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Introduction and Summary

No one has yet managed to measure the state of technical knowledge, much less the rate of change of technological knowledge.

—M. Blaug

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Introduction and Summary

Medical devices are a striking feature of U.S. medical care. The past generation has seen the development of a tremendous range of devices whose use has improved or prolonged people's lives and revolutionized medical practice.

Some medical devices have enabled people with what would otherwise be debilitating conditions to improve their functioning. Artificial hip joints, for example, have enabled elderly people with crippling disabilities to walk and live independently. Other devices have extended people's lives. The Scribner shunt has permitted long-term hemodialysis for end-stage renal disease, and the cardiac pacemaker has controlled certain arrhythmias of the heart.

Still other devices have drastically altered medical diagnosis and treatment. Starting with automated blood chemistry analyzers, clinical laboratories have shifted from manual to mechanized procedures, with consequent improvements in the speed, accuracy, and per-unit cost of tests. New imaging devices, such as the computed tomography (CT) scanner, ultrasound, and mammography, often obviate the use of more dangerous, painful, and costly procedures, such as exploratory surgery. Innovations in needles, sutures, and microscopes have greatly improved cataract surgery.

The industry that manufactures medical devices in the United States has grown in tandem with these developments. From less than $1 billion in 1958, industry sales grew to more than $17 billion in 1983. Even after adjustment for inflation, industry sales increased sixfold during that period. About 3,500 companies now employ more than 200,000 people, compared with about 65,000 employees in 1958.

These changes in the medical devices industry have occurred during an era of growing Federal involvement in the U.S. health care system. The Medicare and Medicaid programs, which were enacted in 1965, have greatly increased health insurance coverage, expanded the market for medical devices, and influenced their development and use. Between 1960 and 1982, primarily because of the growth in Federal programs, the share of medical expenditures paid by third parties rose from 45 to almost 70 percent.

The kind of health insurance coverage that has evolved in this country has insulated the buyers and users of medical technologies—mainly physicians, hospitals, and patients—from the cost of many medical services, especially those provided in hospitals. The purpose of health insurance programs such as Medicare is to permit people to obtain needed medical care without risking financial ruin. But there is discretion involved in the use of medical technology, and for many devices, insurance coverage has reduced the importance of cost as one of the few factors that motivate discretion. Some devices, especially those associated with prevention and rehabilitation, are less likely to be covered by insurance than others and may be relatively underused.

The Medical Device Amendments of 1976 significantly expanded the Food and Drug Administration's (FDA) authority to regulate medical devices for safety and efficacy. This and other Federal activities, such as supporting research and development (R&D), regulating the purchase and use of devices by medical providers, and delivering medical care to veterans, have substantially involved the Government in the market for medical devices.

Congressional committees have been interested since the late 1970s in the effect of Federal policies on the companies that manufacture medical devices. There has been particular concern that the newly established Federal regulatory process for devices might be harming technological innovation and small companies. In early 1982, this interest resulted in a request from the Senate Labor and Human Resources Committee to the Office of Technology Assessment (OTA) for an assessment of Federal policies and their effect on the medical devices industry. The Senate Committee on Veterans' Affairs, in endorsing that request, raised issues related to the Veterans Administration (VA) and its role in technology development and procurement. This report has been prepared in response to those requests.

SCOPE OF THE STUDY

Medical devices span a vast array of supplies and equipment, from frequently purchased items with low unit cost, such as bandages and syringes, to infrequently purchased items with high unit costs, such as clinical laboratory and imaging equipment. The definition of a medical device used for this study is taken from the 1976 Medical Device Amendments (Public Law 94-295) to the Federal Food, Drug, and Cosmetic Act. Thus, the term medical device refers to any instrument, apparatus, or similar or related article that is intended to prevent, diagnose, mitigate, or treat disease or to affect the structure or function of the body. This definition excludes drugs, which achieve their effects through chemical action within or on the body. Medical devices are thus one class of medical technology as defined by OTA.[1]

A wide range of Federal policies helps to frame the social, political, and economic context of the market for medical devices. This report concentrates on Federal policies that have the greatest leverage over the kinds of medical devices produced and the price at which they are sold: policies pertaining to payment for health care, support for R&D, regulation of the safety and efficacy of medical devices by FDA, regulation of medical providers, and development and procurement of devices by the VA. Policies that extend to the entire economy, such as those regarding taxation, financial capital, patents, and export control, are excluded from detailed analysis. Although these broader policies may affect medical devices, any options for changing them would require an analysis that reached well beyond the confines of the medical devices industry or this report.

