STREAMLINING THE MEDICAL MATERIEL ACQUISITION PROCESS: A PREFERENCE FOR NONDEVELOPMENTAL ITEMS

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PREFACE

This report is Volume 2 of a three-volume report on the medical acquisition process.

In Volume 1, we report the results of our analysis and recommendations on requirements identification methodologies and acquisition process management. Volume 3 addresses characteristics – *proven qualities* – and relationships – *roles and responsibilities* – that mark a successful acquisition management structure and recommends the organizational alignment that establishes the relationships necessary for streamlining actions. For a more thorough understanding of the medical materiel acquisition process and the changes needed to streamline it, we suggest reading Volumes 1 and 3 as well as this volume.

In this volume, we discuss and provide recommendations on life-cycle system activities leading to the critical acquisition strategy decision and present our recommendations on the issues affecting the decision to proceed to new development or to use an off-the-shelf or nondevelopmental item.

Executive Summary

STREAMLINING THE MEDICAL MATERIEL ACQUISITION PROCESS: A PREFERENCE FOR NONDEVELOPMENTAL ITEMS

The medical industry continuously produces new and improved materiel for the delivery of health care. It continually evaluates clinicians' needs and treatment trends and moves rapidly to meet the demand for new products. The industry uses all available means – basic research, updating old items, combining old and new products and procedures in creative ways to define new products, and developing products based on new technologies – to fill identified needs. Gaining a competitive advantage and the quest for profits drive a vigorous industry response.

The Army Medical Department's (AMEDD's) acquisition process is challenged to match the industry response to clinicians' needs and go even further. Materiel the AMEDD acquires must be affordable, reliable, transportable, maintainable, and credible over a range of environments. The medical acquisition process must meet this more robust challenge to be successful.

We believe it can meet the challenge and in an earlier study recommended two critical first steps for doing so: First, centralize the process under a Deputy Surgeon General for Acquisition, [DSG(A)]; and second, improve requirements through better coordination of existing methods for identifying requirements. But these steps alone are not enough. The AMEDD's acquisition process needs to capitalize on a preference for nondevelopmental items (NDIs), i.e., those medical industry products that meet both clinical and nonclinical requirements. The AMEDD also needs to integrate the technological expertise found in its research activities into the NDI acquisition process.

To fully capitalize on an NDI preference, we recommend that the DSG(A) take the following actions:

- Clearly reflect the preference for NDI solutions in all acquisition strategy selection guidance provided to members of the acquisition team (the combat developer, the researcher, the materiel developer, and the logistician).

- Approve the acquisition strategy on a go/no-go basis at life-cycle Milestone Zero on three bases: a well-defined and fully explored materiel requirement; clear evidence of continuous market surveillance and thorough market investigation; and completely documented test and evaluation against user-certified acceptance criteria.

- Publish and periodically update planning and modernization goals for equipping the peacetime and wartime health-care missions and provide the financial programming guidance to meet those goals.

Additionally, we feel the increased involvement of the AMEDD's research activities in the NDI strategy may require changing our initial recommendation on establishing a DSG(A). The position may be more appropriately established as a Deputy Surgeon General for Research and Acquisition (DSG[R&A]). We recommend this change be considered as part of further analysis of organizational responsibilities and relationships.

Upon implementing those recommendations and the others made previously, the AMEDD will find itself with a more streamlined acquisition process – a process that fosters well-defined, achievable requirements and tilts to NDIs for materiel acceptable to clinicians and with the qualities that mark successful acquisitions.

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CHAPTER 1

INTRODUCTION

BACKGROUND

In an earlier LMI report on medical acquisition, we recommended ways for the Army to improve its acquisition management and the identification of medical materiel requirements.[1] To improve its acquisition management, we recommended that the Army designate a Deputy Surgeon General for Acquisition, [DSG(A)] and that the DSG(A) exercise greater centralized control of the acquisition process; formulate overall acquisition strategies and guidelines; clarify operating goals, objectives, and procedures; and establish career paths and assignment policy to increase the experience and expertise of acquisition personnel. To improve the identification of medical materiel requirements, we recommended that the Army consolidate four loosely related procedures – the Concepts Based Requirements System (CBRS), technology push, consultant input, and user pull – and follow that consolidation with broad training in the new procedure. A familiarity with the fundings and conclusions leading to our recommendations in the earlier report will aid in understanding this one.

The medical acquisition process exists to provide the Army Medical Department (AMEDD) with the medical capabilities it requires to perform its mission. Medical materiel is an integral part of those capabilities, and its need is satisfied in one of two ways. Either it is purchased from sources outside of the AMEDD or, if no such source is available, it is developed by the AMEDD. Items not developed by AMEDD are called nondevelopmental items, (NDIs); those developed by the AMEDD in-house or under contract are called developmental items (DIs). NDIs, which are defined in Appendix A, are very often existing commercial products and may need little or no modification or further development to meet AMEDD needs.

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[1]Slyman, George L., and Gilbert L. Goldman, *Streamlining the Medical Materiel Acquisition Process: Central Direction, Better Requirements.* Volume 1, LMI AR806R1. August 1990.

PURPOSE

The discussion in this chapter is presented as an introduction. It sets the stage for our findings, conclusions, and recommendations on the role of NDIs in streamlining AMEDD acquisition presented in Chapter 2.

We have assessed the role of NDIs in filling the AMEDD's materiel requirements and how their use makes the medical acquisition process more efficient and effective – more streamlined. In the remainder of this chapter, we discuss how acquiring NDIs can streamline the acquisition process, the risks taken in doing so, and the effects of potential benefits and risks on the AMEDD decision to select an NDI acquisition strategy.

HOW NDIs STREAMLINE ACQUISITION

The hypothesis that NDIs can streamline the acquisition process flows from the theory that "working smarter" saves time and money. One way to work smarter is to conduct sufficient market analysis to recognize when developmental work is unnecessary. For example, since medical NDIs are in use and available, the R&D costs to ensure that item provides the needed medical capabilities has already been paid by the developers and producers, usually business organizations or academic institutions. During the design and engineering phase, they will have studied the environments in which the items are to be operated and applied the knowledge gained, developed and applied innovative technologies to achieve state-of-the-art performance and gain a marketing advantage, and tried to minimize manufacturing costs. Additionally, they will probably have tested the item and collected data on its operation and maintenance. They may also have priced and sold their product in a competitive marketplace and seen it used for the purpose for which they were designed. Users of the products may have even provided feedback or suggested product improvements. Most of those efforts are prerequisites for an NDI and all of them will have required the expenditure of resources in one form or another. As NDI policy states, the AMEDD has no reason to repeat those expenditures.

Another way to work smarter is to add to, or build on, work already completed and by so doing, adapt, modify, or integrate existing products to meet needs that the original products by themselves could not meet. In that way, at least part of the total developmental work effort is avoided. Duplication of any such work wastes time and creates unnecessary expense. By avoiding that unnecessary expense, we streamline

the acquisition process and make it more efficient. The ability to field a state-of-the-art capability earlier by taking advantage of work already completed further contributes to streamlining.

Acquisition of an NDI can streamline the acquisition process by avoiding duplication of all or part of research, design, engineering, marketing, and other product development efforts. Indeed, Congress, DoD, suppliers, and various industry associations all believe that the potential benefits of NDIs include reduced R&D and life-cycle costs, decreased procurement lead-time, and increased use of state-of-the-art technology available in the commercial marketplace. No one disagrees that such benefits are possible. That acclamation explains the DoD and Army preference for NDIs reflected in the policies presented in Appendix B.

A caution is needed: Just because an NDI can help avoid unnecessary expenses and permit earlier fielding of state-of-the-art equipment does not mean that such time and cost expenses are automatically saved. In many cases, the AMEDD faces the risk that in the rush to field products that are available and take advantage of easy cost-avoidance opportunities, it may sacrifice essential performance features and capabilities or fail to provide for adequate life-cycle logistical support. For those reasons, NDI policy provides that NDIs must "adequately serve the Government's requirement" (DoD) or "meet the user need with savings in acquisition time and development cost/risk with adequate supportability" (Army).

