological materials, computer software, computer data bases, circuit diagrams, engineering drawings, integrated circuit chips, prototype devices and equipment, etc. " (83).

COMMERCIALLY AVAILABLE DEVICES

Marketing

The VA's Marketing Research and Analysis program, developed from the VA-National Bureau of Standards Experimental Technology Incentives Program during the late 1970s. It represents a major change in VA procurement in bringing marketing judgment to bear on commercial products' entry into the VA supply system and is central in developing VA procurement strategies. Marketing Research and Analysis is primarily the responsibility of the Testing and Evaluation Staff (T&E) of the VAMKC, although each procuring division of the VAMKC has a product development section supporting the program (128).

As a purchaser of devices, the VA attempts both to obtain the lowest possible prices in contracting and to improve medical care. Marketing Research and Analysis is a resource for procurement by gathering and analyzing information on the range and quality of available commercial products and determining whether they meet VA needs. This is done through surveys, Quality Improvement Reports (discussed inch. 4), and other techniques ranging from informal telephone inquiries (about products acquired by local medical centers) to comprehensive reviews (of products that may improve care VA-wide or effect substantial savings) (130). The aim of this prod-

uct and market research is to determine the need, demand, and best method of supply for items. Recommendations are then forwarded to procurement officers.

This VA program encompasses research in many areas (130):

- product research (on products satisfying VA and other users' needs, product changes required to meet VA needs, product descriptions used in commercial transactions, and new products needed);
- market analysis (on the number and competitiveness of firms, business practices, pricing structures, distribution practices, restrictions on shelf life and storage);
- analysis of the commercial market (on acceptability to likely users in light of such features as reliability and warranty); and
- analysis of product support (on warranty and support procedures).

Such research originates from the VA Central Office, procurement offices at the VAMKC, and T&E.

An obvious priority during the program's first years was to test the hypothesis that because of its size Federal procurement could significantly influence market innovation by providing an early market for products, thus reducing market entry risks (52). Results of this test were mixed.

For example, the program authored the *Directory of Living Aids for the Disabled Person,* having found that no single printed source of such information existed although there was a corresponding demand. Publishing firms were solicited to determine their interest and the feasibility of the endeavor. As an incentive to industry, the VA proposal called for the directory to be published once for distribution to people within the VA health care system but allowed the contractor or any other interested parties to use the same data commercially, with obvious private as well as social benefits. The VA objective, which was reflected later in the publishers' bids, was to have bidders recognize the directory's market potential and publish it at minimal cost to the VA (67).

The program's projects have not always been so successful. Another project determined that syringe needles should be more readily destroyed for disposal. Working closely with a small private firm, the program helped develop such a product, but the company eventually went bankrupt *(67).*

More recently, the program has focused on commercially available products. Criticism of products, poor depot sales, and seeming technological breakthroughs are typical subjects of research. T&E also frequently relates its testing and evaluation, Quality Improvement Reports, and recall and hazard alerts to the program's research (67).

Procurement and Supply[4]

The VA's Office of Procurement and Supply supports the most extensive medical program in the Federal Government and also provides nonperishable subsistence supplies, medical equipment and supplies, drugs, biological, reagents, and chemicals to more than 4,100 installations of other Government agencies. These services are supported by nearly 6,800 employees, including staff at the Central Office, the VAMKC, three supply depots, the Prosthetics Distribution Center, and 172 medical centers.

In fiscal year 1982 the VA's Office of Procurement and Supply spent nearly $1.3 billion on supplies and equipment. Two kinds of mechanisms support this procurement and delivery: the VA's central procurement programs, and the local supply activities of medical centers. Generally, central procurement encompasses all medical equipment, supplies, and rehabilitative device items, while local purchases are usually of disposable medical and dental supplies.

Central Procurement

Several centralized VA procurement programs have been established over the years so that in-

[4]Except as noted, this section is based on U.S. Veterans Administration, ***Brief of Office of Procurement and Supply,*** unpublished (Washington, DC, December 1982) (121).

dividual medical centers can obtain supplies and equipment economically, not having to solicit and award contracts themselves. The VA finances all supply operations through a revolving supply fund, charging customers a percentage markup over the item's purchase price, about 6 percent, to balance the fund (99). The VAMKC provides these centrally managed supply channels, which are also available to other Government agencies, such as Public Health Service hospitals, the Bureau of Indian Affairs, and Federal correction institutions.