As background to an analysis of Federal policies regarding the medical devices industry, it is important to note that medical care differs from many other products that are bought and sold. Patients often do not have the expertise to evaluate medical technologies and therefore tend to rely on medical professionals for guidance concerning which medical services and devices to use.

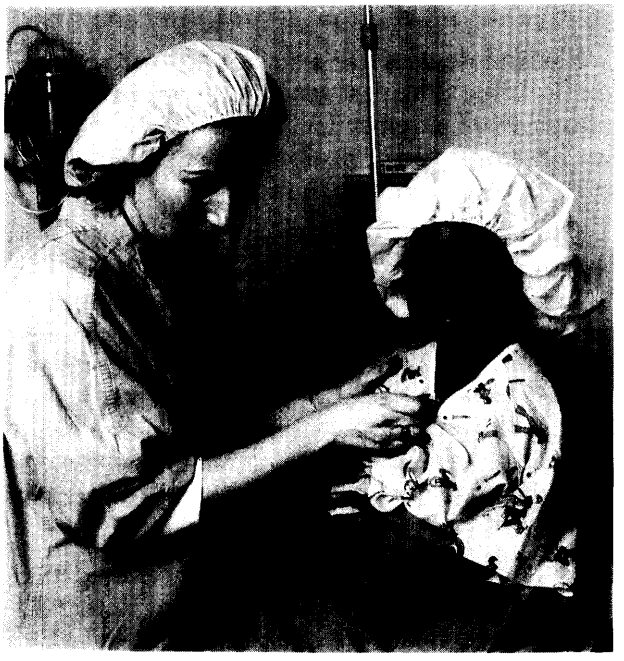

Photo credit: E. /. du Pont de Nemours & Co.

Medical devices encompass abroad range of products, including not only sophisticated, expensive equipment such as computed tomography (CT) scanners, but relatively simple and inexpensive items, such as bandages, syringes, and stethoscopes.

Even medical professionals, however, often lack the expertise to assess sophisticated devices, a fact that underlies the regulatory process established by the 1976 Medical Device Amendments.

Governmental programs such as Medicare reflect the social concern that people be able to obtain some minimum level of care, regardless of their ability to pay. Benefits from the use of some medical devices and other technologies, especially those to prevent and treat infectious disease, include increases in overall levels of health and productivity and are thus greater for society than for the individuals who use the technologies. Governmental public health programs to immunize young children and to test their vision reflect the societal importance attached to the use of such medical technologies.

The remainder of this chapter summarizes the chapters in the body of the report: characteristics of the medical devices industry, payment pol-

[1] IOTA has defined medical technology to include drugs, devices, medical and surgical procedures, and the organizational and supportive systems within which medical care is provided.

icies for health care and devices, FDA regulation of devices, R&D policies related to devices, regulation of providers, and VA policies regarding devices. Appendix A describes the method of conducting the study, and appendix B acknowledges the valuable assistance of several individuals. Appendixes C through I contain material on topics that relate to but are broader than medical devices: innovative activity, patent policy, tax policy, consensus standards in international trade, and foreign regulation of international trade. In addition to this main report, six case studies of specific devices, a technical memorandum on the policies of the VA, and a compilation of inventors' vignettes are being published in connection with this assessment.

SUMMARY

In recent years, a number of problems have been perceived in the cost, efficiency, quality, and innovation of medical devices, all of which relate in some way to Federal health care policies. Since 1978, U.S. expenditures for medical care have been rising at an annual rate of 13 to 16 percent, much faster than the rate of growth in the U.S. gross national product. Although studies have not documented the precise role of medical technology in escalating medical care costs,[2] the adoption of new, sophisticated medical devices, such as CT scanners, and overuse of existing devices, such as automated clinical laboratory analyzers, have often been implicated as contributing factors.

