HEALTH CARE INDUSTRY
STUDY REPORT 1996

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ABSTRACT

Health care, the United States's largest industry, continues to undergo dramatic changes as the government, business, and internal influences attempt to arrest its historically dramatic rate of cost increases. Notwithstanding those efforts, there remains a continuing challenge to balance lowered costs with high quality and increased access to care. This report summarizes the contemporary state of the health care industry. Its ability to effectively respond to change will ultimately affect the morale and national will of the nation's most important resource, the American people.

INTRODUCTION

The U.S. health care industry is a trillion-dollar enterprise. It is the nation's largest single business, consuming almost one-sixth of the U.S. gross domestic product (GDP), or about $4,000 per person (Califano, 1994). It employs approximately 9 million people, including over 600,000 physicians, 150,000 dentists, and 2 million nurses (Silver, 1995). Each of the industry's three complex sectors—health services, pharmaceuticals, and medical equipment and supplies—is undergoing dramatic change as the industry struggles to deliver health care in the face of four conflicting demands: high quality, low cost, increased access, and the preservation of patient choice. To satisfy these demands, managed care with a capitation payment approach to the delivery of care has emerged as the predominant force in the health care marketplace. Its effect has pervaded all sectors of the industry. In examining the health care industry, this report defines each sector, reviews its current conditions and challenges, and offers an outlook and roles for the government. The industry's ability to effectively deliver quality health care in the future will affect all Americans, directly or indirectly, as the nation continues to pursue an improved standard of living. Indeed, the industry's long-term viability will continue to affect national security by ultimately determining the quality of life for the human resources component of the national power equation.
HEALTH SERVICES SECTOR

The Health Services Sector Defined

This sector, the largest in the health care industry, consists of four components, each differentiated by the setting in which care is provided.

Hospitals. Modern hospitals generally have three major functions: patient care, medical education, research, or a combination. They are categorized by their type of care (general or specialized), function (e.g., teaching hospital), or size (community hospital or medical center). The trend is toward more academic medical centers, more ambulatory surgery, and fewer community hospitals (down 17 percent since 1981). Today, there are approximately 6,500 hospitals in the United States with a total of about 1.2 million beds (Carlstrom, 1994).

Provider practices. Approximately 200,000 private medical offices and clinics, about 75 percent of which are primary care practices (internal medicine, family practice, obstetrics, and pediatrics), employ about 1.5 million people. Solo practice is declining primarily as a result of the large debt physicians incur in medical school and the burden of malpractice insurance costs. Most physicians are in salaried staff positions, group practices, or corporate-sponsored medical care firms.

Nursing homes. Nursing homes are long-term care facilities used primarily for the elderly and those who are unable to care for themselves. About 23,000 such facilities in the United States have a patient population of about 1.3 million, 85 percent of whom are over the age of 65 (Silver, 1995). Nursing homes are classified as skilled nursing facilities, which provide around-the-clock supervision by a skilled nursing staff supervised by physicians; intermediate care facilities for patients who do not require a highly skilled medical staff; and custodial care facilities, which do not employ skilled personnel. The number of nursing homes has more than doubled since the 1960s because of the aging of the U.S. population and changing life-styles that separate the elderly from their families. There has been a recent increase in large nursing home chains that seek primarily to house the more profitable private-pay patients (Silver, 1995).
Home care. Home health services, the fastest-growing part of the industry (Freeman, 1995), consists of firms engaged in providing skilled nursing or medical care in the home under a physician's supervision.

Current Conditions

The health services sector is currently undergoing significant restructuring as it adjusts to a more market-driven approach to providing health care. Until recently, the economic structure of the industry shielded it from most of the laws of economic competition. A third party—usually an insurance company—typically paid most expenses, thereby shielding the consumer from the real cost of medical care. Even now, the average American still pays only 22 cents out of every dollar spent on health care (Carlstorm, 1994). Because consumers traditionally have had “imperfect knowledge” of the cost of medical care relative to its quality and benefit, they as well as physicians have had difficulty making rational health-related decisions based on economic considerations. However, under the guise of managed care, competition has been rapidly introduced into the health care system. The new focus on the relationship between cost and outcomes continues to bring dramatic changes to how and where the industry provides health services as well as to its financial structure.

