

**STRATEGY
RESEARCH
PROJECT**

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**MEDICAL SUPPLY READINESS:
MAXIMIZING AND GLOBALIZING THE
DOD PARTNERSHIP WITH INDUSTRY**

BY

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ABSTRACT

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Over the past several years, the U.S. Government has sought to streamline and reengineer its operations. Currently, the DOD is taking a similar approach to develop initiatives that increase efficiencies, particularly in the area of logistics functions. DOD is adopting commercial business practices designed to modernize operations and dramatically reduce costs while maintaining essential combat capability. This study highlights new acquisition practices developed with industry through outsourcing and partnering relationships that focus on increasing efficiencies and lowering costs, while leveraging with the commercial industrial base to maintain readiness. This initiative represents a significant shift in logistics support from "just in case" stockpiling of materiel to "just enough" procurement. This study concludes that a virtually untapped overseas market offers DOD acquisition opportunities to better support wartime and contingency operations. These opportunities maximize supply and distribution processes from the vendor to foxhole and ease transportation requirements on an already overburdened strategic airlift system.

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INTRODUCTION

U.S. forces face profound changes and challenges in preparing to enter the 21st century. Unlike in the past, the U.S. national security focus is no longer on a conflict with a rival superpower. Instead, today's forces must respond "to crises across the full range of military operations, from humanitarian assistance to fighting and winning two nearly simultaneous major theater wars (MTW), and conducting concurrent smaller scale contingency (SSC) operations."¹ This change in national security strategy directly impacts upon the current DOD force structure and defense budget. For example, DOD's force structure is roughly 30 percent smaller than it was in the 1980's.² The defense budget has declined to about 60 percent of its peak in 1985.³ Adding to the decline in defense spending, the U.S. government recently made a firm commitment "to reduce the federal budget deficit to zero by the year 2002."⁴ This commitment will likely mean a continued flat line or possibly a reduction in DOD future budgets.

This anticipated imperative for the U.S. military to do more with fewer resources, poses significant challenges to DOD. How can DOD modernize operations and generate cost savings while maintaining an essential combat-ready capability? Over the past several years, the U.S. government has sought to streamline and reengineer its operations, most notably through Vice President

Gore's National Performance Review. In line with these sweeping reforms, the DOD, under the leadership of Secretary of Defense William S. Cohen, is taking a hard look at developing similar initiatives which increase efficiency. Only recently, Secretary of Defense Cohen announced a program to reform the business operations of DOD. Championed by Cohen, this Defense Reform Initiative (DRI) requires DOD to incorporate successful business practices that American industry is using to eliminate waste, improve operations, and increase efficiencies.⁵ Still another DOD approach focuses on increasing efficiencies, particularly in the area of logistics functions.⁶

To keep in step with these changes and reform initiatives, a revolution in military logistics (RML) is underway. This revolution will streamline inventories and increase efficiencies by adapting industry business practices to support the soldier with the right materiel at the right place at the right time.⁷ Future logistics support to the warfighter will likely depend upon the ability of industry to satisfy DOD requirements through outsourcing and partnering relationships.⁸

This study highlights current DOD medical logistics acquisition strategies that focus on improving performance, increasing efficiencies and lowering costs, while leveraging with industry to maintain readiness. These strategies include acquisition surge contracts and Vendor Managed Inventory (VMI).

The study concludes with a recommendation for an acquisition strategy to access the global healthcare industry marketplace.

The medical logistics community is fully on board this fast-moving RML train. The community is shifting from logistics support concepts rooted in the past, transitioning to industry business practices to include outsourcing and partnerships with commercial manufacturers and distributors. This is truly a sweeping change in logistics support from "just in case" stockpiling of materiel to "just enough" procurement.

MEDICAL SUPPLY READINESS -- A SHIFTING PARADIGM

The overarching military medical mission is "to provide and maintain readiness to provide medical services and support to the armed forces during military operations."⁹ The medical battlefield rules of **be there, save lives, and maintain a healthy command** provide a strategic focus on the importance of the military medical mission.¹⁰ However, for this mission to be successful, appropriate medical supplies must be available to health care providers. When the health care provider asks for a drug or instrument to render necessary medical treatment, the supplies must be there. Unfilled medical supply demands put the military's most precious commodity -- its soldiers, sailors, airmen, and marines -- at risk for unnecessary suffering and possibly death. In essence, a critical core function of the medical supply system is to provide the required Class VIII

materiel in the right quantity, at the right time, and to the right place on the battlefield.