In addition to concerns about the growth or level of health care expenditures, there is concern about whether the benefits gained in improved health or reduced worry have been worth the costs. This concern stems from the prevalence of health insurance, which has changed the balance between costs and benefits for people who buy and use medical technologies. Health insurance, especially Federal programs, was originally intended to make basic medical care accessible to people who might otherwise not be able to pay for it. But recent concerns about costs have muted such distributional issues. And some cost-effective interventions that are not well covered by insurance, especially in preventive and rehabilitative care, are probably underused.

Issues more directly related to medical devices pertain to the quality of products marketed and used, including their safety and efficacy, and to continued innovation in the field. Concerns raised in the early 1970s about fraudulent and hazardous devices culminated in the 1976 Medical Device Amendments to the Food, Drug, and Cosmetic Act. The regulatory process for devices under this act, in turn, has led to concerns about whether such regulation will impede innovation, which has long been a hallmark of the medical devices field, and whether the degree of consumer protection gained is worth the costs.

The Federal policies most prominent and probably most influential in the medical devices field have been those pertaining to health insurance programs, chiefly Medicare and Medicaid, and regulation of marketing. As discussed in this report, however, policies pertaining to R&D, regulation of providers, and veterans have had a substantial role as well.

Federal funding of R&D has been a longstanding Federal activity, mainly within the purview of the National Institutes of Health (NIH). Federal R&D in medical devices, as in other fields, has been intended to stimulate worthwhile innovations that private developers might not otherwise undertake.

Federal and State regulation of providers who purchase and use devices was an early response to rising medical expenditures. Such regulation has had two goals in addition to cost containment: ensuring that people receive care of acceptable quality and ensuring that the distribution of facilities is equitable.

The Federal Government has sought for many years to ensure that veterans have access to medical care, including devices. In carrying out its

[2] See OTA's report *Medical Technology and Costs of the Medicare Program* **(342)** for estimates of technology's aggregate contribution to health, hospital, and Medicare costs.

mandate, the VA has been involved in the full range of activities from R&D through purchase of devices. Because of the many VA medical centers and individual veterans who rely on the agency for devices, the VA has substantial leverage in the market for many devices.

The Federal policies just mentioned are frequently inconsistent, as one would expect of programs that have different, often conflicting, goals: ensuring access to medical care for veterans, elderly and poor people; containing the cost of that care; ensuring acceptable quality of care; protecting public health and safety; stimulating worthwhile innovations; and minimizing the adverse effects of regulation on manufacturers. This report and the remainder of this summary chapter describe and analyze these policies with respect to their effect on the medical devices industry.

A thorough grounding in current and recent Federal policies is particularly important for assessing policy changes that are contemplated or under way. In the area of payment for medical care, tremendous changes are under way that may affect devices. Medicare and some private third-party payers are beginning to pay hospitals a fixed amount set in advance for each case.[3] The adoption of this type of prospective payment method for hospitals may substantially change the market for medical devices and may have implications for the international trade position of U.S. manufacturers. In the process of implementing the new payment system, Medicare is developing policies that will affect medical devices, such as how to pay for capital expenditures and how to ensure use of care that conforms to an acceptable level of quality.

Another important policy area is FDA regulation of medical devices and the balance between protecting the public's health and minimizing the regulatory burden on manufacturers. Major portions of the Medical Device Amendments have yet to be implemented, and implementation of some may not be feasible.

[3]See OTA's technical memorandum *Diagnosis Related Groups (DRGs) and the Medicare Program: Implications for Medical* Technology (341).

Payment Policies for Health Care and Medical Devices

In general, health insurance has stimulated the medical devices field by providing a secure and growing market for the products used in medical care. The effects of insurance on the market for specific devices have varied, depending on the coverage of the devices as benefits, the methods of payment for covered devices, and the financial relationship between the payer and provider of care.

In recent decades, the sales of devices whose use has been well covered by insurance, such as X-ray and electromedical equipment and surgical equipment and supplies, have grown much more rapidly than sales of devices such as dental supplies and ophthalmic goods, for which patients pay a much greater share of the cost. Medicare and most other health insurance programs cover inpatient hospital care more fully than care provided in other locations, such as physicians' offices and ambulatory laboratories. Some kinds of medical care and their associated devices, such as preventive technologies, eyeglasses, and hearing aids, are excluded from coverage or covered to a very limited extent.