Hospitals. By far, managed care is having the greatest impact on the $410-billion-a-year hospital industry. Cost pressures are forcing the closure of hundreds of inefficient facilities and reducing the number of beds in those hospitals that remain open. In the last 10 years, approximately 600 acute-care hospitals have closed, eliminating about 180,000 beds (Burns, 1995). Even after these reductions, as many as 447,000 excess beds remain—a surplus of almost 2,500 hospitals (West, 1994). Managed care reforms are reducing the average length of stay of the typical hospital patient and having a corresponding impact on industry profits. Analysts project declines of 26 percent in hospital admissions and 11 percent in average length of stay over the next four years (Voelker, 1995, 601). These declines could reduce hospital revenues by as much as 30 percent by the end of the decade (West, 1995a). The shrinking patient base has forced hospitals to lower costs aggressively by reducing the number of beds and staff and implementing horizontal and vertical integration strategies that lead to the more economical use of scarce medical resources. Larger hospitals are merging with smaller institutions,
and many are purchasing private physician practices and health maintenance organizations (HMOs) all in the name of market domination and financial survival.

Provider practices. Managed care is also having a profound impact on provider practices. Until recently, this segment, with approximately $210 billion in revenue, was a cottage industry of small, independent entrepreneurs. However, physicians are now joining with hospitals, other medical providers, and third-party payees in vertical alliances to provide the complete spectrum of patient care within a managed care environment. Currently, over 650 vertically integrated health care systems in the United States employ at least 100 physicians (Coddington, 1994). As managed care reforms increase the pressure to cut costs, the number of integrated health care systems will continue to grow. Additionally, hospitals and insurance companies are aggressively establishing cooperative agreements with group practices in order to form regional integrated health care systems.

Nursing homes. While the financial incentive to keep patients out of nursing homes grows under managed care, long-term institutional care for the elderly remains an important component of the services sector. Expenditures for nursing home care total over $70 billion annually, of which the government (mainly through Medicaid) finances about 60 percent, with the remainder being paid by patients or their families (Levit et al., 1994). Proposed reductions in the level of Medicaid reimbursements could hurt the nursing home industry financially.

Home health care. Closely related to the movement toward a more seamless health care system is the growing role of the $25 billion home health care market. There is an increasing reliance on less expensive home-delivered care for the elderly and chronically ill. About 15,000 home care agencies in the United States serve over 6 million patients (West, 1995, 5). The fastest growing segment in the health care industry, home health care has grown 30 percent over the past five years, primarily as a result of the aging of the U.S. population and financial pressures to treat patients outside of high-cost hospitals and nursing homes (West, 1995, 5).
Challenges

Socioethical and market-driven challenges face the health care industry in general and confront the health services sector specifically.

Socioethical challenges. Amazingly, over 41 million Americans do not have health insurance (McDonald, forthcoming). Ultimately, the nation must address how these citizens will receive care and who will pay for it. Perhaps even more important is the eventual aggregate effect of an aging population, continued technological advances, and rising expectations for access to quality and low-cost care—the so-called "iron triangle" dilemma facing health care. Elderly Americans (those over age 65) consume more than a third of U.S. health spending even though they constitute just 12 percent of the population. By 2030, this segment will make up 22 percent of all Americans (Rowley, 1996, 1). Without a change in how the nation takes care of its older population, Medicare costs could triple in 10 years to nearly $450 billion, helping to drive total U.S. health expenditures to nearly 30 percent of GDP by 2010 (Rowley, 1996, 3). Since the nation must accept the future graying of America and cannot—from a competitiveness standpoint—thwart advances in medical technology that increase longevity, the United States must address the attendant difficult ethical questions: How much care is enough? When, for whom, and under what conditions should the natural death process be allowed to occur in lieu of high-technology intervention?