Traditionally, large inventories of materiel at the wholesale level measured medical supply readiness; however, that paradigm is shifting. For example, the Medical Program Guidance, FY 1998-2003 (14 February 1996), identifies core areas that focus on taking the health care mission through the next five years. The Medical Program Guidance readiness core clearly states its goal: "establish and maintain initial operating materiel stocks including potency and dated (P&D) items to support the dual MTW scenarios."¹¹ The guidance further identifies the need to "implement modern business practice improvement initiatives to maximize availability of war reserve materiel from the commercial and industrial base to sustain the rapid deployment of medical forces."¹² This paradigm shift is facilitated by the development of creative acquisition strategies that focus on improving support through efficiencies aimed at gaining rapid access to inventory in the commercial healthcare industry sector. The tenets of future logistics practices are prompting creative strategies in acquisition. These strategies will enable medical logisticians to provide effective medical materiel support.

INDUSTRIAL PREPAREDNESS PLANNING (IPP)

Medical readiness planning at the wholesale level begins with Industrial Preparedness Planning (IPP). Simply stated, the IPP

process helps to identify the military services' materiel shortfalls and measures these shortfalls against the healthcare industry's production capability.¹³ The Defense Supply Center Philadelphia (DSCP), formerly known as the Defense Personnel Support Center, facilitates this entire process through close coordination with commercial manufacturers and distributors.

The IPP process identifies items whose production involve a long lead time and those items that may remain in short supply throughout a particular contingency operation. The Integrated Process Team for Industrial Preparedness Planning (IPT-IPP) reviews and recommends alternate solutions to offset anticipated shortfalls.¹⁴ To a large degree, the IPP process enables DSCP, the medical materiel manager at the wholesale level, to select the most effective acquisition strategy for satisfying the military services' shortfalls. Prime Vendor surge contracts, Vendor Managed Inventory (VMI) contracts, and stock rotation contracts are just a few of these strategies. This study will focus on medical PV surge contracts and VMI contracts.

MEDICAL PRIME VENDOR -- OUTSOURCING WITH INDUSTRY

Beginning in the early 1990's, regulatory changes, primarily brought about by the Veterans Health Care Reform Act, prompted the Defense Logistics Agency (DLA), Defense Supply Center Philadelphia (DSCP), to begin shifting toward a medical Prime Vendor (PV) program. The PV program contracts private firms to

supply a wide range of pharmaceuticals and medical/surgical items directly to a geographic region. Currently, DSCP issues and administers the contracts for 21 pharmaceutical regions and 22 medical/surgical regions, which includes coverage to Europe and the Pacific Rim.¹⁵

The PV process takes full advantage of private sector distribution capabilities and electronic data processing. Following the pattern developed by industry, a prime vendor or distributor buys inventory from a variety of medical manufacturers and stores the inventory in commercial warehouses. In the case of DOD, military health care facilities and field medical logistics units electronically order supplies from the PV, confirm order status electronically, and receive the requested materiel within 24 hours. The PV receives payment for his services electronically. The PV process reduces delivery time from about one month to one day. Further, by using private sector storage and distribution systems, the process reduces DOD wholesale and retail level inventories and associated warehouse and redistribution costs.¹⁶ Implementation of PV has significantly reduced the wholesale medical depot inventory levels, generating substantial cost savings in investment resources. DOD investment in medical supply inventories at military depots has dropped from \$629 million to less than \$200 million -- a cost reduction of over \$400 million.¹⁷ The number of medical supply lines stocked at the depot level has also

decreased. Today, there are less than 100 pharmaceutical line items in the depot system.¹⁸ The PV program has certainly reached its objective to reduce costs and increase efficiencies. However, the PV program, a peacetime acquisition strategy, lacks flexibility to support multiple early deploying field units with their surge requirements.¹⁹ Consequently, in addition to PV, DOD uses complementary creative acquisition strategies to reduce the potential risk to medical supply readiness.