Determining whether particular NDIs meet these provisions is important. Those provisions, of course, determine whether an NDI strategy is likely to streamline the acquisition process and provide a satisfactory capability quickly or result in acquiring a product that will ultimately be judged unsatisfactory and "unstreamlined." Making this determination for NDI medical equipment involves making judgments about the risks associated with acquiring NDIs.

NDI STRATEGY RISKS

Medical NDIs are designed, for the most part, to meet the demands of the multibillion dollar health care market. They are not designed primarily to satisfy the needs of wartime field health care: the effects of nuclear, biological, and chemical (NBC) contamination and decontamination; extremes of temperature and humidity; rough handling during off-road relocations; variances in power supply; and reduced availability of maintenance support (parts and labor). Nor are such items designed to

fully withstand the effects of peacetime training: use by inexperienced operators, repeated unpacking and repacking, service as a training aid, and irregular preventive maintenance and operating checks. NDIs are usually designed for one environment and acquired by the AMEDD for use in another.

The wartime environment may, at times, be identical to that for which a product was designed or, at other times, it may be considerably different. If the equipment does not have to experience the extremes of wartime, its chances of successful performance are about the same as though it were used in the civilian, fixed-facility health-care environment for which it was designed. If, on the other hand, it must undergo wartime hardships for which it was not designed or from which it is not protected, its chances of poor performance or failure increase, perhaps dramatically. The level to which risk of failure must increase before an NDI strategy is felt to be unacceptable depends on the decision maker's willingness to accept that risk to gain the cost avoidance, state-of-the-art, and timely fielding benefits the NDI presents. Different risk tolerances can explain different opinions about the acquisition strategy that should be pursued given the facts in a case.

To decide whether to purchase NDIs or pursue development, the AMEDD must estimate the probability and consequences of poor performance or failure and weigh them against the benefits to be achieved. If the consequences of inadequate NDI performance or repeated item failure are not significant and the benefits of an NDI strategy are large, the risk associated with use of NDIs is small. Conversely, if failure would result in dire or catastrophic consequences for mission performance and the costs that can be avoided are relatively small, NDI risks are high and should not be taken. Instead, a DI strategy would be appropriate. Gauging the level of risk and thereby deciding whether or not an NDI will serve the Government's requirement and meet the user's need is tantamount to the selection of an acquisition strategy.

The wisdom of selecting an NDI strategy depends, then, on the probability of three events occurring together: the NDIs will experience hardships for which they were not designed; they will perform poorly or fail as a result of that experience; and the poor performance or failure will be significant enough to degrade mission performance (i.e., the provision of quality care). Should all of these events occur, the cost avoidance and timely fielding of state-of-the-art products that justified the NDI strategy will have been proven flawed. The estimated probability of the events

occurring represents the decision maker's tolerance for risk. If any one of the events fails to occur, the decision to acquire an NDI will have proven a good one.

ACQUISITION STRATEGY SELECTION

Adequate requirements identification and market analysis are essential if we are to compare the risk of NDI performance failure with the potential benefits of using NDIs. If a requirement is vague, we cannot know with certitude whether an NDI can meet it. If market analysis is incomplete, we have equal difficulty knowing whether the NDI satisfies the requirement or whether excessive risk is present. If comparisons of requirements with products available in the market analysis provide reliable estimates of potential benefit and risks, they will also provide valuable insights into the probable outcomes of DI or NDI acquisition strategy selection decisions. As the AMEDD understands the possible outcomes of an acquisition strategy better, it should have greater confidence in its decisions and should make better decisions. Such understanding and confidence, coupled with the experience of repeated acquisition successes – and even an occasional failure – increase the expertise of those involved in the decision and produce a more efficient, effective, and streamlined acquisition process.

The acquisition process must be designed and directed so that its requirements identification and approval procedures are amenable to reasonable comparisons of the potential benefits and risks for acquisition strategy selection. The following strategy selection guidelines can influence the collection and development of necessary comparison data and thus facilitate requirement approval and acquisition strategy selection:

- If a needed materiel capability is not available, the DSG(A) should pursue a DI strategy. As the decision maker, the DSG(A) should be certain that the capability, as defined in the draft requirement document, is needed and that it is worth the estimated life-cycle costs in the face of other approved and anticipated requirements. The DSG(A) should also ascertain that availability has not been too narrowly defined. Should the need not be supported or if costs are believed excessive or availability has been too narrowly determined, the DSG(A) should disapprove the requirement. Disapproved requirements should be reconsidered only after they are more effectively defined.

- The DSG(A) should pursue a DI strategy if the needed materiel capability is available but the item that provides that capability has not been designed for wartime use, cannot be modified for such use, and will probably be used

in wartime and fail, thus degrading mission capability unacceptably. Personnel who prepare the draft requirement must consider the item's affordability, its design and modification issues, and the probabilities and consequences of the item's failing. Those considerations should be rigorous insofar as cost-effectiveness, staff availability, and available analytic tools will permit. If these issues are not sufficiently considered, the draft requirement should be disapproved.

- The DSG(A) should pursue an NDI strategy for all other materiel requirements. Cost avoidance, increased readiness, and state-of-the-art improvements anticipated should be documented. As time passes, anticipated benefits should be compared with the actual benefits achieved. Such comparisons should provide useful experience for future assessments of benefits and risks and acquisition planning.

Decision rules, such as those above, guide the acquisition team as it prepares to select a DI or an NDI strategy. The vision and risk tolerance of the acquisition decision maker can be identified and used to guide their efforts. Analytical weaknesses are easier to pinpoint. The acquisition team's efforts can focus on supporting decisions by providing required estimates, data, assumptions, and justifications (rather than less meaningful and superfluous information displayed in prescribed formats). With such decision rules available and clearly in mind, the team can assign responsibilities and align resources in a way most conducive to quick, sound acquisition strategy decisions and, therefore, timely, effective fieldings.

SUMMARY

We have examined how NDI acquisition strategies can streamline the acquisition process and the risks associated with those streamlining opportunities. We have considered how benefits and risks should be weighed in making acquisition strategy decisions. High-quality requirements identification and market analysis are critical for streamlined acquisitions. If requirements determination, market analysis, and acquisition strategy decision making are of high quality and thoroughly yet nimbly coordinated, it should be possible to field materiel with quality equal to or exceeding that of the commercial marketplace years sooner than would otherwise be expected.

CHAPTER 2

FINDINGS, CONCLUSIONS, AND RECOMMENDATIONS

FINDINGS

During our review, we found that medical NDIs have a great potential for streamlining the acquisition process, AMEDD market analysis is inadequate to support the determination of requirements and the selection of acquisition strategies, and AMEDD materiel requirements are frequently too subjective, and often frustrate streamlined acquisitions. Together these findings suggest that the opportunity for NDIs to truly streamline acquisitions is being missed because potential benefits and risks are not sufficiently considered or understood.

Finding 1 – Medical NDIs Have Great Acquisition Streamlining Potential

Large expenditures on R&D can be avoided and up-to-date equipment capabilities can be quickly provided to medical units if medical NDIs are aggressively located, thoroughly evaluated, and appropriately incorporated into unit design. Four factors combine to create this significant potential: the overriding civilian, for-profit nature of the medical materiel community yields, for all health-care providers including DoD, a wide range of products and an extensive, innovative R&D base; reasonably priced, state-of-the-art medical materiel is readily available for relatively quick delivery; the consumable and durable nature of medical materiel, authorization in redundant quantities, and its ready replacement all lead to low-risk medical products; and NDIs are credible, attractive, and acceptable to user and purchasing organizations.

Civilian, For-Profit Nature

Fewer than 500 medical materiel items are listed as unique to the military, and of those, many are open to challenge. In any event, 500 military-unique items represents less than 1 percent of the approximately 60,000 items listed in the medical portion of the Federal Supply Catalog. Thus, since nothing is really unique about the

military medical commodity, we can reasonably characterize medical materiel as a civilian commodity.

A broad group of nondefense-related commercial companies, academic institutions, and health-care organizations is responsible for the R&D and marketing and fielding of more than 99 percent of the medical products used in military health care today. This R&D and supplier base is in business to earn a return on invested capital. Indeed, it is that return which supports occasional philanthropy and drives constant innovation and product obsolescence. A review of *Fortune* magazine's list of the 500 largest industrial corporations reads like the medical bidders list at the Defense Personnel Support Center (DPSC). Several well known pharmaceutical companies, suppliers of health-care products, and many other medical suppliers are prominently listed. In addition to these very large firms, many small businesses and suppliers of generic products are involved in the medical marketplace. With such an extensive, sophisticated medical supplier base, only those required items that civilian manufacturers deem unprofitable would seem to require development.