Marketplace challenges. The services sector is undergoing a profound transformation as it adapts to a marketplace increasingly characterized by competition based on price and quality. It faces three key challenges: integrating comprehensive delivery of care, adopting outcomes management, and shifting to wellness and prevention.

1. Wellness and prevention: One of the key tenets in approaching the future of health care is to focus on “health” not “care” (Hancock and Garrett, 1995). Instead of just providing care, the U.S. health care system must change its focus from “repairing after the fact to a new paradigm that focuses on predicting, preventing and managing care” (Bezold, 1995a, 999). It is more cost effective to prevent disease and illness than to cure them (Bartling, 1995, 8). Lowering health care costs necessitates a shift in emphasis from acute and emergency care to wellness and
preventive medicine and entails a major change in the way health care providers interact with patients, since providers are traditionally trained to cure disease and illness, not to prevent them. Most wellness and prevention methods involve life-style choices over which providers exercise little direct control and the patient exerts almost total control. Therefore, patients can no longer be passive recipients of health care but must be active participants in maintaining their health (Goldstein, 1995, 62). Convincing patients to adopt and maintain healthy lifestyles requires education and incentives (Battagliola, 1995, 18). Such a major commitment of time and funds is problematic for an industry still charged with maintaining a world-class capability to cure and manage prevailing disease.

2. Integrated health care delivery: Stand-alone, independent health care provider organizations delivering a small array of health care services will find it increasingly difficult to compete in today's cost-containment environment as purchasers search for one-stop shopping for health care services (Lopez, 1995, 31). Providers that can deliver a full range of integrated health care services--primary care, acute and emergency care, rehabilitation services, long-term care, and home care--will have a competitive advantage. Achieving complete horizontal and vertical integration of all operations and structures--clinical, functional, organizational, and informational--is absolutely essential if a system is to be capable of delivering high-quality, low-cost, truly seamless health care (Goldstein, 1995, 60; Gillies et al., 1993, 468; Pointer, Alexander, and Zuckerman, 1995, 6-7). Coordinating business, management, and clinical practices among previously unrelated organizations represents a monumental challenge to the industry.

3. Outcomes management: The emphasis placed on high quality and low cost by health care purchasers produces the same forces in health care that drive innovation in other industries. Innovation requires a constant search for treatment protocols that produce the "best" outcomes in patients. Identifying the best outcomes presents several challenges. First, health care providers must define a best outcome and the aspects of patient health to measure in order to ascertain when it is achieved. Second, the industry must comprehensively analyze alternative treatment protocols to determine which ones produce the "best" outcomes since little analysis of this type has been accomplished to date (Mariner, 1994, 37-38). Finally,
if they are to maximize their competitive advantage, provider organizations must standardize patient care by establishing clinical practice guidelines based on those treatment protocols that produce the best patient outcomes (Shortell et al., 1993, 462). Outcomes management requires significant time and funding, but it carries with it many benefits, particularly for integrated health care delivery systems. It ensures that patients benefit from best clinical practices, minimizes the need for retreatment, provides for continuity of patient care, and reduces overhead costs for health care providers. These benefits translate into a competitive advantage for the provider and, it is hoped, lower costs for the consumer.

Outlook

As stated, the future of U.S. health care is more health and less care, more self and less provider, and more here and less there. The United States is embarking on a journey toward a future in which holistic health will become both a community- and a self-initiated norm. “Healthcare in America must go through a transformation in the early 21st century because the current system is unsustainable” (Rowley, 1996, 4). Perhaps a holistic approach to health improvement centered on prevention and expanded treatment approaches (e.g., chiropractic, acupuncture) can make up the shortfalls in the current U.S. civilian and military systems. Such “simple” foci as life-style changes offer tremendous payoffs. A former U.S. surgeon general has stated that variation in disease can be attributed to behavior 50 percent of the time, to environment 20 percent of the time, to genetic composition 20 percent of the time, and to medical care the remaining 10 percent of the time (Bezold, 1995b, 32). Currently, 96 percent of U.S. health care resources are spent on curing diseases or other existing problems, leaving only 4 percent for prevention (Olsen, 1995).