In response to this potential risk to readiness, DSCP has drawn up strategic plans to incorporate surge options into peacetime PV contracts. Today, PV contracts "in Europe and the Pacific provide specific tailored surge options for both pharmaceutical and medical/surgical items."²⁰ As just one example, the terms and conditions of the PV pharmaceutical contract for the National Capital Region require the vendor to provide specific tailored medical supply packages to support Army requirements worldwide.²¹ This approach is similar to the swing stock concept used throughout the U.S. Army logistics community. The terms of the contract are very specific and rely heavily on the capabilities of the PV to meet initial surge requirements. The PV must have the capability to provide, at least 95 percent of all DOD requests within 72 hours. If required, the PV must satisfy subsequent requests for up to a 30 day period.²² This particular acquisition strategy focuses on those critical first

few days and weeks in a deployment when units are quickly trying to fill supply sets to 100 percent strength.

PRIME VENDOR READINESS TEST EFFORTS

How effective is the PV surge capability at satisfying readiness requirements? Over the past three years, PV readiness tests have achieved positive results. The first PV readiness test took place at Fort Lewis, Washington, in August 1995. This test demonstrated McKesson Wholesale Drug Company's (MWDC) capability to support PV surge requirements. The PV effectively supplied a mobile army surgical hospital (MASH) with 98 percent of its pharmaceutical needs within contract time frames.²³

In November 1995, a second PV readiness test occurred as U.S. forces deployed from Germany into Bosnia. This particular deployment exercised the surge clause with the PV for Europe, the Kendall Division of Bindley Western Drug Company. This test was the first to substantiate a regional PV's capability to provide an overseas theater with all pharmaceutical requirements. The PV supplied 100 percent of items for 30 sick call and 20 trauma treatment sets; additionally it achieved a 98 percent fill rate for two large Army field hospital resupply sets.²⁴

The most recent PV surge test evaluated the readiness capabilities of the Pacific region PVs, Bergen Brunswick Medical Corporation (BBMC) and McKesson Healthcare Corporation. The test also evaluated the distribution network capabilities of express

carriers Emery Worldwide and Federal Express. The evaluation required BBMC and McKesson to process requisitions, assemble stock from inventory, and coordinate for shipment. Emery Worldwide and Federal Express, the distribution carriers, were responsible for shipping the materiel to the 16th Medical Logistics Battalion in the Republic of Korea.²⁵

Overall, the test successfully demonstrated McKesson and BBMC's ability as regional PVs to quickly provide shipments of medical supplies to the Pacific area. McKesson provided 50 sick call and 50 trauma treatment sets within the time limitations set forth in the contract. "Federal Express, utilizing Raymond Express, Inc. as their ground distribution agent both in San Francisco and Korea," delivered the shipments to the 16th Medical Logistics Battalion within three days of receipt.²⁶ Although these are encouraging results, this test did not fully demonstrate the PVs ability to satisfy surge requirements for multiple early deploying units, as would be required in a MTW scenario.

VENDOR MANAGED INVENTORY (VMI) -- PARTNERING WITH INDUSTRY

A significant piece of DSCP's readiness strategy depends on materiel acquisition via Vendor Managed Inventory (VMI). The VMI strategy develops a partnership between DOD and industry to

perform two functions. First, VMI guarantees quick access to inventory needed to support the military services immediate readiness requirements; second, this program provides essential sustainment materiel until the industrial base mobilizes.²⁷ VMI and PV surge contracting, used in tandem, provide a powerful dual approach strategy to satisfy early deploying units with pharmaceuticals, particularly potency and dated (P&Ds) materiel.

Two years ago, DSCP awarded a 10-year VMI contract to the Tennessee Wholesale Drug Company (TWDC). This contract, written with "1 base year and 9 option years," requires the vendor, TWDC, to maintain and rotate medical inventory stock levels for DOD.²⁸ This service includes all the logistics functions that DOD normally accomplishes, such as quality control measures to include disposal of unserviceable materiel and replenishment of expired stocks. For its services, the vendor receives an annual management fee. Although the VMI contract is in its early stages, the program covers over 450 pharmaceutical items, with an additional 800 potential lines under review.²⁹

Partnering with industry minimizes the up-front investment costs in stock. The VMI program provides access to \$7.54 of vendor managed stock for every DOD dollar invested. This strategy insures that the military services funds remain available until the actual purchase and management of materiel occur. The terms of the contract allow DOD the flexibility to add and delete line items and adjust stockage levels at any time.³⁰