For example, a product currently under development, oral, sustained-release pyridostigmine – a nerve agent pretreatment drug – is a "civilian" rather than "military-unique" product. Oral pyridostigmine is commercially marketed but not in the sustained-release formulation stated in the Army requirements document. While the sustained-release formulation permits a 4-hour longer period between doses, it might be more responsive and cost-beneficial to avoid R&D expenditures and buy the commercially available product. The point is that some "military-unique" items are not truly unique to the military. A more vigorous evaluation of the requirement can often result in the product being acquired under an NDI acquisition strategy and being made available to the user more quickly.

Ready Availability

The availability of NDIs is greater than that of products that require extensive R&D effort. Two complete phases of the Life Cycle Systems Management Model (LCSMM) – demonstration and validation, and full-scale development – possibly totaling 4 years in duration, can be saved by an NDI strategy. That does not mean that the exact item required is sitting on a shelf in a warehouse simply waiting to be shipped to a purchaser. It means that some of the work necessary to prepare the product for manufacture, sale, and use has been completed. In today's competitive

business world, large inventories of raw materials, work in process, and finished goods are known to dampen profits. Medical equipment items having unit prices of thousands of dollars are typically only produced to order and will not normally be found "on the shelf." Relatively inexpensive consumable supplies, on the other hand, are likely to be found in finished-goods inventories available for immediate shipment. Companies who can flexibly manufacture and deliver high-quality, innovative products in the shortest lead-time, including basic and modified NDIs, are considered to be among the most competitive.

Low-Risk Nature

A high percentage of the total medical supply and equipment items used by the Army in medical treatment can be classified as durable and consumable. Those items are not capital investment items. Typically, they are present in fairly large quantities to support the volume of patients projected to be seen by specific units over specific periods of time. These quantities themselves, while on hand to support the care of many patients, provide a kind of "accident insurance" against mission failure through their numbers. Sometimes redundant standby items are used for such "insurance"; if one item fails, it is simply disposed of or sent for repair and another similar item is used. Such redundancy helps avoid catastrophic mission failure associated with the complete and total absence of an important item. A large percentage of medical items can be categorized as low risk because they are authorized to units in redundant quantities. This practice suggests that the requirements for most medical products lend themselves to and support the streamlining potential of NDI acquisition strategies. In some cases, it may be simpler to purchase additional NDIs rather than develop a "ruggedized" version of the item.

NDI Credibility, Attractiveness, and Acceptability

The potential benefits of NDIs are probably what makes the role of the Defense Medical Standardization Board (DMSB) as a "combat developer" attractive to those in policy-making positions and to many others as well. The DMSB clearly espouses a preference for NDIs. In our discussions with AMEDD personnel involved in the acquisition process, some interviewees felt that the DMSB's preference for NDIs is sometimes followed at the expense of performance characteristics essential to the Army. The Board frequently champions new products (in a generic sense) brought to

it for introduction into the Federal medical supply system and will grant the Services an exception from using the standard product. The Board does not task the AMEDD or other Services to develop an item or even modify an NDI.

The DMSB also stays abreast of the nonstandard, commercial products that are being purchased locally by military medical facilities. Products showing large demand qualify for standardization and type classification for DoD use. In this way, the DMSB performs market analysis and keeps an eye on the emerging preferences of clinicians. To those users unfamiliar with the intricacies of the acquisition system and the delicacy of tradeoffs involved, such a clearly chosen and straightforward approach is easily understood and, therefore, credible and more worthy of support than the complex weapon system approach to acquisition. DPSC, whose mission is concerned mostly with common (and by extension, commercial) items, finds it easy to support the DMSB position since it aligns with DoD policy and generally simplifies workload and contracting efforts.

Quite often commercial products define the requirements rather than the requirements defining products. A picture (as long as it does not contain a brand name giving unfair preference to a single supplier) has long been worth 10,000 words. Expressing a need as equivalent to an existing product has always been easier than preparing a complex specification or set of essential characteristics. In a world in which the complex legal and technical aspects of acquisition and procurement are neither well understood nor appreciated, such simplicity constitutes a significant advantage. Since the AMEDD ultimately remains responsible for its acquisition decisions, it might well aggressively market its requirements through an NDI acquisition strategy. Such an effort would allow DMSB input to AMEDD acquisitions to be ratified and would increase the confidence of clinicians in the acquisition process.

Summary

Medical NDIs or modified NDIs, as described in the discussion of the four factors above, present a potential to streamline the acquisition process that very closely approaches an imperative. It seems that only in rare cases would development be justified.

Finding 2 – AMEDD Market Analysis Inadequately Supports Requirements Determination and Acquisition Strategy Selection

We found that AMEDD market analysis fails to adequately support the processes of determining medical materiel requirements and selecting acquisition strategies for three principal reasons: (1) market surveillance activities to equip table of organization and equipment (TOE) units are either not conducted or, if conducted, are incomplete, poorly coordinated, and poorly documented; (2) market investigations, while often extensive, are insufficient for decision-making purposes because they do not provide the benefit/risk comparisons necessary for the selection of acquisition strategies; and (3) market investigation results, even if they were more relevant, are considered too late in the acquisition process to be of maximum value. After a brief explanation of the relationship among market surveillance, market investigation, and market analysis, we discuss these three causes of inadequate support for acquisition.

According to Army Regulation (AR) 70-1, *Systems Acquisition Policy and Procedures*, market analysis consists of two activities: market surveillance and market investigation. Together these two activities provide information on technologies, existing hardware, and inherent industrial capabilities that determine the basic data necessary to satisfy a materiel need. Market surveillance is a systematic, continuing effort to gather information about, and maintain an awareness of, marketplace technologies and products with potential for Army use. From the background of continuing market surveillance and in response to an operational and organizational (O&O) plan, market investigations are conducted to gather specific technology and product information to satisfy specific Army needs. The information gathered forms the basis for developing the acquisition strategy to satisfy the identified materiel need.

Market analysis plays a critical role in the development and processing of requirements. We cannot overemphasize the importance of knowing what is available in the marketplace. For example, NDI availability can influence required fielding dates, training requirements, funding, and many other critical tradeoffs. Market analysis must be considered formally and thoroughly from the inception of the intent to prepare an O&O plan. Certainly, if legitimate acquisition strategy alternatives are to be offered to acquisition decision makers, adequate market analysis must be performed prior to seeking approval of the initial requirement

document. The current LCSMM used by AMEDD and documented in the *Medical Materiel Acquisition Management Handbook* does not require market *investigations* until *after* initial approval of the requirement. This condition biases the LCSMM toward development strategies and away from NDI strategies. Such bias must be recognized and overcome.

Poor Market Surveillance

We found that AMEDD market surveillance activities, for the purpose of equipping TOE units, are either not conducted or, if conducted, are incomplete, poorly coordinated, and poorly documented. Furthermore, we found nothing to indicate that a more comprehensive market surveillance program would have a high likelihood of being properly targeted.

Understanding a technology and its market dynamics is more than simply trying to determine the availability of equipment. The kind of surveillance and subtle analysis necessary to take effective advantage of the marketplace requires the expertise of specialists. In the AMEDD, these specialists are the medical researchers and professional consultants to The Surgeon General (TSG). It is this kind of expertise that we feel the AMEDD TOE acquisition process (including the combat developer) fails to use. In our earlier report, we recommended that the AMEDD make more effective use of consultant input during the requirements identification process.[1] For the peacetime health-care mission, that process makes extensive use of expert consultants. The DMSB maintains a low level of expert surveillance, mostly through the clinical inquisitiveness of its staff.

Part of the AMEDD surveillance deficiency arises from its failure to understand the acquisition system. Another part of the deficiency is the absence of a useful "repository of medical or medical-related product information."[2] The Army Medical Department Board (AMEDDBD) is responsible for maintaining such a repository for "commercially marketed (not prototype) materiel for potential use by TDA (Table of Distribution and Allowance) medical facilities, and the materiel inquiry process in support of all TOE and TDA medical activities." The AMEDDBD, however, does not perform this function. We found that it had not received the resources to do so nor

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[1]LMI Report AR806R1, op. cit.