Civilian health services. Civilian health care organizations continue to reorganize, improve efficiency and quality, and fight for their very survival. “From 1987 to 1990 the number of hospitals owned, leased, sponsored, or managed by healthcare systems increased 13% to 2,567, accounting for 53% of all acute-care hospitals” (Rowley, 1996, 5). However, the 900,000 hospital beds in 1989 will probably fall to 300,000 beds in 2010 (Bezold and Mayer, forthcoming). Cuts in bed capacity and in the time patients spend in the hospital could reduce hospital revenues by as much as 30 percent by the end of the decade (West, 1995b, 9-10).
Furthermore, nearly 70 percent of respondents to a Health Research and Development Institute survey of over 2,000 hospitals stated that 20-40 percent of their total revenue comes from outpatient, not inpatient, care (Burns, 1995). The aim is clearly less expensive, outpatient care.

Military health services. With the “right-sizing” of the Department of Defense (DoD) came the need to reevaluate the philosophy of military health care. Reemphasizing its primary mission—readiness of the operating forces—military health care has redefined itself collectively as the Military Health Services System (MHSS). “MHSS is positioned to be the benchmark health care delivery system of the 21st Century, emphasizing readiness, health promotion, and managed care for all . . . entitled to care” (West, n.d.). Future decisions on resources and directions derived from this project are expected to position the DoD to provide optimal and efficient health care in the coming century. The formation of the MHSS may be a critical first step toward horizontal integration of service medical departments.

TRACER: The DOD’s TRACER, which introduces the managed care approach into the military health care system, has given rise to complaints about the exclusion of Medicare-eligible retirees and about enrollment and per-visit fees. While very modest copayments may eventually become more acceptable, the more contentious issue is the widely held perception that the DoD intends to renege on a commitment to provide retirees care for life. Medicare “subvention”—reimbursement to DoD facilities for the costs of caring for Medicare-eligible retirees—would enable the DoD to continue to provide care to these loyal veterans. However, subvention requires congressional action, which has not yet been forthcoming. Hope on this issue still exists in the form of a provision in the 1996 Defense Authorization Bill expressing the “sense of Congress” that military facilities should be reimbursed for care to Medicare-eligible patients. Acknowledging that it is cheaper to provide such care in military facilities, the provision recommends that funds for such reimbursement be included in the FY 1997 budget (West, 1996). Medicare subvention merits continued pursuit to sustain the long-term cohesion of the military community. But because additional DoD cuts (including cuts in medical resources) are nearly certain, TRACER is not enough. While TRACER will place most service members and beneficiaries into some type of managed care setting, there is more to optimal health than managing.
access and cost. The foregoing discussions on wellness and outcomes management must apply to the DoD as well.

**Government Goals and Role**

The government's interest in quality, cost, and access to care is paramount because health care spending consumes 14 percent of GDP. By 2000 nearly 19 percent of U.S. GDP will go toward health care alone (West, 1993). The federal government funds care for a substantial portion of society: the elderly, the poor, veterans, and U.S. military personnel. For reasons of policy and values, the United States remains firmly committed to guaranteeing affordable health insurance for all Americans.

*Legislative actions.* With the defeat of the president's Health Security Act of 1993, the governmental impetus for health care reform has moved to Congress, and reform bills continue to surface. On April 23, 1996, the Senate unanimously passed the bipartisan Health Insurance Reform Act of 1996, which was intended to provide greater health security for millions of families by reforming health insurance provisions. While this legislation contains several contentious issues that must be worked out in a House-Senate conference committee, if it prevails, (1) individuals will find it easier to retain their health care coverage as they change jobs, (2) insurance companies will be restricted in excluding coverage for preexisting medical conditions, and (3) it will be easier for small employers and individuals to band together to purchase insurance. The recently passed H.R. 3103, also intended to improve the portability of insurance, promotes the use of medical savings accounts, improves access to long-term care facilities, and limits malpractice liability. Whether the bill prevails—given the different philosophies of U.S. political parties and the exigencies of election-year politics—also remains to be seen. Nevertheless, there seems to be bipartisan consensus on the need for health care reform even if reaching agreement on methods and approaches remains difficult.