Centralized procurement programs are organized into procurement divisions, each headed by a commodity manager, specializing in different areas: pharmaceuticals, medical supplies, medical equipment, surgical supplies, and nonperishable subsistence supplies. These VAMKC programs include a national depot distribution system, Federal Supply Schedules (FSS) for items that the General Services Administration assigns to the VA *to* manage, contracts for direct delivery to medical centers, and decentralized contracts for direct ordering by medical centers.

VA Supply Depots

During the 1940s, wartime demands and poor distribution systems made it necessary for the VA and the Department of Defense (DOD) to establish depot inventories of hospital stock. These depots have been continuously maintained to the present day (34). Under this program, volume purchases are made at low prices and items are managed through three VA supply depots, in Somerville, New Jersey; Hines, Illinois; and Bell, California. A Prosthetics Distribution Center in Denver, Colorado, also serves the approximately *200,000* veterans with service-connected disabilities.

Medical center supply requests are transmitted to the VA's Data Processing Center in Austin, Texas, recorded in the automated supply system (the Integrated Procurement, Storage, and Distribution System, or "Log 1"), and then sent to the appropriate depot to be filled. In fiscal year 1982, VA medical centers obtained about $198 million in about 650 different supply and equipment items (over 95 percent supplies) from the supply depots. Depot shipments and receipts are also recorded in Log 1 for the VAMKC'S management of depot stock (100).

Federal Supply Schedules

Under the FSS program, Government agencies contract with commercial vendors for many supplies and services. The schedules allow VA medical centers and other agencies to order directly from contractors at preestablished prices. ' The VAMKC manages FSS contracts for certain drugs, chemicals, subsistence supplies, and medical supplies and equipment (the General Services Administration manages VA FSS contracts for such items as furniture and office supplies and equipment) (100). In fiscal year 1982, VA medical centers purchased materials worth about $434 million through this program. Table 3 gives a more specific breakdown of FSS purchases for selected devices.

Decentralized Contracts and Direct Delivery

The VAMKC also administers decentralized contracts for medical centers. These contracts are for specialized medical equipment, for example,

[5]The schedules contain a "bu, American differential" clause. Essentially, a price differential (percentage) must be applied to a foreign-made item before placing an order if foreign and domestic products are listed under the same special item number in the FSS and both products satisfy an item requirement (148). This discourages purchase of the foreign-made item unless the price of the U.S.-made item is higher by a certain percentage.

Table 3.—Selected Device Purchases by the Veterans Administration Using Federal Supply Schedule Contracts, Fiscal Year 1983[a]

Items	Expenditure (millions of dollars)
Medical supplies (mainly consumables). . .	$120.0
Dental supplies and equipment	17.5
Medical supplies and equipment.	46.7
Pacemakers	5.0
Wheelchairs	9,6
Surgical gloves	1.3
Eyeglasses	1.3
Medical X-ray film	6,0

[a]Estimated,

SOURCES: U.S. Veterans Administration, *1982 Annual Report* (Washington, DC, 19S3); U.S. Veterans Administration. *Brief of Office of Procurement and Supply,* unpublished (Washington, DC, December 1982).

electrocardiograph and stress test equipment, sterilizers, pacemakers, and intravenous pumps, which are usually not available through the depot or FSS programs. VA medical centers are the primary users of this program, but other Government agencies may participate. For direct deliveries, the VAMKC not only administers contracts but also orders for the medical centers. Vendors then deliver material to them directly. This program is used primarily for radiological and nuclear supplies and equipment (100). In fiscal year 1982 these two programs accounted for $158 million in medical center purchases.

Other Activities

The VAMKC directly procures medical supplies for other Government agencies including the Agency for International Development, the Bureau of Indian Affairs, DOD, the U.S. Air Force in the Philippines (CT scanners), the U.S. Army in Germany, the U.S. Army Medical Materiel Agency (nuclear diagnostic equipment for world wide distribution), and the U.S. Embassy in Moscow. In addition, the VAMKC has processed 2,600 individual orders for direct delivery to various Army hospitals within the 48 contiguous States and has provided radiographic equipment for U.S. health services in the Virgin Islands. In fiscal year 1982 the total value of this direct procurement was $15 million.