[2]Army Regulation 40-61, *Medical Services, Medical Logistics Policies and Procedures*, Headquarters, Department of the Army, Washington, D.C., 30 April 1986, page 7.

had it established any reliable system to encourage the flow of product information. The Board cannot be responsive to the combat or materiel developers nor to those organizations that wish to make materiel inquiries. Because the centralized function is not adequately performed, all AMEDD organizations involved in acquisition, both TDA and TOE, perform some form of "ad hoc" market surveillance and investigation often augmented by the visits of medical materiel salesmen. The peacetime health-care system has an acceptable if not fully effective market surveillance program, highly decentralized, but yielding results that satisfy the staff's immediate and short-range equipment needs. The TOE units "market surveillance" consists primarily of what they see being used in the TDA hospitals and being displayed at trade shows. In today's environment of automated databases and catalogs, a more focused and effective effort should be possible. That effort should consider prototypes and other technological opportunities as well as information sources, such as the property books of the AMEDD's TDA medical facilities.

Related to the issue of market surveillance and the identification of technologies to surveil are two different schools of thought regarding R&D. In his book on military procurement, McNaugher quotes Thomas J. Peters (author of the best selling book *In Search of Excellence*) in stating that most inventions seem to come "from the wrong industry at the wrong time for the wrong reason."[3] According to Mr. McNaugher, planning for orderly innovation to provide better military equipment is not possible; at best, military organizations can plan only to respond creatively as innovations appear.[4]

On the other hand, Arno Penzias, Vice President for Research at AT&T's Bell Laboratories and winner of the Nobel Prize in Physics in 1978, says that "finding good problems makes the difference between good research and bad research."[5] According to this thought "it's not a question of how much R&D we do, but how we do it. The real question is how well is that R&D focused on our needs." He states that "the worst thing you can do to a research [and development] organization [his meaning would include the role of the combat developer] is to isolate it." He indicates

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[3]Peters, Thomas J., "The Mythology of Innovation, or a Skunkworks Tale", pt. 1, *Stanford Magazine*, Summer 1983, Vol. 11, pages 3, 14.

[4]McNaugher, Thomas L., *New Weapons, Old Politics: America's Military Procurement Muddle*, The Brookings Institution, Washington, D.C., 1989.

[5]Penzias, Arno, "On Making R&D Pay Off", Interview, *High Technology Business*, July/August 1989, Vol. 9, No. 7, Info Technology Publishing Corporation, New York, N.Y., page 24.

that exposure to customers is essential for stimulating ideas. He also says that innovative manufacturing companies motivate their people to create a steady stream of new products. They challenge them to find and solve "good problems" (not unlike AMEDD capability requirements) that will increase the competitiveness and profitability of the firm.

The lesson for the AMEDD in the comments of Mr. Peters, Mr. McNaugher, and Dr. Penzias is that R&D investment strategies should be selective, focused, and attuned to the continuing R&D in the marketplace and cognizant of current and projected clinical experience and needs. An effective market surveillance program and effective requirements identification are critical to the development of R&D investment strategies. Our research indicates that the acquisition process attempts to identify and set priorities for requirements and to surveil the marketplace. However, the resulting information is not used effectively. For example, the CBRS employs continuing mission-area analysis to identify essential requirements, i.e., the problems and opportunities that should drive the R&D program. Another source of essential requirements may well be the mid- and long-term medical threat forecast that comes from the intelligence community. Research programs, however, are structured according to research areas, program elements, and Department of the Army (DA) projects, technical areas, and tasks that may or may not only coincidentally relate to the problems and opportunities identified in mission-area analyses and medical-intelligence summaries. This structuring occurs despite attempts to link the two more closely through the mission-area materiel plan (MAMP).

In AMEDD, the roles of the combat developer, medical researchers, scientists, and materiel developers in relating essential needs to market surveillance is not clear. All have visions of the AMEDD's future but not necessarily from the same perspective. As we discussed in our earlier report, the dual AMEDD mission can lead to a divided vision of the AMEDD future that must be recognized and managed in order to accomplish both the wartime readiness and peacetime health-care missions.[6] Maintaining market surveillance for the requirements of the peacetime mission happens because the clinicians make it happen. TOE units do not have counterparts doing the same for their requirements.

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[6]LMI Report AR806R1, op. cit.

Inadequate Market Investigations and Poor Acquisition Strategy Decisions

We have suggested that, if acquisition personnel can determine the availability of NDIs with precision and skill, their strategies can be developed with relative ease. But availability is not necessarily a simple yes or no determination. Product variations among suppliers and manufacturers can complicate an otherwise simple question. Brand-name pharmaceutical manufacturers and medical-equipment giants promote their products as being superior to generics and start-up companies because of product quality. In such a discussion, the complex issues of bioavailability, engineering, and added value also quickly surface. Some differences are significant, others are not; and market analysts at the AMEDD must be able to separate the two. Is it an old item in a new package? Is it two old items put together to make a new one? Or is it an old item made over by adding new technology externally? An error in this judgment could deny the AMEDD a legitimate acquisition alternative or clog the acquisition process with unnecessary information. The degree of accuracy required should be commensurate with the importance of the requirement in both capability and dollar terms. The level of expertise applied in performing the analysis should similarly vary.

Product demonstrations, examinations, and evaluations (including formal testing against specific criteria) fully coordinated with contracting personnel, should play a critical role and should employ requisite levels of expertise in making the necessary determinations. High levels of technical expertise are necessary if it appears that products will have to be modified to meet AMEDD requirements. In short, thoroughly understanding the medical marketplace means understanding the medical technology required and being able to compare it with existing products that can be quickly supplied. Tradeoffs can then be evaluated and acquisition strategies can be developed.

Besides understanding the technology and its effects on availability, the market analysts must understand the medical marketplace in terms of business (economic, accounting, production, and contracting) dynamics to develop coherent and balanced acquisition strategies. The marketplace can vary depending upon the products and services required.

The major weapon system marketplace can be characterized as a monopsony – one primary buyer, DoD, and a few sellers. In a developmental effort, the ultimate

price paid is usually the result of negotiations rather than the more purely competitive interaction of supply-and-demand market forces. Negotiations depend on leverage, and in the beginning, the Government has most of the leverage. Competition, an important part of early leverage, places downward pressure on prices and can lead to a "buy-in." As a project evolves, sunk costs rise and the winning firm moves into a monopolistic position from which it can deal with more authority. With increased leverage, it can begin to recoup from the "low bid" it may have used to "buy in." Because this kind of monopsonistic marketplace has the appearance of performing more competitively, much regulation is misguided and results in what has been called an "accidental industrial policy."[7] To streamline acquisition actions, the medical acquisition process must recognize when its marketplace is like that of weapon systems and when it is not. If the marketplace is not accurately recognized, an appropriate acquisition strategy is clearly unlikely to develop.

We found that the medical marketplace – particularly for expensive, technologically complex items – can behave like the weapon systems marketplace when developmental acquisition strategies are pursued. We also found that it usually approximates a more purely competitive marketplace when nondevelopmental acquisition strategies are pursued.

In a more competitive marketplace, consumer needs (including those commercial needs of military medical facilities that are monitored by the DMSB) are efficiently communicated to private firms. Responding to those needs, private firms (at their risk) produce what are subsequently defined by the Government as NDIs. Those products are approved and regulated by the Food and Drug Administration (FDA), distributed through commercial distribution channels, and made available in the marketplace to contracting offices that support both fixed (TDA) and field (TOE) military hospitals. Hospitals with contracting authority and funding can purchase the nondevelopmental products using relatively simple contracting procedures. Alternatively, for quantity price discounts, force integration, and war reserve stock rotation, nondevelopmental products may be centrally purchased by DPSC and distributed to hospitals and units by the U.S. Army Medical Materiel Agency (USAMMA). In the case of central procurements, contracting procedures are more rigid than those used at decentralized contracting offices, but if

[7]McNaugher, op. cit.

competitively awarded, they are usually simpler and quicker than developmental contracts.