*Medicare.* Spending on Medicare, Medicaid, and other government health programs will rise from 3.3 percent to 11 percent of GDP by 2030 unless policy and programs change dramatically. The problem is how to reshape the current patchwork of regulations, payment systems, and conflicting incentives into a workable system without inflicting financial chaos on
providers and beneficiaries (Clarke, 1995). Medicare provides health insurance for most people aged 65 years and over and certain other disabled individuals; however, its funding is already severely out of balance. Medicare hospital insurance outlays now exceed its tax revenues, and predictions are that at the current rate of use the United States will deplete the Medicare trust fund by 2001. Home care, like other alternatesite approaches, has come under increased scrutiny as the government looks for ways to reduce payments to fraudulent providers. This scrutiny must be judicious and not disregard the lower cost of nonhospital care.

**Domestic emergency response.** In addition to the challenges of health care reform, the government is responsible for responding to civil emergencies and disasters. Its emergency response structure includes a consortium of 27 federal agencies, including the Department of Health and Human Services (DHHS), which is responsible for Emergency Support Function #8 (ESF-8), Health and Medical Services, under the Federal Response Plan. The Federal Emergency Management Agency (FEMA), as lead agency for the plan, has a strategy that addresses the need for surge and mobilization of health care during civil crises. The U.S. Public Health Service’s National Disaster Medical System (NDMS) plays a key role.

**Recommendations for government.** The government should

1. Continue to pursue national health care reform as a priority, including initiatives that address health care access, coverage, cost containment, and quality assurance.

2. Reassess and change antitrust laws that might thwart horizontal integration (and its attendant efficiencies) within the health care industry.

3. Reform Medicare to include increased consumer choice and cost-conscious decision making for the elderly; incentives for accessible, high-quality, patient-oriented care; and innovative, cost-reducing delivery systems from the private sector that lay the groundwork for a fiscally solvent Medicare program.

4. Facilitate partnerships between federal and state governments on health care reform initiatives.
5. Promote more effective partnerships within the FEMA consortium and periodically exercise a coordinated government response for ESF-8 actions.

6. Ensure that wellness and outcomes management practices are incorporated into TRACER and given heavy emphasis in the MHSS 2020 Project.

7. Enact Medicare subvention to keep the faith with a loyal veteran population—if Medicare is to pay for their care, it makes good business sense to pay for it in DoD facilities, which provide care substantially more cheaply than civilian counterparts do.

8. Charge the DOD’s MHSS with examining the integration of health care in the services. (Three separate service medical departments may be providing duplicative services in many geographic areas and conducting research and development [R&D] under redundant commands.)

9. Examine where health services and functions can be consolidated throughout the government; the civilian sector’s lesson in horizontal integration and consolidation should be instructive in this regard.

PHARMACEUTICALS SECTOR

The Pharmaceuticals Sector Defined

This dynamic, high-technology, and high-risk U.S. industry sector pursues the mission of discovering and developing new medicines or vaccines for the prevention, treatment, or cure of diseases. Currently the world’s leader in the discovery and development of new medicines, the sector is highly dependent on R&D and must commit substantial resources to it early to attain acceptable long-term returns on investment. The sector is in a revolutionary transition period. Dramatic changes such as mega-mergers of large corporations will likely continue, and analysts predict that the number of drug companies could be halved within five years.
Current Conditions

The pharmaceuticals sector has also been influenced by managed care; however, it has still been able to sustain growth. Many areas of the sector warrant review.