Most methods of third-party payment for medical care used in the past have encouraged the adoption and use of medical devices because providers have received more payment with greater use of technology. Physicians and clinical laboratories have been paid by Medicare, some Medicaid, and many Blue Cross/Blue Shield plans for the charges they have billed, subject to limits set according to the fee levels prevailing in the area. Besides stimulating use of technology, these charge-based payment methods have encouraged price increases because insurers have used recently billed charges to set new levels of payment.

Hospitals have traditionally been paid according to the charges they have billed or the costs they have incurred. Traditional hospital payment methods have encouraged the adoption and use of medical technologies and have discouraged price or cost containment.

Recently, however, Medicare and some States have begun to pay hospitals prospectively (i.e.,

with rates set in advance of the time when they apply). In October 1983, Medicare started to pay hospitals a fixed amount per admission that varies across 470 different diagnosis related groups (DRGs). The amount now covers only inpatient operating costs; capital, outpatient, and teaching expenses are continuing to be paid on a cost basis for the time being.

Medicare's DRG payment system provides incentives for hospitals to become much more cost conscious in their adoption and use of medical devices and other resources. Whereas hospital payment methods in the past have encouraged providers and manufacturers to emphasize nonprice factors, DRG payment encourages them to give more prominence to price considerations. Especially favored by DRG hospital payment are devices that lower the cost of a hospital stay by reducing the costs of services provided or by shortening the length of stay. Hospitals are likely to increase group purchasing, standardize their purchases, and require competitive bidding for equipment and supplies.

How DRG rates are changed in future years to reflect changes in prices and technology will affect incentives to develop and use new devices. As payment incentives change, many U.S. device manufacturers will face an adjustment in their product development and marketing strategies, from stressing quality to placing more emphasis on price. However, such a change promises to make U.S. devices more competitive internationally if U.S. companies can more effectively challenge foreign ones on the basis of price as well as technology.

The exclusion of capital expenses from the DRG hospital payment rate fosters the adoption of durable equipment and facilities relative to more labor-intensive services, with inadequate regard for the total benefits and costs of each. Congress has stated its intention of including capital in the prospective rate by 1986. Another problem is that because Medicare's DRG payment system applies only to operating costs for inpatient care, it encourages the adoption and use of devices and other resources in settings such as home health care and hospital outpatient facilities, where DRG payment is not in effect. In some cases, such as surgery for cataract removal and placement of an intraocular lens, it is possible that the movement away from inpatient care may reduce cost and benefit the patient. But DRG payment as now established fosters changes in that direction with inadequate regard for the effects on total costs of care or benefits to patients.

Policy options can address these problems in specific areas of medical care and device use. One approach would be to develop payment methods with financial incentives that are more neutral with respect to physicians' decisions to use devices and that encourage physicians to select the least costly settings of use. Currently, for example, physicians have financial incentives to order and perform clinical laboratory tests in their offices

Photo credit: E. I. du Pont de Nemours & Co.

Automated clinical chemistry analyzers, first developed in the 1950s, improve the speed and accuracy and lower the per-unit costs of laboratory tests on blood samples. Their use, however, has been implicated as a source of rising medical expenditures,

and to use procedures associated with new devices for which high fees may be set. Congress could require Medicare to experiment with payment methods for laboratory and physician services that are mindful of incentives regarding the use of different technologies and locations of care.

Congress could also encourage Medicare to experiment with alternatives to reasonable charge reimbursement of durable medical equipment and to unify payment policies regarding parenteral or enteral nutrition therapy for patients receiving and not receiving home health services. Congress might also consider including capital in Medicare's DRG hospital payment rates, so that hospitals consider the cost of equipment and facilities when making decisions about resources to purchase and use.