The VAMKC also participates in the Medical Shared Procurement Program with DOD, one of many Federal interagency agreements for sharing or exchanging materials, facilities and services.[b] Commonly used items are procured by one agency to secure the best possible price, while simplifying procurement for both the agencies and private firms. As of July 1983, the total annual dollar value of contract awards under the VA-DOD program was $295 million.

The VA has executed over 200 supply agreements with 17 other Federal agencies worth $45.2 million per year in exchange for support services. Of the $45.2 million, $33.7 million represents VA supply support to other Federal facilities. Table 4 shows the source, dollar value, and type of supplies provided during fiscal year 1982. The remaining $11.5 million represents the coordination or exchange of medical, laboratory, and laundry services; automatic data-processing systems; research and development projects; maintenance of facilities, roads and grounds; and training.

Finally, the VA has established an Office of Small and Disadvantaged Business Utilization as part of a larger Federal program that reserves some procurement for the exclusive bidding of small and minority-owned businesses. The program was designed to give these businesses equal opportunity to compete for Government contracts and subcontracts (102).

Medical Center Supply Activities

All VA medical centers have similar supply and procurement characteristics. Generally, each center has its own supply service that acquires and distributes supplies and manages center inventories. In a few metropolitan areas, centers share a supply service and warehouse.

The departments within a center, such as dietetics, engineering, radiology, and pharmacy, or-

[6] Agreements have developed pursuant to the Economy Act of June 1932, as amended (31 U.S.C. 1535); Public Law 97-258, September 1982, as amended; and Public Law 97-332, October 1982.

[7] Information in this section is based on U.S. Congress, General Accounting Office, *VA Needs Better Visibility and Control Over Medical Center Purchases,* PSAD #81-16, Washington, DC, Dec. 12, 1980 (100).

Table 4.—Veterans Administration Supply Support to Other Federal Facilities, Fiscal Year 1982

Items	costs (dollars)
From VA depots:	
Drugs and medicines	$8,776,006
Other medical supplies	5,335,163
General supplies	332,437
Subsistence supplies	6,869,817
Equipment	11,177,690
Subtotal	$32,481,113
From f/e/d stations to:	
Territorial governments	$ 371,980
Other government agencies	803,861
Subtotal	$ 1,175,841
Total	$33,656,954

SOURCE: U.S. Veterans Administration, *Brief of Office of Procurement arrd Supply,* unpublished (Washington, DC, December 1982).

der through the center's supply service. The supply service is required to fill requisitions appropriately and promptly, ensuring that vendor competition is adequate and prices are reasonable. Expendable supplies received by a medical center are either stocked in the center's warehouse (posted) or delivered directly to the appropriate department (unposted).

The VA's automated supply system provides information for medical centers, as well as the VAMKC, to use in procurement. The medical centers contribute data on their stock orders, receipts, and distribution, and use Log 1 to manage local stock, whereas the VAMKC uses this information not only to manage depot stock but to identify posted items with central management potential. Log 1 has files on three types of medical center procurements: expendable posted and unposted supplies and nonexpendables (equipment).

As described above, the VAMKC centrally manages items commonly used by VA medical centers and provides several centrally managed supply channels, but it purchases very little directly for the centers. The VAMKC mainly selects items based on medical center usage, on the assumption that it can obtain lower prices and more reliable sources than individual medical centers can. VA priorities for sources of medical center supplies are listed in table 5.

To ensure proper supply channels are selected, the VA requires that the medical centers' supply services review each purchase request. The open market may be used to purchase items not available from centrally managed (so-called mandatory) sources, when they are needed for an emergency or are available at lower prices than through FSS.

The VA's Impact on Product Quality

An important responsibility of the VAMKC is ensuring product quality. This responsibility has proved difficult to fulfill. In fiscal year 1980 the VAMKC began using Commercial Item Descriptions (CIDS) in place of more detailed product specifications and standards to purchase medical supplies and equipment, in response to a new Federal procurement policy to "purchase commercial products and use commercial distribution systems" whenever possible (117).[8] CIDS and purchase descriptions (the latter used only for small or special purchases) are simplified product descriptions of the functional or performance characteristics of commercial products acceptable for Government use (115). These descriptions are still to ensure that items purchased are satisfactory.