Sales. The pharmaceuticals sector continues to grow. It has experienced significant cost efficiencies from major reorganizations and mergers, changes in Food and Drug Administration (FDA) regulations, and the adoption of the 1994 General Agreement on Tariffs and Trade (GATT), which extended the lives of many drugs. Also a factor in its growth is the demographic shift toward a more elderly population. However, the pace of annual sales growth is moderating; sales increased less than 5 percent in 1994 versus 11 percent in the previous decade. This moderation is attributable to the decline in the fee-for-service patients and political attention to lowering costs. Pharmaceutical revenues for 1995 increased just 5 percent, but projections are that sales will increase approximately 10 percent to almost $97 billion in 1996. The generic drug market is expected to explode commencing this year as over 51 prescription drug patents expire. By 2000, over one-third of the 300 best-selling brand-name drugs will probably be available in generic form. The number of prescription drugs being converted to over-the-counter (OTC) medications is also on the rise. OTC drug treatment is becoming the preferred way to treat conditions once treatable only through inpatient or outpatient hospital care. Sales of nonprescription medications, a $14 billion market in 1994, are projected to double by 2010.

Research and development. Research continues to be heavily endowed by the sector; investment in research is expected to reach almost $16 billion in 1996, representing almost one-fifth of anticipated sales. The average cost of a successful R&D project is almost $360 million over 12 years, but only 3 of every 10 new medicines put on pharmacy shelves in 1970 earned enough to repay manufacturers’ R&D costs. Hence R&D investment is a fundamental but costly and risky undertaking that companies must pursue if they are to continue to compete in this critical industry sector.

International market and competitiveness. The European Community (EC), the largest importer of U.S. pharmaceuticals, accounts for 50
percent of U.S. exports. While Russia and the other members of the Commonwealth of Independent States are new potential markets for U.S. sales, there are many inhibitors, such as registration, testing, and license regulations. The EC and Japan are enforcing cost-containment programs in their countries—the EC in the form of reference prices and direct government price controls, and Japan in the form of automatic price reductions at various intervals in a product’s life.

This sector is one of the few high-technology industries in which the United States still leads the world. U.S. drug firms generated a substantial excess of exports over imports in 1994. Despite international trade restrictions, U.S. companies remain strong competitors; sales account for over one-third of the $225 billion world pharmaceuticals market.

*Productivity trends.* Many U.S. companies are improving their productivity by reaping material cost efficiencies from major mergers. Others are benefiting from corporate realignment and restructuring. Reportedly, 18 leading drug makers pared some 38,000 jobs from their payrolls in 1993 and 1994. Nevertheless, the pharmaceuticals sector’s manufacturing base, both in the United States and abroad, continues to exceed present requirements. Close to half of its capacity is believed to be idle. Further cutbacks in R&D and general administrative costs are expected to make firms more productive and competitive.

*Challenges*

The pharmaceuticals sector will face several challenges to its future. The most pressing is economically driven: firms must balance the continuing pressure to contain costs with the ability to generate funds for R&D in order to produce high-quality products, which requires innovation and continual appraisal of efficiencies. As Americans age and health care remains focused on managed care, the pharmaceuticals sector will have to make some difficult choices. Managed care, accounting for 50 percent of the pharmaceuticals market, is extremely price conscious, which will drive the cost of drugs down. Although drug-price inflation was curbed for a short period, it is once again creeping up. The FDA, negatively perceived by most domestic drug firms, remains cautious and conservative. However, because of increased pressure, it has improved the new drug review and approval process by reducing the median review time from 23
months to 19 months. However, the lengthy and complicated process still needs to be made more efficient. In addition, environmental issues will continue to challenge firms as new air emission standards and toxic pollution rules are enforced.

**Outlook**

Following a rough period of about two years, the short-term outlook for the U.S. pharmaceuticals industry is positive. However, the road ahead is not without problems.