The above options that address problems in specific areas of medical care and device use would continue payment methods with basic shortcomings. These methods encourage the use of medical technologies, including devices, because providers are paid more for using more services, and encourage technology use to shift to less restricted, more lucrative locations. The resulting pattern of use of devices and other technologies is unlikely to reflect their relative costs and benefits. A different policy approach would be to move Medicare in the direction begun with DRG payment. Congress could encourage Medicare to set overall limits on the amount to be paid for care and to permit providers and patients to determine the use of specific devices and other technologies within that limit. Such methods of per-case or per-person payment could be applied to physician services, all hospital care, or the full range of medical care.

Regulation of Medical Devices by the Food and Drug Administration

FDA regulation of medical devices was intended to protect consumers' health and safety by ensuring that marketed products are effective and safe. The Medical Device Amendments of 1976 provided more effective methods for dealing with fraudulent devices and attempted to anticipate and minimize the potential risks associated with increasingly sophisticated devices. Congress also intended that the regulation impede innovation in the field as little as possible.

The Medical Device Amendments provided for regulation according to the degree of potential risk posed by a device. Devices that had been marketed before 1976 were to be assigned to one of three classes: Class I, encompassing devices for which general controls such as good manufacturing practices were deemed adequate to ensure safety and efficacy; Class II, an intermediate category, for devices for which general controls were deemed insufficient to ensure safety and efficacy and for which performance standards could be developed; and Class III, for devices that support life, prevent health impairment, or present an unreasonable risk of illness or injury and require FDA approval before marketing.

With limited resources, FDA has set priorities in implementing the 1976 Medical Device Amendments. By early 1984, while the majority of the medical specialty classification panels set up by FDA had completed classification of the device types[4] assigned to them, the others had only proposed classifications. Twenty-seven percent of the device types are in Class I; 64 percent are in Class II; and 8 percent are in Class III.

To obtain FDA's market approval, all Class 111 devices are required to show evidence of safety and effectiveness. However, preamendments Class III devices were given a 30-month grace period before FDA could require such evidence, and FDA may extend that period. Furthermore, until evidence is required for their preamendments equivalents, postamendments devices found "substantially equivalent" to Class III preamendments devices may be marketed without additional proof of safety and effectiveness.

FDA could have expedited the classification of potentially high-risk Class III device types within *each* medical specialty category, thereby starting the grace period after which evaluation of Class

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4 A device type may include all products of a particular type (e. g., cardiac pacemakers) or grouping of devices that are similar (e.g., obstetrics-gynecology specialized manual instruments).

III preamendments devices of these types could begin. Instead, FDA has completed classifications of device types in the medical specialty categories in which most of the device-associated deaths and injuries have been and continue to be reported—e.g., cardiovascular (pacemakers, heart valves) and obstetrics-gynecology (intrauterine devices (IUDs)). Furthermore, in September 1983, FDA expressed its intention of reviewing evidence of safety and effectiveness for 13 preamendments Class III device types that it considers of highest priority. Documentation of safety and effectiveness of products of these types will be needed for their continued marketing.

Another of FDA's priorities has been to implement the premarket approval process for postamendments Class III devices. Guidelines for the procedures by which investigational Class III devices may be tested and evidence gathered had been completed by FDA by 1980.

FDA's premarket approval process has been applied to only a small fraction of the devices marketed after 1976. Postamendments devices that are found substantially equivalent to a device already on the market are automatically classified and regulated like their preamendments equivalent. By the end of fiscal year 1981, only about 300 of the 17,000 products submitted for clearance to FDA after 1976 had been found not substantially equivalent. Although products that are not substantially equivalent are automatically placed in Class III, the manufacturer can petition FDA for reclassification, and some manufacturers have done this.

No performance standards have yet been developed for Class II devices. In practice, therefore, Class II devices have been regulated like Class I devices. In mid-1983, FDA identified 11 priority Class II device types for which it was starting to develop the first performance standards. There is a consensus among industry and consumers that although an intermediate class of devices is advisable, it is impractical for FDA to formulate performance standards for the more than 1,000 device types now designated as Class II.

Other examples of how FDA has set priorities in implementing the Medical Device Amendments can be cited. In 1980, for example, FDA exempted 30 Class I device types in the General Hospital and Personal Use category from the requirement that their manufacturers notify FDA before marketing them. The manufacturers of these device types, which include medical absorbent fibers and specimen containers not represented to be sterile, continue to be subject to FDA registration and surveillance for conformity with good manufacturing practices regarding manufacture, packing, and storage.