VMI READINESS TEST EFFORTS

Given the increased role of VMI in readiness support, both DSCP and the United States Army Medical Materiel Agency (USAMMA) are working diligently to lay the necessary groundwork to support Army field units via VMI. In a critical first step, USAMMA, the U.S. Army Surgeon General's focal point for strategic medical logistics actions and issues, sponsored a VMI test in April 1997. The test evaluated the readiness capabilities of the VMI contractor, Tennessee Wholesale Drug Company (TWDC), to receive and process requests for medical supplies held at their facility in Nashville, Tennessee. Federal Express, the distribution carrier, was responsible for picking up the shipment and delivering it to the 424th Medical Logistics Battalion, a reserve unit participating in the Roving Sands Exercise at Fort Bliss, Texas.³¹

Overall, the VMI test was a success. TWDC promptly processed, pulled, and released the shipment to the distribution carrier within 24 hours. Federal Express, in turn, delivered the materiel to the customer at Fort Bliss, Texas, within the specified time frame. The test demonstrated TWDC and Federal Express' capability to effectively support the VMI program from a "processing and shipping" standpoint.³² This particular evaluation focused on supporting multiple orders from one unit. USAMMA and DSCP should consider expanding the evaluation of TWDC

and Federal Express' capability to support supply requests from multiple units as future training opportunities develop.

LEVERAGING WITH INDUSTRY FOR READINESS

The Army Medical Department (AMEDD) is currently wrestling with ways to fix the systemic problem regarding the availability of potency and dated (P&D) medical materiel. P&Ds are Class VIII consumables with a shelf life equal to or less than 60 months. The most common types of P&D's are pharmaceuticals. However, laboratory reagents, x-ray supplies, and some medical/surgical consumables have a shelf life and require special inventory management. P&Ds normally require climate-controlled storage and, in some cases, special handling due to the environmental hazards and strict control measures. Reduction in defense dollars and associated constrained unit operating budgets have made it almost impossible for deployable field medical units to adequately maintain, properly store, and effectively rotate P&Ds in their unit basic loads. For example, the P&Ds to outfit one U.S. Army combat support hospital's unit basic load costs over \$435,000 dollars; the estimated annual cost to replace expired materiel in that one hospital is \$100,000. In most cases, field medical units lack the climate-controlled warehouses and facilities needed to meet the special handling and storage requirements for P&D's.³³

Due to the cost of managing and replacing P&Ds in field medical units, the U.S. Army Forces Command (USAFORSCOM) altered its policy for medical readiness reporting. The USAFORSCOM policy relieved medical field commanders of the responsibility for reporting P&Ds on their unit status report (USR). However, the policy still required commanders to take appropriate action to maintain mission readiness and deployment posture through quick access to these supplies.³⁴ As DOD and, to some extent, the commercial sector inventory structure continued to shrink, skepticism existed within the military that inventory stocks were not robust enough to meet P&D surge needs of early deploying medical units.

In 1996, the Army Medical Department (AMEDD) leadership addressed this issue in the Department of the Army (HQDA) Functional Area Analysis (FAA) and December 1996 Monthly Readiness Review (MRR). As a result of these two forums, the Chief of Staff of the Army approved the central management of P&D materiel for Force Package (FP) one and two field medical units. The Army Surgeon General, in turn, assigned USAMMA the mission to centrally procure and gain access to P&D materiel required to support FP one and two field medical units through day 31 of a contingency mission.³⁵

To accomplish this central management of P&D materiel mission, USAMMA is using a combination of strategies to gain access to industry stocks or to purchase P&D materiel outright.

Two of the strategies highlight the use of Prime Vendor surge contracts and Vendor Managed Inventory contracts. The third strategy involves building and storing pre-configured sets.

Although its goal is to buy access rather than build inventory, USAMMA is currently in the process of purchasing quantities of P&D materiel outright to store in pre-configured sets at various locations worldwide. Once completed, this strategy will quickly outfit ten early-deploying army hospitals with necessary P&Ds. These ten sets will remain unflagged and will function as swing stocks.³⁶

An additional eight P&D basic load sets and up to 30 P&D resupply packages will be vendor-managed under this new central management concept. These eight P&D basic load sets will fill out remaining FP one and two unit surge requirements beginning day one through day ten. The resupply packages will cover anticipated unit requirements beginning day 11 through day 31. Medical planners anticipate the P&D basic load and resupply sets will satisfy the majority of surge requirements until the medical logistics sustainment pipeline gears up around day 31.³⁷

The program seeks to fix the early deployers' P&D problem. DOD plans to use a combination of contracting tools such as PV surge, VMI, and the use of pre-configured swing stocks to maintain medical supply readiness. The U.S. Army is making substantial progress with this focused approach designed to help

reduce the cost associated with readiness and, at the same time, to minimize risk.