A 1982 General Accounting Office (GAO) study found that the VA had applied the new policy improperly (101). The VA's purchase descriptions were only one or two sentences long and

[8]VA specifications were detailed documents, typically covering design, materials, workmanship, and other product features; sampling, testing, and inspecting procedures to be used; packaging and marketing requirements; and other measures to determine whether a product qualified for purchase. Specifications are not to be confused with standards, which typically include only a product description and performance requirements. However, specifications often incorporated standards (12).

Table 5.—Priority Purchasing Sources for VA Medical Centers

Supply channel	VA priority ranking	Approximate annual purchases (millions of dollars)	Percentage of total
VA excess	1	NA[b]	NA[b]
VA supply depots	2	$197.9	15.3%
Other government excess	3	0.4	—
Federal prisons and correctional institutions, blind-made and severely handicapped products	4	1.0	1
General Services Administration stock	5	34.1	2.7
VA decentralized contracts	6	41.4	3.2
Federal Supply Schedule contracts	7	434.4	33.6
Open market purchases	8	498.2	38.5
Other	None	86.0	6.6

[a]Fiscal year 1982.
[b]Not available.

SOURCE: U.S. Veterans Administration, *Brief of Office of Procurement and Supply,* unpublished (Washington, DC, December 1982).

contained little specific information. In addition, GAO concluded that in developing purchase descriptions, the VAMKC marketing divisions did not communicate with users and suppliers. As a result, the VA purchased many medical items that were either unneeded or inferior.

GAO also found other problems in the new CID system. Before using CIDS, the VA had relied on three elements for quality control:

- the marketing division, through its specifications, standards, and qualified products lists;
- the depot inspectors, through inspections upon delivery; and
- individual medical centers, through professional opinions and assessments.

When the VA stopped using detailed specifications, it also discontinued this three-element quality assurance program, believing that the program was based on using detailed specifications and was therefore no longer applicable. As a result of this change, however, quality standards were not consistently established in purchasing devices, and inspection programs were no longer dependable. Again, GAO found that stocked items were frequently poor or inappropriate. Surgical instruments had defects, such as cracks, pits, or rough edges, that could prevent sterilization. Some did not close properly or failed to meet VA test standards. Other items had missing or broken parts and misaligned components. Finally, when medical centers received these defective items, their complaints were often ignored.

In response to the GAO study, the VA reinstituted some of its traditional measures for quality assurance:

- reestablishing a qualified products list for surgical instruments,
- developing inspection criteria for depot items to supplement purchase descriptions, and
- transferring responsibility for quality complaints from the purchasing divisions to T&E to improve objectivity and responsiveness (as discussed at length in ch. 4).

The VA has now taken a further step through an interagency agreement with the Food and Drug Administration (FDA). As of March 1982 the FDA assumed certain quality assurance responsibilities for VA medical device contracts, including depot stock inspection and investigating the manufacturing practices of potential contractors (116).

There is still concern, however, that CIDS and purchase descriptions will contribute to the lower quality of VA medical equipment and supplies. Surgical instruments, for example, have drawn complaints from VA medical centers, and for the same defects (67,79).

The issue of quality has also arisen regarding hospital beds. VA testing and evaluation led to the recommendation that beds be purchased with specific safety controls for repositioning, and this recommendation was incorporated in earlier product specifications. VA marketing research also found that certain positioning features significantly increased cost, yet that VA hospitals rarely used these features. Neither of these findings, however, has been consistently applied in VA centralized purchasing contracts using CIDS. Instead, more expensive beds and beds with fewer safety features have often been purchased because of poor product descriptions (67,79).

Nevertheless, such problems do not demand a return to the old specifications. The VA, veterans' service organizations, and private manufacturers and vendors agree that device specifications were often too rigid, stifling innovation given the size of the VA market. One private firm made wooden canes considered obsolete by every other purchaser, yet it maintained a profitable operation for several years because of the VA's outdated specifications. Bradburd also found that VA specifications for medical equipment were often written by considering a particular manufacturer's product, putting other manufacturers at a serious disadvantage (14) (see app. C). Other VA specifications were simply unenforced given the range of suppliers (12,54,67).