*Sector growth.* Although the sector is not likely to return to double-digit growth levels anytime soon, the pace will improve steadily in 1996 and the ensuing years as a result of improving price trends, firmer drug markets overseas, and cost benefits from restructuring and cost-containment measures undertaken by leading firms. For the longer term, prospects for growth are mixed. On the positive side, the pharmaceuticals sector remains recession resistant. It continues to benefit from demographic shifts, particularly growth in the elderly population, which tends to use more prescription drugs. Finally, recognition that pharmaceuticals are more cost effective than hospital-based therapies should boost growth. On the negative side, the sector will continue to face considerable pressure from managed care organizations to control prices, the increased use of generic and OTC drugs, weak foreign economies, and uncertain prospects for health care reform. The overall outlook for this sector depends on its level of R&D, expansion of international markets, and, of course, the outcome of U.S. health care reform. Therefore, firms must pursue four strategies to remain global leaders:

1. Continue to restructure to achieve cost savings through synergy in new product development, manufacturing, marketing, and R&D.
2. Increase global markets and overcome price controls, illegal use of patents and copyrights, and foreign regulations.
3. Focus on disease management so that products become an integral part of the buyer's patient care plan.

12-16
4. Use risk-sharing programs with managed care partners so that both are equally at risk for the success or failure of products.

National security requirements. DoD peacetime requirements make up less than 5 percent of the total market for pharmaceuticals. The sector could support national security surge requirements during a major mobilization with little difficulty through stock on hand and minor production surges. However, current stocks of vaccines, antibiotics, and autoinjectors are inadequate for the threat of multiple biological warfare agents that the United States faces.

Government Goals and Role

The federal government’s role in the pharmaceuticals sector should center on achieving the following goals:

1. Reform and streamline the FDA drug approval process consistent with public health requirements; form a partnership with the industry.

2. Support high-priority R&D efforts at academic research centers.

3. Broaden the effect of price competition by allowing advertising.

4. In association with the pharmaceuticals sector, develop agents for prophylactic and post-exposure use against chemical and biological threats.

MEDICAL EQUIPMENT AND SUPPLIES SECTOR

The Medical Equipment and Supplies Sector Defined

The technologically diverse medical equipment and supplies sector is divided into five components: surgical and medical instruments, surgical supplies and appliances, dental equipment and supplies, X-ray apparatuses and tubes, and electromedical equipment. It encompasses equipment and supplies ranging from heart pacemakers and implants to bedpans and bandages. The sector is highly dependent on R&D and has strong linkages with other high-technology industries such as semiconductors, computerized imaging, electronic data transfer,
superconductivity, artificial intelligence, virtual reality, and advanced materials. Approximately 10,000 U.S. firms are involved in manufacturing medical devices, and about three-quarters have fewer than 50 employees. The sector averages employment growth of just over 3 percent; current employment is estimated at over 287,000.

**Current Conditions**

Thirteen of the world’s 20 largest medical technology firms are based in the United States. These firms accounted for nearly $50 billion in sales in 1992, or over half of the global sales of medical equipment and supplies. International demand for U.S. products increased approximately 10 percent to $10 billion in 1995. The sector has consistently produced trade surpluses: $1.6 billion in 1989, $4.5 billion in 1995, and estimated at $5 billion in 1996. In 1993, the industry spent 7 percent of sales on R&D.

U.S. firms are most competitive in areas of medical implants, diagnostic imaging, and patient monitoring. Although initially costly, compliance with International Standards Organization (ISO) 9000 Series standards may result in the most efficient access to the EC market. Trade tariffs cost the industry approximately $6 billion in delays. In the development of information technology, a significant part of this sector, the military leads in R&D and the application of information systems. The advent of telemedicine services linking medical teams throughout the world to U.S.-based hospitals has resulted in fewer medical evacuations, decreased care time by 28 percent, decreased costs, and decreased the medical force footprint overseas. Through 1996, the sector expects a 10 percent growth rate and worldwide sales of medical information systems exceeding $800 million.

**Challenges**

FDA regulations have caused many U.S. firms to relocate their R&D and production to Japan and Germany, where they benefit from lower production costs, more timely development, and proximity to foreign markets. Overseas investment by U.S. medical device firms increased threefold to more than $1 billion from 1989 to 1992.

12-18
European and Asian firms enjoy foreign-government subsidies and preferential export credits; those in Asia are increasing their ability to produce high-technology medical equipment and are moving into markets to compete with U.S. firms. As a result, the share of the $93 billion global market held by U.S. medical equipment and supplies decreased from over half to just 49 percent in 1995.