OVERSEAS ACQUISITION -- TARGETS OF OPPORTUNITY

As we have discussed, the Defense medical logistics community has made a major effort to partner with U.S. domestic healthcare industry manufacturers and distributors. This partnering process promotes efficiencies in inventory management and guarantees access to pharmaceutical readiness items for early deployers and for sustainment materiel until the industrial base mobilizes. Given these domestic initiatives, is DOD now ready for an overseas contracting arrangement? Precisely this issue is addressed in the Joint Medical Logistics 2010 (JML 2010) Basic Concepts for Future Doctrine, Joint Theater Support draft (JML 2010):

.... the ability to procure significant amounts of the medical materiel directly from local or regional third party national suppliers is expected. This both shortens the lead time needed to obtain materiel and reduces the strategic and operational transportation requirements to support the theater. On the other hand, it requires the development of new contracts and procurement vehicles which are as of now completely unavailable to deployed U.S. forces.³⁸

There is a tremendous untapped world market of pharmaceutical manufacturers and distributors. Preliminary estimates indicate that the U.S. accounts for only 30 percent of the world's pharmaceutical market. Seventy percent of the international pharmaceutical market lies with overseas

manufacturers and firms.³⁹ In Japan alone, the "American Chamber of Commerce Membership Directory" mentions many of the major medical companies to include "Johnson & Johnson, Dupont, Baxter, Beckman, Cybex, and Bristol-Myers."⁴⁰

But how does DOD target these overseas markets? The Logistics Management Institute (LMI), a federally funded think tank that primarily supports DOD, is already working to answer this question. LMI recently obtained access "to international industry directories for Europe and the Pacific Rim area as well as information on global and regional clearing houses/trade associations for multinational pharmaceutical firms."⁴¹ LMI has also obtained "multi-volumes of detailed analysis on overseas manufacturing industry profiles." The analysis includes "product specific information on sales, distribution, research and development, and business partnerships for major international firms located in Germany, Switzerland, Britain, Japan, and France."⁴²

In their preliminary review, LMI divided the pharmaceutical world market place into general segments. LMI determines these segments by point of production or manufacturing origin and the intended sales market. For instance, one segment of healthcare companies manufactures products in the U.S. for distribution overseas. Another segment of U.S. and foreign firms manufactures products overseas for ultimate sale in the U.S. The last segment

includes products manufactured by foreign firms for sale exclusively outside the U.S.⁴³

Many of the products in these segments are fully useable by U.S. forces assuming they meet quality assurance standards set by the Food and Drug Administration (FDA). Products manufactured outside the U.S. offer the advantage of procurement at or near the point of overseas origin, thereby shortening the supply pipeline and distribution networks from vendor to the foxhole.⁴⁴

ADVANTAGES OF OVERSEAS ACQUISITION

What advantages can DOD gain by procuring approved healthcare products, particularly pharmaceuticals, overseas? The advantages that come to mind immediately are a shortened supply pipeline, to include distribution and transportation networks, and a smaller logistics infrastructure. Overseas contracting offers two overriding strategic advantages:

Shorter supply pipeline and distribution network. The second and third order effects ease the strategic airlift burden for bulky, high demand medical items such as intravenous (IV) fluids and medical gas cylinders.

Reduced infrastructure and materiel cost of prepositioned medical materiel primarily in the area of Army War Reserve - Sustainment.