Few medical development item strategies call for in-house design and prototype fabrication. Most require complex solicitations leading to development contracts. Optimistic firms vie for the contract. Their optimism can be based on a plan to buy in early and recover costs during contract change negotiations and follow-on production contracts. Many firms recognize that as competition increases they must reach earlier and earlier into the basic science and research effort. Concurrently, they realize that their products will encounter FDA regulatory requirements that will require additional time. Companies that have no access to basic science can ultimately end up in the second tier of suppliers or be forced from the marketplace. Developmental contracts can finance some basic science research, but the profit motive is the major driver of innovation.

Poor Timing of Market Analysis Inputs

In our earlier study, we indicated that well-defined, effective requirements are the sum of many tradeoff decisions.[8] Many of the tradeoffs depend on market analysis and technology-base information for a consistent acquisition strategy. Draft O&O plans need to give at least preliminary consideration to the acquisition strategy prior to approval. These draft O&O plans are approved at Milestone Zero. We found that, at present, formal and systematic market investigation is not undertaken until after the O&O plan is approved.

The earliest acquisition decisions are often the most important. Research into weapon system programs indicates that 70 – 80 percent of the life-cycle support costs of a system are determined by acquisition decisions that are made prior to Milestone 1. While this statistic may not necessarily apply to medical requirements, it suggests that it would be prudent to consider less-expensive NDI options as early as possible. For effective acquisition streamlining and acquisition-strategy selection, the products of market analysis must be considered early in the process, preferably even before approval of the requirement at Milestone Zero.

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[8]LMI Report AR806R1, op. cit.

Summary

We found that the AMEDD does not effectively conduct or focus its market surveillance nor do AMEDD market investigations provide effective intelligence, in technology or business terms, about medical marketplace dynamics. Additionally, even if surveillance and investigations were more effective, their results are available too late to support the processes of determining medical materiel requirements and selecting materiel-acquisition strategies. We also found that the absence of market analysis stifles any attempt to coordinate R&D investments with high-priority AMEDD needs and industry R&D activities.

Finding 3 – AMEDD Materiel Requirements Are Frequently Too Subjective and Often Frustrate Streamlined Acquisition

Medical materiel requirements are frequently too subjective and frustrate the acquisition process because they prevent meaningful comparison of alternative DI and NDI acquisition strategies. In the absence of an evaluation of the potential benefits and risks of NDI alternatives, the acquisition personnel cannot consider important issues and tradeoffs having a bearing on the requirement and subsequent acquisition process actions. Further, without an evaluation of the benefits and risks, test and evaluation criteria are difficult to develop. That difficulty, in turn, hinders or prevents sound milestone decisions and ultimate product certifications. As a result, acquisitions are frequently delayed and probably cost more than necessary. Failure to evaluate risks and benefits is attributable to three causes: (1) lack of fundamental modeling and analyses of operations in a manner that permits evaluation of tradeoffs and medical-equipment alternatives; (2) insufficient acquisition management control; and (3) inexperience and lack of understanding on the part of acquisition team members.

Failure to Model and Analyze Operations

We discuss tradeoffs and influences at length in our earlier report.[9] We believe the acquisition team must identify those tradeoffs and influences and must make decisions about them that improve the effectiveness of requirements. We suggest that acquisition experience and expertise is crucial in making good tradeoff decisions. Making informed tradeoff decisions requires information about the likely outcome of

[9]LMI Report AR806R1, op. cit.

each alternative. The availability of data on the outcomes of alternatives improves the quality of decisions, and those data are developed through experience and analysis. One reason the AMEDD has not made appropriate tradeoff decisions is that it has not had objective, reproducible estimates about the consequences of alternative decisions because of insufficient analytical support during the development of requirements. That poor support, in turn, contributes to the imprecision, subjectivity, and ineffectiveness that characterizes the requirements.

In our context, models are analytical tools to simplify and study systems that are too complex to be understood by intuition. We found that the models being used did not sufficiently represent the function or process being modeled or were not responsive enough to be of value in assessing acquisition alternatives for decision making. Inadequate analytical and/or modeling capability makes it impossible to determine the costs and benefits of acquisition alternatives objectively. And, without thorough estimates, poor acquisition decisions, the selection of inappropriate acquisition strategies, and violation of the preference for basic, modified, and/or integrated NDI become likely. Acquisition delay will invariably result from the need to go back and examine alternatives not previously considered.

Requirements we reviewed neither presented, compared, nor assessed costs and benefits in sufficient detail to adequately support acquisition decisions. Increased analytical capability would provide more objective linkages and justifications, would increase the effectiveness of requirements, and would facilitate good acquisition approval/disapproval and milestone decisions.

Insufficient Acquisition Management Control

The Army Health Services *Long-Range Plan 1990–2020* is published but we did not find evidence that it is effectively influencing acquisition management.[10] AMEDD acquisition management does not have enough vision and guidance in certain key areas of strategic and financial planning and affordability determination, systems engineering, and decision support. Deficiencies in those areas increase the difficulty in accurately defining setting priorities for requirements and allocating and committing resources to them in stable and coherent ways. As a result, acquisition objectives become vague and the acquisition team's singleness of purpose

[10]*HSLRP Publication 1. Health Services Long Range Plan.* Office of the Surgeon General, U.S. Army. 31 October 1989.

is diluted. Such an atmosphere precludes balancing benefits and risks correctly; potential benefits are wasted and risks are unknowingly taken. The aggressive, knowledgeable, focused (centralized) action we envision (and recommended in our earlier study[11]) is essential to firmly establish a sense of purpose and create the functional balance and teamwork necessary to recognize and seize streamlining opportunities.

One area of concern is the fundamental rate at which medical specialties advance in their standard of practice. That rate is important in defining the state of the art, estimating the life expectancy of materiel, and developing requirements for financial resources. A sound management strategy and implementation plan will effectively synchronize the rate of advance with resource forecasts and mission goals and objectives and, therefore, programs for field unit modernization and fixed facility technological advancement.

Closely linked to the synchronization of advances in medical specialties and equipment modernization is the rate at which a new technology can be absorbed into receiving units, the rate at which displaced equipment can be cross-leveled to other operational units or to pre-positioned unit equipment sets, and the disposition rate of assets that percolate down through various other requirements strata such as training needs, war reserves, and perhaps even foreign military sales. Such asset and inventory management considerations require some type of configuration control and imply that, at any given time, medical-unit equipment sets will be in different stages of life-cycle modernization. Getting to the modernization objective might require making tradeoff decisions such as choosing between a less-rugged item than specified and no item; or choosing between an off-the-shelf commercial item and a modified version of the same item. A well-conceived and comprehensive acquisition strategy reflects the face-off between readiness and requirements. The living table of organization and equipment (LTOE) was invented to facilitate this type of management control. Some units will be more modern than others by design. The AMEDD can maximize the effective and economical use of equipment, subject to training constraints, in such a manner. Without guidance, such an overall approach to modernization can complicate the selection of appropriate acquisition strategy alternatives.

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[11]LMI Report AR806R1, op. cit.

Long-term financial program forecasts can assist the AMEDD in planning, controlling, and integrating the equipping and modernization programs. For example, the medical-care support equipment (MEDCASE) program relies in part on the ages and purchase values of equipment on the property books in TDA medical units to project future funding needs. Similar mechanisms do not exist for TOE medical units in part because the AMEDD has few policies establishing programming responsibilities, and those it does have are not clear. For example, the relationships among research, development, test, and evaluation (RDT&E); procurement; retail and wholesale level stock funds; and operation and maintenance (O&M) funding are not clearly stated nor is the way they are marshaled to support the range of Army Components (Active, Reserve and National Guard) and major commands managed in sufficient detail to achieve desired objectives and levels of modernization. In the absence of these policies, it is difficult or impossible to develop procedures for describing how coherent medical programs are built and coordinated so that all key participants have the information they need to make effective decisions and contribute to the acquisition effort. Yet, such knowledge is essential for streamlined program execution. We found the AMEDD unable to assess the affordability of requirements effectively and, therefore, unable to maintain discipline in requirements and to capitalize on streamlining opportunities associated with design or supply to cost.