Because of costly product liability suits, suppliers of crucial materials and components have restricted their products’ use, especially in implants and invasive procedures, a development that threatens future technological innovations. Prime-vendor contracts have decreased the cost of medical equipment and supply for military treatment facilities during peacetime, but the shift to just-in-time production and delivery raises a serious concern about the potential for mobilization, despite industry representatives’ claims that they can meet surge requirements.

**Outlook**

Regulation, the international market, and mobilization surge potential are key areas to watch over the next few years. While not the largest part of the health care industry, the medical equipment and supplies sector will ultimately provide the tools with which low-cost and high-quality health care is provided.

*Regulation.* The FDA currently regulates about 1,800 types of medical devices and estimates that there will be over 100,000 more new and improved devices by 2000. According to several firms, “user fees” paid to the FDA have not substantially shortened its review and approval process. Although the FDA has decreased its average review time for medical devices similar to existing devices by one-fourth, most firms are adopting the “Europe First” production strategy.

The recent U.S.-Japan Framework Agreement calls for an increase in Japan’s purchases of medical devices. A trade promotion group is working to remove regulations to increase exports, and the FDA’s Global Harmonization Task Force should decrease duplication and disparity in regulations in the United States, the EC, Canada, and Japan.
International market. The increases in per capita income and health care spending expected in Argentina, the Association of Southeast Asian Nations, Brazil, Chile, China, Hong Kong, Taiwan, India, Mexico, Poland, South Africa, South Korea, and Turkey will likely translate into heightened international demand for and exports of U.S. medical devices. Development of integrated health care systems, networked to interstate telemedicine services, can increase access to care and decrease costs for the consumer. Also, the United States’s significant competitive advantage in advanced medical research and specialty clinical practice will enhance its opportunities to sell advanced information systems for worldwide telemedicine consultative services.

Mobilization/surge potential. The military’s Global Medical Logistics Operations Center, tasked to identify and set priorities for surge requirements, will ensure support for U.S. first-deployed units while theoretically allowing the production base time to meet full surge requirements. Industry’s position is that it can meet U.S. requirements, but without periodic exercises and notional supplier participation, there is no way to validate this claim.

Government Goals and Role

The government can have a substantial effect on the future ability of the medical supplies and equipment sector to provide the materiel support necessary to sustain U.S. leadership in health care. Four recommendations follow.

1. Privatize product review for Class 1 and Class 2 devices, leaving only the more sophisticated review requirements within the realm of the federal government; motivated by competition, the industry can police itself.

2. Encourage and offer incentives to firms that comply with ISO 9000 Series standards in the interest of U.S. global competitiveness and increased access to overseas markets.

3. Subsidize the development of dedicated national and international telemedicine information systems to enhance military medical readiness and seize market opportunities for U.S. firms in global consultation services.
4. Institute tort reform for product liability to decrease costs to companies and increase the supply of crucial products.

CONCLUSIONS

Health care is an enormous and complex industry that will continue to undergo dramatic changes in the next several years. Managed care will fulfill its mandate to contain costs; yet, as it matures, it will shift its focus from low cost and access to quality of care and the many attendant ethical issues. Horizontal integration and consolidation of health care organizations will continue to promote efficiencies, but the government needs to apply the same strategy within its construct to render beneficiary and entitlement health care efficiently.

Legislative actions are needed to lift antitrust prohibitions that might thwart private sector reorganization for efficiency; transform the FDA’s relationship with industry into a partnership; keep the faith with the military and veteran community to which the government is indebted for its very existence; guarantee the solvency of the Medicare Trust Fund; and protect the U.S. populace as the landscape of health care continues its dramatic change.

The government must also be more proactive in the development of pharmaceuticals for chemical and biological defense preparedness. Finally, the government, business, and the people must adopt a new paradigm emphasizing wellness and prevention as the principal modalities of health care.
BIBLIOGRAPHY