The VA, then, has tried to strike a balance in using CIDS, writing device product descriptions both to maximize the number of potential suppliers and to prevent an influx of inferior items. Commodity managers, who are responsible for both contracts and developing CIDS, now work closely with T&E to incorporate device evaluations and market research into product descriptions (12).

However, despite the attempted cooperation of T&E and purchasing divisions, problems may still arise because their individual goals of quality and efficiency may conflict. Purchasing divisions are charged to contain VA costs as well as to see that supplies are available. Also, factors other than price and availability (e.g., product reliability and performance), while taken into account, are more difficult to quantify in purchasing.

The VA's Impact on Product Cost

The impact of the VA's procurement system on product cost depends on supply conditions, the type of procurement (centralized or decentralized), and VA contract procedures and policies. Many industries believe that the VA and other Government agencies obtain the best buy (44). Becker and his colleagues found the "overriding premise" in selling to Government agencies is that they expect low prices. However, industries still can benefit (9):

> Government orders are sought by most manufacturers that would be unacceptable and unprofitable if normal accounting practices were followed. The manufacturer generally sells at these reduced prices based on the premise that this is "incremental" or add-on business. . . . With smaller margins than would otherwise be realized . . . the manufacturer may . . . increase manufacturing . . . utilization of otherwise unused production time and facilities.

The VAMKC decides to manage an item centrally based on several factors: usage, need, customer service, and cost.[9] Certain minimum criteria must additionally be met:

- $15,000 in potential sales for new items,
- an estimated savings of at least 15 percent for supplying an item through depot stock,
- annual sales of at least $10,000 to retain an item supplied through depot stock,
- the use of an item by at least 10 percent of all VA hospitals to retain an existing method of supply, and
- a realized savings of at least 5 percent on any centralized contract.

These criteria have probably contributed to efficiency and savings in VA centralized procurement.

There is also some empirical evidence that VAMKC policies result in lower product costs. A recent study by IMS America, Ltd., under contract to the VA, concluded that the VA is a "most favored customer," even compared to large institutional buyers (44). The study compared the prices of selected items for the VA and the Hospital Corp. of America, including catheter needles, syringes, surgical tape, surgical blades, and common pharmaceuticals. The study found that the VA consistently obtained the best buy and concluded that the results probably would have been the same had another sample of products been compared. "The size of the VA as a buyer alone clearly places the VA at an advantage, " the report observed (44).

VA centralized procurement has also compared favorably with other Federal procurement. A recent survey of *25* hospitals in 10 States by the Inspector General of the Department of Health and Human Services found that the price of cardiac pacemakers was about 17 percent higher for Medicare than for the VA (120).

Two studies have criticized the VAMKC'S management of the depot system. The 1982 GAO report and the 1983 President's Private Sector Survey on Cost Control found that VA inventory management techniques increased costs (34).[10] The VA is now simplifying and automating its ordering and storage systems.

OTA examined the likely effects of VA policies on the costs of procuring nine types of major medical equipment: X-ray equipment, computerized tomography (CT) seamers, digital imaging equipment, nuclear diagnostic equipment, nuclear magnetic resonance (NMR) and positron emission tomography (PET) scanners, ultrasound diagnostic equipment, patient monitoring equipment, electro-encephalogram (EEG) and electrocardiogram (ECG) equipment, and hemodialysis equipment (this study is presented in app. C). The study focused on how the VA affects and is affected by

[9] Once a decision has been made to procure an item centrally, contracts are developed through either a formal bid or negotiation, depending on need, demand, and number of manufacturers (12).

[10] The President's Private Sector Survey on Cost Control further recommended the complete dismantling of the VA depot system based on its own cost-accounting analysis. Analysis of this issue, however, is beyond the scope of this report.

market conditions, and especially on how VA procurement policies affect the prices and products manufacturers offer to the VA. Five official contract procedures and one unofficial VA policy were examined for their effects on equipment costs: 1) brand name justification, 2) the firm fixed price clause, 3) public disclosure requirements, 4) no volume commitment, 5) the most favored customer clause, and 6) the unofficial reluctance to procure mixed equipment systems.