Strategic mobility is key to getting rapidly deploying U.S. military power to the fight to win wars and favorably resolve conflicts. In order to prevail in two MTWs as required by the current National Military Strategy (NMS), strategic airlift is an essential component. In 1995, the Mobility Requirements Study Bottom-Up Review (MRS BURU) identified shortfalls in strategic airlift capability to execute two nearly simultaneous MTWs.⁴⁵ Although improvements in airlift capability have occurred since 1995, the U.S. Air Force will not reach its cargo airlift requirement of 49.7 million ton miles per day (MTM/D) until the year 2004.⁴⁶ Even then, the U.S. Air Force will reach the requirement only after full Air Reserve Component (ARC) mobilization and Civil Reserve Air Fleet (CRAF) Stage III activation, which DOD has yet to test.⁴⁷ The 1997 Air Mobility Master Plan (AMMP) Commander's Assessment identifies cargo airlift as partially capable to meet the requirement through the year 2003.⁴⁸ The challenges facing the strategic airlift system are overwhelming. Whether strategic airlift can support the NMS dual MTW scenario through the next four to six years is questionable.

Using the Army War Reserve Automated Process (AWRAP), Table 1 shows the time phased IV fluid requirements to support a dual MTW scenario.⁴⁹ IV fluid resuscitation is absolutely the cornerstone to casualty care management in any contingency operation. It is essential that IV fluids are immediately available on the

battlefield in the proper quantities at the right place, and right time. In this particular example, IV fluid requirements peak during the third and fourth months of engagement. In month four alone, either 51 C-141 aircraft, 21 C-17 aircraft, or 18 C-5A aircraft are needed to transport IV fluids to sustain dual MTWs. As Table 1 depicts, airlift requirements peak before the first MTW ends.

	M-1	M-2	M-3	M-4	M-5	M-6	Total
Weight (lbs) MTW-1	201,700	2,191,358	3,093,978	3,151,192			
Weight (lbs) MTW-2		14,568	124,113	392,304	578,024	371,203	
Total (lbs)	201,700	2,205,926	3,218,091	3,543,496	578,024	371,203	10,118,440
Total Tons	100	1102	1609	1771	289	185	5059
Cube MTW-1	1,407	6,918	10,743	10,951			
Cube MTW-2		74	3,275	6,294	8,282	4,421	
Total Cubic Feet	1,407	6,992	14,018	17,245	8,282	4,421	52,365
AIRCRAFT MAX CAP							
C130-46,900	4.30	47.03	68.62	75.55	12.32	7.91	215.74
C141-69,925	2.88	31.55	46.02	50.68	8.27	5.31	144.70
C5A-197,500	1.02	11.17	16.29	17.94	2.93	1.88	51.23
C17-172,200	1.17	12.81	18.69	20.58	3.36	2.16	58.76

Table 1. IV Fluids, Strategic Airlift Requirements (MTWs)

Although this example focuses on IV fluids only, the number of aircraft needed to lift this materiel from the Continental United States (CONUS) to an overseas theater of operations is significant. It potentially influences the time phase movement of other critical supplies and equipment competing for the same airframes. An overseas acquisition strategy enables contracting for high demand items such as IV fluids from a manufacturer at or near the point of production. This reduces the strategic airlift requirements from the CONUS base to overseas theaters of operation.

Implementation of an overseas acquisition strategy similar to the VMI-type arrangement can reduce pharmaceutical requirements in the Army War Reserve - Sustainment (AWR-S) program. Currently, the Class VIII AWR-S program asset requirements for fiscal year 1998 cost \$782 million.⁵⁰ Available on-hand assets equal \$99 million. The resulting shortfall is \$683 million.⁵¹ An aggressive overseas acquisition strategy will help to reduce this shortfall by driving down AWR-S infrastructure and materiel costs. For example, DOD is beginning to acknowledge that a VMI-type arrangement will generate resource savings most notably by reducing:

- Investment costs in purchasing inventory outright.

- Inventory infrastructure and facility upkeep cost.

- Care of Stocks in Storage (COSIS) associated costs.

Annual replacement costs for expired medical items.

Disposal costs for expired medical items.

HURDLES TO SUCCESS

By their very nature, medical products are manufactured, distributed, and stored under stringent controls to insure suitability and safety to the consumer. The federal government acknowledges that the medical commodity, drugs and pharmaceuticals in particular, requires strict control in production, distribution, and use. In light of these special requirements, the Food and Drug Administration (FDA), a Federal agency within the Public Health Service, provides the control necessary to insure suitable and effective medical products.⁵²

The FDA plays a key role in managing quality assurance aspects of medical materiel. This role dates back to 1974, when the FDA took the lead in the development of a government-wide quality assurance plan. The following year, the FDA and DOD entered into an agreement covering the military services' quality assurance requirements for centrally managed medical materiel contracting.⁵³