Adding to the uncertainty surrounding the linkage among technology, modernization rates, and financial programming is an inherent difficulty in relating the "importance" of individual medical materiel items, alone or in combination with other items, to medical readiness, to unit prices, and to the intensity of their management including the degree of R&D attention they should command. This difficulty is encountered when trying to determine what items should be listed as separate line items on TOEs and what items can be managed as components of a set, kit, or outfit. It is also encountered when trying to determine the appropriation that should be used to purchase an item and at what management level the requirement should be approved. Since readiness; asset visibility; and inventory management, financing, requirements approval, and medical care are inextricably linked in the acquisition process, it is important that the relationships among them be understood if the AMEDD is to have effective and streamlined management. We found that in the AMEDD, these relationships are often unevenly understood and sometimes based on shallow and insufficient analysis. Improvements are being made, but continued

progress is necessary if the AMEDD is to effectively integrate the management of sets, kits, and outfits.

Because of the difficult relationships just described, the medical acquisition process deals with medical sets, kits, and outfits as collections of individual items rather than as systems representing defined capabilities, a diametrically opposed management philosophy. The first, a collection of consumable and durable NDIs, is a "management short-cut"; the second is a systems-engineering approach. We found the "short-cut" management philosophy predominates in the AMEDD. While attempting to streamline acquisition by pushing standardization, the AMEDD gives insufficient consideration to systems-engineering issues. Performance goals are not specified for set, kit, and outfit modules individually or when collectively configured into unit equipment sets. Without goals and standards such as mobility and patient throughput, critical design criteria remain unstated and thus the AMEDD has collections of items that are viewed as "good enough" when assembled and fielded. However, no one compares the results achieved with those that could have been attained if the module had been engineered in greater detail for integration of its own components and for external integration with other modules forming a stream of capability – a system.

The shortcomings in strategic and financial planning, affordability determination, and systems engineering that we have considered thus far result in wrong or inadequate information being used in making acquisition decisions. All members of the acquisition community need crisp, concise guidance (not to be confused with more complex acquisition regulations of which sufficient numbers currently exist) that explains what decision-making information is most important and must be supplied.

Inexperience, Lack of Understanding

In Chapter 1, we considered the analysis that should be completed to effectively weigh the potential benefits and risks of NDI and alternative acquisition strategies. Further, as in any system or integrated process, we must understand the complex linkage between requirements identification and other acquisition functions. Engineering, medicine, and business disciplines are all involved. Defining requirements is not merely a job; it is not enough to fill out the prescribed format of a requirements document, put it into the acquisition process, and prepare to announce

imminent delivery. We found that many members of the AMEDD do not understand the complex issues presented by the acquisition process well enough to contribute to managing them effectively. Insufficient self-evaluation and study, a tendency to short-term action with scant regard for long-term consequence, and a dearth of meaningful acquisition experience all contribute to defects in understanding that, when coupled with poor strategic planning, inadequate financial management and control, and poor systems engineering and decision support, lead to the specification of subjective requirements and to missed streamlining opportunities.

Summary of Findings

In this chapter, we presented four reasons why NDIs offer a large streamlining potential; we identified three reasons why AMEDD market analysis does not adequately support the development of requirements and the selection of acquisition strategies; and we described three weaknesses that contribute to the development of subjective AMEDD materiel requirements that, in turn, frustrate acquisition streamlining and prevent meaningful test and evaluation and NDI certification. Taken together, these findings show that the AMEDD can and has missed the opportunity to use NDIs to truly streamline acquisitions and satisfy user needs.

CONCLUSIONS

In assessing the role of NDIs in streamlining medical acquisition and based on the findings discussed in the previous section, we draw three conclusions:

- AMEDD does not achieve the NDI streamlining potential.
- The AMEDD does not sufficiently understand the medical marketplace.
- The AMEDD does not coordinate the use of its acquisition resources.

Streamlining

The AMEDD neither achieves the full streamlining potential of NDIs nor systematically avoids NDI risks. This failure is principally the consequence of subjective requirements; inadequate market-analysis support; and inadequate test, evaluation, and product certification. In our earlier study, we showed that the fragmented approach to determining requirements complicated consensus and, therefore, discouraged coordinated action. We recommended that the AMEDD consolidate four requirements methodologies (CBRS, technology push, consultant

input, and user pull) into a single approach and that it establish a DSG(A) to increase centralized management and overcome fragmentation. We believe there is a significant role for the AMEDD R&D organization in streamlining through an NDI preference. The AMEDD's research capabilities should be an integral part of the DSG(A)'s oversight structure. With those capabilities added to the acquisition management process, the AMEDD can intensify its market-analysis efforts and increase the likelihood of developing effective requirements – those requirements that balance benefits and risks and, when filled, provide the needed capability. Effective requirements are necessary for streamlined acquisition. They focus the efforts of the acquisition process, eliminating constant revisions. Clearly stated and achievable requirements avoid premature introduction of volatile technologies into production contracting and integrated-logistics processes. Better up-front planning and analysis eliminates or at least minimizes the need to revise requirements. Intensified requirement approval procedures that stress NDI opportunities increase requirement effectiveness and drive market-analysis improvements, and both are keys to streamlining the acquisition process.

The Medical Marketplace

The AMEDD acquisition team – the combat developer, the researcher, the materiel developer, and the logistician – do not sufficiently understand the medical marketplace. We do not imply that the AMEDD has no experts in various aspects of medical acquisition. Some of its research experts are world renowned, but that expertise tends to be applied to biological or pharmaceutical technologies rather than to medical equipment. Furthermore, the ability to use the AMEDD medical equipment expertise that does exist at critical times during the acquisition process is spotty. The researcher is rarely, if ever, asked to provide potential technology-base solutions, maintain surveillance of emerging technology, or perform clinical test and evaluation. The combat developer represents the user but often has limited access to the real user clinicians in TDA hospitals and non-clinicians in TOE medical units. The combat developer's access is further limited because many users do not know who the combat developer is, how the combat developer can help them, or how to contact him/her. Even though the combat developer must interact with suppliers, her/his technological sophistication seems more limited than users in the field and in the R&D laboratories.

The combat developer and the materiel developer lack a certain appreciation for the complexities of sustainment-support planning and the flexibilities of contracting. The logistician and contracting official, on the other hand, lack a fundamental appreciation of the requirement, how it is intended to expand a capability, and how the technology meets the needs of the medical specialty. Again, we do not imply that such a system of separation cannot work. It can and has; however, if left to itself, it will not result in a streamlined acquisition. In view of the AMEDD's market surveillance weaknesses and the extensive availability of NDIs, we do not believe it is possible to approve a requirement and expect it to be processed and filled in a streamlined manner without thorough consideration of any NDI strategy alternatives that may be available. Approval of an O&O plan that lacks a comparison of the risks and potential benefits of any possible NDI strategy is, we feel, unwise. Communication, cooperation, and teamwork must be carefully supervised, particularly in the absence of integrating mechanisms such as strategic-planning guidance and financial-management controls.

Resource Coordination

The AMEDD needs to employ its acquisition resources in a more coordinated and productive manner. Available expertise needs to be brought to bear at the critical times; users need to be consulted when tradeoff decisions are being made; and consultants to TSG, researchers and developers, and contracting officials need to be involved in various aspects of market analysis. Since the acquisition-strategy decision is so closely tied to the comparison of benefits and risks, no longer can DI or NDI decisions exclude any acquisition team members. Integrated financial programs and umbrella acquisition guidance should be woven into the fabric. Testing, materiel demonstrations, examinations, and other evaluations and systems engineering must be used liberally to augment and extend available expertise. Such tests must be designed to improve the effectiveness of requirements and must be carried out with the full cognizance and cooperation of the contracting officials who will be expected to award development and production contracts. Acquisition personnel must take extreme care to recognize the relationships between developmental and production contracts. Materiel-development responsibilities must be clearly designated. Dividing them may incur the loss of integration and streamlining opportunities. R&D programs need to be effectively targeted and coordinated with the R&D efforts conducted elsewhere yet available to the AMEDD in order to devise appropriate

investment strategies. On the acquisition team, the efforts of the DMSB and DPSC need to be effectively coordinated.