Analysis of the likely effects of these policies indicated that they have different, perhaps conflicting results on procurement prices:

- *Brand Name Justification.* —When a VA hospital is authorized to buy equipment, the VAMKC forwards to the hospital a list of suppliers on contract whose equipment meets the requirements of the purchase order, ranked by order of cost. The hospital is required to buy from the least-cost supplier unless it can justify purchasing from a different source (e.g., because of service availability). This requirement is called brand name justification. Because suppliers are anxious to maintain their share of the VAMKC market, the requirement almost certainly results in lower prices.
- *Firm Fixed Price Clause.* —Under the terms of a VAMKC contract, suppliers cannot increase prices during the contract year. Furthermore, if they lower the price at any time during the year, the lower price holds for the remainder of the contract year. The firm fixed price clause may or may not result in lower procurement costs. Suppliers offer temporary price discounts in the private market to promote their products. Normally, promotional offers would probably be extended to the VAMKC as well, but because of the firm fixed price clause, suppliers are reluctant to make them. Even the requirement that prices not be increased during a contract year has indeterminate effects on procurement costs. Although the requirement does protect those who buy~ through the VAMKC from price increases, suppliers may charge a higher price at the start to ensure a profit. Altogether, it is extremely difficult to determine the net effect of the firm fixed price clause.
- *Public Disclosure Requirements.—By* law, the public has access to VAMKC procurement prices for medical equipment. Both theoretical and empirical evidence support the view that this results in higher procurement costs for the VAMKC. First, a firm's benefits from cutting its price are in part a function of the so-called retaliation lag, the length of time before rivals learn of the price cut and cut their own prices in response. Price disclosure requirements reduce the retaliation lag, and therefore discourage price cutting in the VAMKC market. Because other buyers of medical equipment also have access to the price data, the VAMKC price may serve as the other buyer's target in pricing negotiations, which can also inhibit price cutting in the VAMKC market. Suppliers of X-ray, nuclear medical, patient monitoring, and hemodialysis equipment have stated that prices offered to the VAMKC are higher because of the contract disclosure requirement. Some suppliers said the disclosure requirement did not affect pricing in their markets because pricing information was widely available from other sources.
- No *Volume Commitment.* —Having a contract with the VAMKC does not imply any contractual volume commitment in procurement. For most equipment categories (other than X-ray and nuclear diagnostic equipment), the absence of a volume commitment is a major factor in pricing. There are two likely reasons why volume commitment would be unimportant in some industries, but very important in others. First, when equipment is purchased from stock and is fairly standardized, a volume commitment can reduce manufacturing costs that can be passed on to the buyer, but not when the equipment is custom made. Second, the effects of volume commitment seem to depend on whether equipment is expensive or inexpensive. When equipment is inexpensive, the costs of preparing contracts and marketing

are higher relative to the purchase price of the equipment. In this situation, the cost savings that come with volume commitment are more significant. Some suppliers indicated that they might lower prices by 5 to 10 percent in exchange for a volume commitment. One supplier in the ultrasound market stated that a group purchase of even 15 to 20 units would suffice for a larger price discount than is now offered.

- Most Favored *Customer* Clause .—Under the terms of a VAMKC contract, suppliers are prohibited from selling their equipment under a "like contract" to any private buyer at a price lower than that offered the VAMKC. If a lower price is offered to a private buyer, this price must be given to the VAMKC for the rest of the contract year. This stipulation helps ensure that the VAMKC'S clients benefit from vendor competition in the private market. Although the strictness with which the most favored customer clause is interpreted varies from one equipment category to the next, it almost certainly reduces VAMKC equipment procurement costs. The most favored customer clause can also have a powerful impact on private buyers. In a few markets, private buyers are offered lower prices than the VAMKC when they make contractual volume commitments, on the grounds that these are not "like contracts. " The effect of the clause is obviously less in these markets. However, in cases of no volume commitment, the most favored customer clause may have the effect of increasing prices that private buyers must pay for medical equipment, especially for X-ray, nuclear diagnostic, ultrasound, patient monitoring equipment, and CT scanning devices.
- *Reluctance to Procure Mixed Systems.*— Although there is apparently no formal requirement to this effect, VAMKC personnel are reluctant in practice to purchase mixed medical equipment systems, those in which items of different companies are interconnected. The most important reason for this is the difficulty of assigning financial responsibility for repairs under warranty, in addition to that of determining responsibility for actually making the interconnection. Unfortunately, this VA policy may practically eliminate many smaller companies from the procurement process, causing higher initial procurement costs.