Today, a formalized memorandum of understanding (MOU) continues this DOD - FDA relationship.⁵⁴ Under this MOU, the "FDA provides the quality assurance support for DOD centrally managed contracts for drugs, biologicals, and medical products as defined by the Federal Food, Drug, and Cosmetics Act (FDC

Act).⁵⁵ DOD Directive 4140.26-M (May 1997), assigns and designates the Defense Supply Center Philadelphia (DSCP) as the integrated manager for medical products.⁵⁶ In accordance with this MOU, under normal conditions DSCP stipulates in all their centrally managed contracts that items supplied to U.S. forces must comply with all FDA regulatory requirements for drugs and medical devices.⁵⁷ In addition to compliance with the FDC Act, drug manufacturing facilities must comply with the current good manufacturing practice regulation (CGMP), 21 Code of Federal Register (CFR), parts 210 and 211.⁵⁸ The FDA uses the CGMP as the quality standard applied to "the healthcare industry for the manufacturing, processing, packaging, or holding of medical products acquired on government contract."⁵⁹

How would this regulatory arrangement apply to an overseas acquisition strategy possibly implemented through an overseas VMI arrangement? First, DOD must work very closely with the FDA concerning this issue. The FDA has the final word in determining whether quality standards are being met. Second, overseas manufacturers and distributors must answer key questions concerning product registration and production methods. These questions include:

Is the firm currently registered with the FDA?

Does the firm manufacture or hold medical products in accordance with CGMP standards?

Does the firm possess an FDA approved new drug application or abbreviated new drug application for each of its product lines?

It is critically important to get answers to these fundamental quality control questions. FDA CGMP inspections for healthcare industry manufacturing facilities are not product specific. Therefore, to be compliant with the FDA, the manufacturer must also have an approved drug application or abbreviated drug application for each particular product they will provide to DOD.⁶⁰ This also applies to overseas manufacturers and facilities with which DOD plans to develop a partnering relationship.⁶¹ The FDA screens copies of all DSCP pre-award contracts for manufacturer compliance before the contract is issued. For instance, if inspection data is already available for overseas manufacturing facilities, the FDA can respond quickly to DSCP pre-award contract requests.⁶² Additional time is necessary to validate overseas companies and product lines where no data is available. In this case, the FDA requires the manufacturer to comply with a CGMP inspection, an FDA registration, and an FDA approved drug application(s).⁶³

Although the FDA will perform the CGMP at no cost, the inspections will likely involve considerable lead time for the FDA to conduct them to respond to DSCP. Thus, gathering industry profiles and overseas manufacturing data become even more critical in determining FDA compliance and identifying potential sources of supply. DOD must take the lead now to lay the

preliminary groundwork necessary to identify overseas market targets of opportunity and still maintain compliance with FDA regulations.

DOD must wrestle with several other key questions before implementing an overseas acquisition strategy. And the answers may not be readily available. Although these questions are beyond the scope of this study, that does not negate their importance to DOD. They require careful consideration in the decision process. These questions are:

To what degree can DOD rely upon overseas manufacturing and distribution networks for them to remain a viable option during other-than-peacetime conditions?

Can DOD expect overseas commercial firms to fulfill contracting obligations in a combat environment?

Will trade or treaty restrictions and international business laws provide hurdles to the contracting process?

What will be the political and economic consequences of buying products overseas, rather than from domestic U.S. sources?

What is the military's back-up plan if the commercial sector distribution networks fail or are interdicted through asymmetric enemy threats?

The answers to these questions may in fact drive acquisition strategies to a particular world region, a particular overseas manufacturer, or to multiple regions and manufacturers. The selection of a particular DOD approach will likely take into

consideration many factors. These include ease of access to overseas inventory, ability to satisfy DOD requirements through an unrestricted procurement process, redundant and reliable worldwide transportation networks, and cost effective management efficiencies. DOD must focus on these concerns throughout the process of defining overseas market targets of opportunity.

RECOMMENDATIONS

First, DOD must continuously assess the commercial partnering relationships developed thus far and examine additional acquisition strategies to meet the demands of a full spectrum military force. Multiple acquisition strategies must be complementary and mutually supporting, as are PV and VMI. These strategies require frequent testing and validation of all compliance standards specified in the conditions and terms of the contract. In this regard, as DOD develops additional commercial partnering relations, it is critical that performance monitoring and metrics are used to evaluate and determine contractor strengths and weaknesses. The bottom line: DOD must hold commercial partners accountable in all formal contracting relationships.