RECOMMENDATIONS

The decision to pursue an NDI strategy as a means to streamline acquisition is at the very heart of the AMEDD acquisition-management processes. It is difficult to examine this crucial decision without considering the impact as it ripples throughout the process. Systems analysis and management tells us, however, that such interdependencies must be considered when considering prescriptions for improvement and change. We have endeavored to do this. It has led us to the recommendations presented here.

From our findings and conclusions, we build our recommendations on two themes. The first is that acquisition planning in the AMEDD needs to be better integrated, and the second is that acquisition operations need to be more effectively coordinated. Each theme has several interrelated recommendations whose implementation will permit the AMEDD to take advantage of the acquisition streamlining potential of NDIs by accurately balancing benefits and risks. Their implementation will also allow the AMEDD to take maximum advantage of the medical marketplace and will contribute to more effective and productive employment of available acquisition manpower and financial resources. We recommend that the AMEDD take the following actions with regard to integrated acquisition planning:

- Incorporate medical research capabilities into the acquisition team and apply those capabilities to identifying NDI solutions to requirements.
- Publish acquisition-strategy selection policy that gives preference to an NDI solution and guidance to the acquisition team that directs their efforts toward that policy.
- Develop and publish, on a periodic basis, strategic planning and modernization guidance and financial programming guidance that describes realistic equipping goals and objectives for AMEDD TDA and TOE units and the programming responsibilities necessary to attain those goals. The Army Health Services should include this acquisition planning guidance in its long-range plan.

- Correlate at least part of its request for RDT&E funding with its high-priority TDA and TOE requirements and with the medical materiel R&D being conducted and available elsewhere.

- Increase its systems engineering and configuration management efforts with regard to sets, kits, and outfits.

With regard to coordinated acquisition operations we recommend the following actions:

- The DSG(A) should approve O&O plans, the results of market analysis, and the proposed acquisition strategy at Milestone Zero.

- The DSG(A) should require explicit consideration/discussion of the effectiveness and feasibility of requirements and should ensure that each requirement contains the following:

  - Evidence of quantitative analytical (modeling) support

  - Evaluations of all NDI opportunities, however remote, to demonstrate that sufficient consideration has been given to technological and contracting issues

  - Evidence of thorough and meaningful coordination, including contact with DMSB and DPSC.

- The AMEDD should improve the comprehensiveness and responsiveness of medical market analysis and the medical product information repository without respect to the division between TDA and TOE equipment. To do so, the AMEDD needs to take the following actions:

  - Assign the MRDC responsibility for market surveillance and identification of potential technology-base solutions to requirements.

  - Support the appropriate test and other technical data where available. TDA experience should be used extensively, and hands-on testing and evaluation should be much more extensive.

  - Realign resources among the U.S. Army Biomedical Research and Development Laboratory for technical testing, the U.S. Army Medical Materiel Development Activity for technical test planning, USAMMA Readiness Directorate and National Maintenance Point for sustainment and liaison with DPSC, AMEDDBD for user testing and the product information repository augmented with improved human and equipment technical capabilities.

As the above recommendations are implemented, the DSG(A)'s oversight role will expand. To reflect the increased involvement of the AMEDD's research

activities, we feel the DSG(A) may be more appropriately established as the Deputy Surgeon General for Research and Acquisition. We recommend this change to our initial recommendation be considered as part of further analysis of organizational responsibilities and relationships.

During the course of this review, we have become convinced that the recommendations made in our earlier report and those we now make in this report are essential if the AMEDD is to effectively define its materiel future and, in a streamlined way, marshal the necessary resources and management skill to effectively and efficiently achieve that future.

GLOSSARY

AMEDD	=	Army Medical Department
AMEDDBD	=	Army Medical Department Board
AR	=	Army Regulation
CBRS	=	Concepts Based Requirements System
DA	=	Department of the Army
DI	=	developmental item(s)
DMSB	=	Defense Medical Stadardization Board
DoD	=	Department of Defense
DPSC	=	Defense Personnel Support Center
DSG(A)	=	Deputy Surgeon General for Acquisition
DSG(R&A)	=	Deputy Surgeon General for Research and Acquisition
FDA	=	Food and Drug Administration
LCSMM	=	Life-Cycle Systems Management Model
LTOE	=	Living Table of Organization and Equipment
MAMP	=	mission-area material plan
MEDCASE	=	medical care support equipment
MRDC	=	Medical Research and Development Command
NBC	=	nuclear, biological, and chemical
NDI	=	nondevelopmental item
O&M	=	operations and maintenance
O&O	=	operational and organizational
R&D	=	research and development
RDT&E	=	research, development, test, and evaluation

TDA	=	Table of Distribution and Allowances
TOE	=	Table of Organization and Equipment
TSG	=	The Surgeon General
USAMMA	=	United States Army Medical Materiel Agency
USAMMDA	=	United States Army Medical Materiel Development Activity

APPENDIX A

DEFINITIONS OF NONDEVELOPMENTAL ITEMS

Section 907 of the Defense Acquisition Improvement Act of 1986 established a statutory preference for nondevelopmental items (NDIs) in DoD. The act requires the Secretary of Defense to ensure that DoD defines and fulfills its requirements for the procurement of supplies through NDIs to the maximum practicable extent. The statute defines an NDI as being one of the following:

- An item of supply that is available in the commercial marketplace
- A previously developed item of supply that is in use by a department or agency of the United States, a state or local government, or a foreign government with which the United States has a mutual defense cooperation agreement; an item meets the above use criterion and requires only minor modification to meet the procuring agency's requirements
- An item currently being produced that does not meet either of the first two criteria solely because it is not yet in use, or is not yet available in the commercial marketplace.[1]

The Army divides NDIs into three categories and each category requires a different acquisition strategy.[2]

- *Basic NDIs.* Off-the-shelf U.S. commercial, foreign, or other Service items to be used in the same environment for which the items were designed. No development or modification of hardware or operational software is required.
- *NDI's adaptation.* Off-the-shelf U.S. commercial, foreign, or other Service items adapted for use in an environment different from that for which they were designed. These items require some modification of hardware or operational software (for example, they need what the Army refers to as "militarization" or "ruggedization") and therefore one or more forms of testing or verification are required.

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[1]Report to the Chairmen, House and Senate Committees on Armed Services, *Procurement, DoD Efforts Relating to Nondevelopmental Items*, National Security and International Affairs Division, United States General Accounting Office, GAO/NSIAD-89-51, B-233021, 7 February, 1989, page 8.

[2]Army Regulation 70-1, *Research, Development, and Acquisition, Systems Acquisition Policy and Procedures*, Headquarters, Department of the Army, Washington, D.C., 10 October 1988, page 20.

- *NDI integration.* Maximum use of NDIs as subsystems, modules, or components contributing to a materiel solution that entails low-risk systems integration. An R&D effort is needed for systems engineering, software modification, and testing to ensure the total system meets user requirements and is producible as a system.

APPENDIX B

NONDEVELOPMENTAL ITEM POLICIES

DoD POLICY

DoD Directive (DoDD) 5000.37, *Acquisition and Distribution of Commercial Products*, states that DoD should "purchase commercial, off-the-shelf products (products in regular production sold in substantial quantities to the general public or industry at established market or catalog prices) when such products will adequately serve the Government's requirement, provided such products have an established commercial market acceptability." (A commercial product is said to be market acceptable when it is sold in substantial quantities to the general public. Substantial means that sales to the general public predominate over sales to the Government.) Furthermore, the DoD policy indicates that "commercial distribution channels will be used in supplying commercial products to users when it is economically advantageous to do so and the impact on military readiness is acceptable."[1]

ARMY POLICY

The Army implements the DoD preference for NDIs in Army Regulation (AR) 70-1, *Systems Acquisition Policy and Procedures*. Army policy states that an "NDI acquisition strategy is preferred when ... market analysis reveals a high probability that already developed items are available that can meet the user need with savings in acquisition time and development cost/risk with adequate supportability."