Perhaps the greatest effects on VA product costs are the result of its generally decentralized procurement. Many purchasing decisions are made by individual VA facilities, not by the VAMKC.

Two decades ago, VA medical centers needed to make few purchases on the open market, only 10 percent of their supplies. When the military draft ended, it was hard to keep physicians in the Armed Forces, partly because they could not obtain the medical instruments and supplies that they preferred. For this reason, VA and DOD hospital physicians were allowed to purchase more items through the open market (34), the purchasing arrangement that now accounts for $498 million, or 38 percent, of VA medical center supplies and equipment (table 5).

A 1980 GAO report on VA medical center purchasing analyzed the large proportion of open market purchases (100). GAO concluded that the VA was paying too much as a result of the following:

- The VA had not standardized many common items. Medical centers were therefore independently purchasing many different products for basic needs, which increased purchasing costs.
- The VA lacked sufficient visibility over medical center purchases to address central procurement issues effectively, and needed an improved information system.
- Medical centers failed to use the VA's "mandatory" supply sources, even though common items were available at lower cost from these sources.
- Competitive bids, although required by Federal procurement regulations for purchases above $500, were not often obtained, providing little assurance that reasonable prices were paid.
- Neighboring VA medical centers independently obtained common supplies, failing to share product and vendor information and purchasing and contracting experience.

The VA generally agreed with GAO's conclusions, and the Central Office tightened control over some aspects of local purchasing by instituting quarterly reports on medical centers' purchases from other than mandatory sources. Medical centers have complained, however, that their purchasing patterns have often stemmed from problems with the VAMKC, for example, the problems of product quality discussed earlier in this chapter. The VAMKC also delayed from 3 to 6 months in sending mandatory source listings to the medical centers, though apparently at least in part because of the change to a newly integrated system of Federal stock numbers .11 Because of such delays, items may be centrally managed, but medical centers are unaware of it when ordering supplies and equipment. These delays also weakened the control sought by the Central Office in initiating quarterly reports (43,51).

In other areas, there has been little or no response to the 1980 GAO report. Neither the Central Office nor neighboring VA medical centers have further consolidated purchases or shared product or vendor information. Such coordination has been achieved by VA medical centers on occasion, but only rarely and by coincidence; for example, buyers from VA medical centers in Washington, DC, Baltimore, Maryland, Martinsburg, West Virginia, and Perry Point, Maryland, came together for a few years to buy plated media for clinical laboratories. One factor inhibiting consolidated buying is the relative lack of automated data management systems for supply officers at local medical centers, providing little opportunity to share contract and purchase experience (18,43,51).

More recently, the President's Private Sector Survey on Cost Control criticized the open market purchasing by VA medical centers, and called for more central purchasing to achieve the price advantages of buying standard items in quantity. The report commends the recent VA-DOD shared procurement efforts, but suggests that VA (and DOD) management provide more routine, detailed reports highlighting the number or value of items purchased on the open market locally that might be more economically purchased under nationally negotiated contracts. With better developed information systems for supply management and by "aggressively seeking out commonly purchased items to be included in contract negotiations, " VA hospitals could expect to attain the following (34):

> . . . a level of local purchases that approximates the 15 to 25 percent rate experienced by private sector hospital management firms. This level should be given to local hospital personnel as a management objective. These personnel have performed well toward other goals and it is reasonable to believe that they can also achieve these goals. This method has worked well in the private sector hospital chains.

[11] The VA Cataloging operations are centralized at the VA supply depot in Hines, Illinois. Data on items entering the supply system and on changes in existing items are submitted by medical centers and central procurement programs to the Cataloging Division to be cataloged in the Federal Catalog System. Cataloged data are then submitted to the Defense Logistics Services Center in Battle Creek, Michigan, for national stock number assignment. The national stock number identifies an item through all phases of logistics by all Federal agencies. A VA master computer file of all repetitively procured items contains the national stock numbers and relevant descriptive and management data for all supply transactions involving these items. User catalogs are produced and regularly updated for centrally and noncentrally managed items. Additionally, nonexpendable items are cataloged for property accountability. The major problem in cataloging is eliminating duplicate stock numbers for identical items. The VA-DOD Shared Procurement Program is coordinating the cataloging of all new medical items and reviewing those already cataloged to eliminate duplication. The VA also participates in the Federal Supply Management Council Working Group for Cataloging Systems in developing Government-wide cataloging policies and practices for improved supply management. On Nov. 1, 1982, the VA became the cataloging agent and manager for civil agencies of Federal Supply Group 65, Medical, Dental, and Veterinary Equipment and Supplies (121).