Second, the Defense Medical Standardization Board (DMSB), in conjunction with DSCP, must engage the FDA to resolve issues concerning overseas contracting initiatives. The DMSB performs an important role with regard to all clinical and technical

matters pertaining to medical materiel. Because of this relationship, the DMSB can make a significant impact in streamlining acquisition strategies with the FDA that satisfy both medical quality assurance concerns and medical readiness objectives. DOD Instruction 6430.2 (17 March 1997) further stipulated the DMSB staff shall "provide clinical and technical expertise in support of the procurement process by recommending strategies and services best able to satisfy Military Department requirements."⁶⁴ The DMSB has conducted an initial meeting with the FDA; however, much more work remains before DOD opens the door to overseas contracting.

Lastly, DLA, through the Directorate of Medical Materiel, DSCP, must continue the lead in developing an overarching acquisition strategy that can best support the warfighting CINCs' medical supply requirements. The DOD medical logistics system must prepare to obtain medical items available in the world market to support our healthcare providers. To develop this flexible strategy, DOD must:

- Research industry profiles and identify world market targets of opportunity.

- Assess manufacturer and distributor capabilities through IPP and other evaluation mechanisms.

- Adjust business decisions based on market experience and continuously conduct risk assessment and analysis.

Be prepared to access multiple manufacturers and distributors in the international healthcare industry.

Be ready to implement contingency plans if overseas manufacturing and distribution partnerships fail.

CONCLUSION

The DOD is transitioning to a new paradigm that shifts the logistics inventory process from traditional "just in case" stockpiling to "just enough" procurement. Application of best business practices that American industry has successfully used to become leaner and more efficient is shaping the strategic frame of reference for future DOD logistics goals and objectives. As stated in Joint Vision 2010, to prepare for the future DOD and the services should "integrate with the civilian sector where required, to take advantage of advanced business practices, commercial economies, and global networks."⁶⁵

This study has reviewed advanced business practices involving increased reliance on civilian manufacturers and distributors to provide medical supply support. This study also examined an acquisition strategy designed to tap the international healthcare market to gain overseas access to the global commercial medical supply base.

Preliminary analysis suggests that PV surge and VMI contracts, as complementary acquisition strategies, can satisfy a significant portion of the initial medical supply requirement for

early deploying field medical units. However, it is more difficult to fully determine just how well PV and VMI will support the National Military Strategy and ultimately the warfighters' medical logistics readiness requirements. One thing is for sure: DOD cannot afford to keep logistics functions in-house as it has in the past. To this end, outsourcing and partnering with industry must become a success story for DOD, not only in peacetime, but in supporting the very challenging demands of a full spectrum force. We have no other recourse than to improve upon the accomplishments already achieved through outsourcing and partnering strategies of PV and VMI, and to examine additional strategies to include overseas contracting.

Clearly, there is a global commercial healthcare market place that currently remains untapped by the DOD medical logistics community. DOD, the military services, and industry must coordinate actions to determine the best strategies available to access this global market place. Certainly one option is to implement an overseas contracting arrangement similar to the VMI program currently in existence in the U.S. DSCP is already examining courses of action to establish an overseas IV fluid contract. DSCP is currently preparing to meet with representatives from the Army and healthcare industry (Baxter, McGaw, Abbott) to lay out the Army's overseas IV fluid requirements, related issues, and anticipated strategy.⁶⁶ The meeting will call for industry, as the expert, to either confirm

the Army's strategy as the best approach or provide the Army with a smarter alternate plan.⁶⁷ DSCP is taking a significant step forward to develop contracting strategies that jointly satisfy established standards of national healthcare and meet military medical logistics readiness objectives.

Implementation of advanced business practices is essential to achieving the DOD logistics mission "To provide responsive and cost-effective support to ensure readiness and sustainability for the total force in both peace and war."⁶⁸ Despite some concerns of over-reliance upon the private sector, DOD medical logisticians as a corporate body, must insure new logistics practices succeed -- without diminishing readiness. We owe it to all members of the Armed Forces who deserve nothing less than the world's best health services system throughout the full spectrum of military operations. Word Count is 5,875.

ENDNOTES

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