POLICY PERSPECTIVE

The Defense Acquisition Improvement Act, mandating a preference for NDIs, became law in November 1986 but the idea that "reinventing the wheel" should be avoided is much older. As early as 1972, the Commission on Government Procurement recommended buying more commercial products rather than relying on products designed to meet unique Government specifications or purchase

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[1]DoD Directive 5000.37, *Acquisition and Distribution of Commercial Products*, 29 September 1978.

descriptions. The DoD policy above, initiated in 1976, was intended to emphasize acquisition of commercial products, eliminate unnecessary Government specifications, tailor essential specifications to reflect commercial practices, and minimize the administrative burden of Government acquisition procedures. The 1986 NDI statute simply expanded and strengthened existing emphasis on procuring commercial products, and it included NDI weapon systems and components.

In spite of the above policies, the Defense Science Board has found that regulations and practices have had opposite the intended effect. The preference for military specification items in DoD overall has been increasing as protection against protest by possible suppliers. Government buyers have been demanding more cost data despite the fact that items are commercially market priced. Full-and-open competition has been interpreted to mean obtaining the maximum number of bidders regardless of qualifications. The atmosphere surrounding commercial acquisition has become increasingly hostile but, due to the rate of technological innovation, even more compelling.

To attain acquisition objectives, the Defense Science Board, in 1986, made recommendations to shift DoD toward far greater use of commercial products and commercial buying practices. Doing so, they argued, would achieve the triple benefits of reduced life-cycle costs, increased operational capability, and more rapid fielding of equipment. Reduced life-cycle costs, they said, would come from reduced R&D costs, reduced production costs (from larger production runs), increased competition, and reduced maintenance and upgrade costs. Increased operational capability would come from the fact that today's commercial parts are often more advanced than military parts, have built in supportability, and are frequently designed to be more robust in terms of tolerance of both inapplicable use and failures. Finally, commercial equipment is often more readily fielded in response to new technology and to changing threats because less R&D is required and it has been designed for both modularity and upward compatibility, thus lending itself to modification when required.[2]

The Board's recommendations, while not limited solely to electronics, were often supported by examples from that industry. Commercial electronic microcircuits, for example, were reputed to provide higher performance, lower cost,

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[2]Report of the Defense Science Board on *Use of Commercial Components in Military Equipment*, Office of the Under Secretary of Defense for Acquisition, Washington, D.C. 20301, June 1989, page 1.

and higher quality and reliability when employed in a comparable environment than those developed by DoD.

A July 1989 article in *Military Forum Magazine* indicated that technology in the field will always lag advances in laboratories.[3] The lag was said to be true for auto manufacturers and chemical firms, for example, as well as DoD. What Pentagon officials found disturbing, the article said, was that in "dual-use" technologies with wide civilian application, U.S. defense equipment is often inferior, not just to the state of the art in research centers but to run-of-the-mill commercial products. The congressional Office of Technology Assessment (OTA) was said to have concluded that "dual-use technology in defense systems often lags significantly... what is available in consumer markets."

The Defense Science Board report suggests a reason that DoD might start out ahead of industry technologically and then begin to lag in the commercial marketplace. Again it cites the electronics industry as an example. As the initial major user of a new semiconductor in a hostile or stringent environment, DoD, through R&D, establishes rules and standards for design, inspection, test, and certification to achieve the high-quality performance and reliability required by a new mission. As time passes two things happen. First, DoD continues to rely on the now-aging standards and specifications rather than tailoring them for new but perhaps less-demanding missions or applications that could use cheaper technology. Second, the commercial market exploits the original technology and, in a competitive, for-profit, environment, makes improvements in materials, design, manufacturing, packaging, and testing and now provides low cost, high quality, and reliable devices for numerous commercial applications as well as the capabilities now required by DoD.

The Board goes on to say that DoD should recognize these market dynamics and structure its acquisition processes to take advantage of them. Namely, as a general policy, DoD should focus its R&D efforts on needs that cannot be met elsewhere and purchase commercial or nondevelopmental materiel when it is available and will meet Government requirements in all other cases. Doing so, they say, will expose DoD to potential benefits which can far outweigh any risks. Current DoD NDI policy, therefore, should be reinforced. To do this, management and resource emphasis

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[3]Grier, Peter, *DoD's Computer Hardware Paradox, Military Forum*, Washington, D.C., July 1989, page 36.

should be placed on technology surveillance and extensive market investigation and analysis.

The Defense Science Board expects that commercial practice procurements will be initiated with a public notice requesting that interested sources make submissions describing their products and explaining how they meet the advertised needs. The public notice would be issued as soon as contracting officials were able to explain needs in conceptual terms. The early adoption of specifications would be avoided. To qualify for consideration, products would be required to have achieved commercial market acceptance and to comply with minimum fundamental requirements synopsized in the public notice. These could include commercial standards; minimum function and performance levels; essential form and fit specifications; and, in appropriate cases, DoD manufacturing process qualification standards.

After receiving product information from interested sources, contracting officers (and project managers) would be encouraged to continue to refine requirements based on knowledge gained through reviewing the product information. Only products qualifying under the public notice would be considered in that review. Permitting contracting officials to focus on the characteristics of the qualified products would allow efficient determination of any additional mandatory requirements necessary to ensure suitability for DoD use or, if necessary, to narrow the competitive field to those products most likely to be selected. Specifications and evaluation criteria could be adopted up to the point that best-and-final offers were solicited. The premise underlying this commercial-style model is that market research needs refinement and specification development should be visible. Both are *dynamic* activities that are performed concurrently and recognized as essential elements of the formal competitive process. Contracting officials/program managers would have an efficient means for integrating their analyses of program needs, commercially available options, and budgetary considerations with the aim of determining the optimal tradeoffs. Based on this rationale, the Defense Science Board report appended a copy of draft legislation they recommended for submission to, and approval by, the Congress.

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Streamlining the Medical Materiel Acquisition Process: A Preference for Nondevelopmental Items

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Volume 2 of 3 – Volume Report. For a thorough understanding of the medical materiel-acquisition process and the changes needed to complete its streamlining, we suggest reading all three volumes.

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19. ABSTRACT *(Continue on reverse if necessary and identify by block number)*

The medical industry continuously produces new and improved materiel for the delivery of health care. It continually evaluates clinicians' needs and treatment trends and moves rapidly to meet the demand for new products. The industry uses all available means – basic research, updating old items, combining old and new products and procedures in creative ways to define new products, and developing products based on new technologies – to fill identified needs. Gaining a competitive advantage and the quest for profits drive a vigorous industry response.

The Army Medical Department's (AMEDD) acquisition process is challenged to match the industry response to clinicians' needs and go even further. Materiel the AMEDD acquires must be affordable, reliable, transportable, maintainable, and credible over a range of environments. The medical acquisition process must meet this more robust challenge to be successful.

We believe it can meet the challenge and in an earlier study recommended two critical first steps for doing so: First, centralize the process under a Deputy Surgeon General for Acquisition, [DSG(A)] and, second, improve requirements through better coordination of existing methods for identifying requirements. But these steps alone are not enough. The acquisition process needs to capitalize on a preference for nondevelopmental items (NDIs), i.e., those medical industry products that meet both clinical and nonclinical requirements. The AMEDD also needs to integrate the technological expertise found in its research activities into the NDI acquisition process.

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19. Abstracts (continued)

To fully capitalize on an NDI preference, we recommend that the DSG(A) take the following actions:

- Clearly reflect the preference for NDI solutions in all acquisition strategy-selection guidance provided to members of the acquisition team (the combat developer, the researcher, the materiel developer, and the logistician).
- Approve the acquisition strategy on a go/no-go basis at life-cycle Milestone Zero based on a well-defined and fully explored materiel requirement, clear evidence of continuous market surveillance and thorough market investigation, and completely documented test and evaluation against user-certified acceptance criteria.
- Publish and periodically update planning and modernization goals for equipping the peacetime and wartime health-care missions and provide the financial programming guidance to attain them.

Additionally, we feel the increased involvement of the AMEDD s research activities in the NDI strategy may require changing our initial recommendation on establishing a DSG(A). The position may be more appropriately established as a Deputy Surgeon General for Research and Acquisition. We recommend this change be considered as part of further analysis of organizational responsibilities and relationships.

Upon implementing those recommendations and the others made previously, the AMEDD will find itself with a more streamlined acquisition process – a process that fosters well-defined, achievable requirements and tilts to NDIs for materiel acceptable to clinicians and with the qualities that mark successful acquisitions. .