DISCUSSION

With regard to marketing, purchasing, and supplying medical products, the VA has three general goals: product innovation, product quality, and low product cost. Individually, these goals have been accomplished in various ways. Ideally, they should also be attained together. At least with respect to commercially available devices, however, the VA's organization and decisionmak-

ing have at times exacerbated the inherent tension among these goals.

Available evidence indicates that the VA's centralized procurement programs, through various contract and distribution mechanisms, have often ensured low prices for their medical centers' equipment and supplies. Manufacturers also generally express a positive view toward the VAMKC process. The VA is perceived as "progressive" in its purchasing, and VA central procurement staff are generally viewed by device manufacturers as knowledgeable and fair (see app. C).

Nevertheless, the VA's procurement of medical equipment can be improved. For example, the VAMKC could consider making contractual volume commitments, in particular, for patient monitoring, EEG, ECG, hemodialysis, and ultrasound equipment. Even if the VA practice of decentralized purchasing continues for these types of equipment, enough VA hospitals may want a given supplier's product to warrant a volume commitment that would ensure a greater discount.

The VAMKC might also alter contract disclosure requirements so that contract price information is not accessible until 6 months after the beginning of a contract year. This policy would provide virtually all the protection of public disclosure requirements but could increase the willingness of manufacturers to discount their products.

Last, the VAMKC should explicitly recognize that the purchase price of major medical equipment often amounts to a small fraction of annual operating costs. Perhaps the major complaint of device manufacturers is that the VA considers purchase price only—not total operating costs—in determining its suppliers (see app. C for analysis).

Lower equipment and supply costs of course, must not be obtained by sacrificing product quality. The VA has implemented new quality assurance policies over the last few years, attempted to improve the objectivity and responsiveness of its quality complaint system, and established a special agreement with the FDA to obtain its expertise in quality assurance. Even so, there must be closer monitoring of the VA's use of specifications, purchase descriptions, and CIDS to ensure quality control.

The VA has adopted over 60 CIDS for medical supplies and expendable alone, and is in the process of adopting some 90 more (12). These documents have influenced the purchase of medical devices and will continue to.

Given its use of purchase descriptions and CIDS, the VA should consider the merits of comparative evaluations. These would more explicitly identify device alternatives for VA customers. Comparative evaluations could also identify, and perhaps evaluate, positive and negative features of the different devices. Product quality features (e.g., safety, durability, and performance) could then be considered along with cost in making choices about devices.

The potentially most useful comparative method now is cost-effectiveness analysis. In considering both economic and clinical information, this method integrates concerns about costs with those about quality. In a cost-effectiveness analysis, an outcome is specified (e. g., a patient's functional status) and the costs of alternative means to achieve it (e.g., using devices) are compared .12

Although cost-effectiveness analyses and similar analytic techniques have certain methodological weaknesses, they can still illuminate issues and synthesize relevant data. Comparative analyses are neither simple nor necessary for every type of device. Yet they can improve decisions and purchasing contracts, depending on the VA's use of them. More generally, integrating all the VA's information in purchasing seems as promising as it does challenging.

[12]For more discussion on cost-effectiveness analysis, see U.S. Congress, Office of Technology Assessment, The ***Implications of Cost-Effectiveness AnaJysis of Medical Technology,*** GPO stock No. 052-003-0076 (Washington, DC: U.S. Government Printing Office, 1980) (107),

Increased procurement through centralized contracts would promote the VA's leverage in the market because the size of its market would grow. The large number of medical centers' open market purchases now reduces the VA's advantages as a large buyer. Among the possible benefits of the VA's being a larger buyer of medical supplies ~ are at least two important ones: 1) greater price discounts, and 2) the encouragement of device innovation by providing a larger early market for new products (52,128).