Substantial negative effects of the 1976 Medical Device Amendments on the medical devices industry have not been documented to date. Perhaps this result is not surprising, because major sections of the law have not been fully implemented. Patents on medical devices, one indicator of innovative activity, have shown the same trends as before the law, with a higher rate of awards continuing for more sophisticated devices. Manufacturers have reported increases in R&D, sales, and new devices introduced since the Medical Device Amendments, and national data bear out these reports. One-third of the manufacturers responding to a national survey in 1981 had entered the industry after the amendments, and 80 percent were optimistic about business in the field during the next decade. Surprisingly, however, almost half of the survey respondents stated that Federal regulation had been a major problem for them.

The regulations have been more burdensome to small manufacturers than to large ones; smaller manufacturers reported higher regulatory costs per employee than larger ones. Small establishments are particularly important in the medical devices field: about 70 percent of all establishments have fewer than 20 employees, and these small establishments have historically accounted for substantial innovation. The law expressed particular concern about small manufacturers by requiring that FDA establish an office to provide them information. Although large manufacturers in the 1981 survey were much more likely to consider producing a Class 111 device, it is noteworthy

that this situation existed before the amendments as well. Thus, regulation may intensify this pattern but did not originate it.

The amendments have posed the greatest problem for small manufacturers of contact lenses. Because some contact lenses were regulated as drugs before 1976, the newer types of lenses were automatically placed into Class III. Over the years, small manufacturers have found it difficult to enter the market because of the expense of gathering clinical evidence on safety and effectiveness. The public policy goals at odds in this case are preserving the confidentiality of information from manufacturers who have already received approval to market their devices versus increasing the availability of products, with price competition as one result.

Available information does not permit an assessment of consumer protection under the Medical Device Amendments. Although the primary goal of the amendments is to protect public health and safety, there exists no systematic information on the extent to which problems of safety and effectiveness are occurring. Without such information, one cannot assess the effect of FDA's choice of priorities in implementing the law. Information from FDA's present voluntary system of reporting device hazards and from product recalls is inadequate, because it does not indicate the magnitude or frequency of device-related problems. Voluntary reports and recalls for high risks have mostly involved implantable devices, often with electrical problems, and cardiovascular devices. Since 1980, FDA has proposed several approaches to mandatory reporting by manufacturers and expects to issue a revised proposal in 1984.

Congress has several options to improve FDA's regulation of medical devices. Insofar as an overall regulatory approach is concerned, Congress could continue the basic framework and intent of the 1976 law and adjust specific provisions to reflect judgments on the appropriate balance between methods of ensuring safety and effectiveness and the costs of these methods. An alternative strategy would be to revise the law to reflect the status quo with regard to FDA's implementation of the law. A third approach would be to revise the law to exclude certain device types from regulation on the basis of their potential risk.

To address the issue of what evidence of safety and effectiveness should be required for preamendments Class 111 devices, Congress could continue FDA's emphasis on high-priority device types, limit requirements for evidence of safety and effectiveness to device types identified as problems, or encourage FDA to accept a greater range of evidence. To address the issue of when the evidence should be required, Congress could allow FDA to continue its interpretation that the end of the grace period is the *earliest* date that FDA can require evidence, or could establish the end of the grace period as the date when FDA *must* call for evidence. Other congressional options pertain to possible revisions in the substantial equivalence method of market entry for postamendments devices.

There is widespread agreement that performance standards cannot be developed in a timely fashion for all of the devices types that have been placed in Class II. Congress could authorize FDA to use other methods, such as voluntary standards or designation of prescription devices, to regulate Class II devices. Other options include legislating an additional category of Class II devices with different requirements or reclassifying most existing Class II device types into other classes.

Information on risks associated with medical devices is crucial to assessing the 1976 law and its effectiveness in consumer protection. Congress could require FDA to develop better systems for monitoring and providing information on device risks or encourage FDA to selectively apply postmarketing controls to regulate Class II devices.

To help manufacturers, especially small ones, through the regulatory process, Congress could encourage FDA to use publicly available information to down-classify Class 111 devices as soon as possible. FDA might also act as a broker between small firms with promising devices and clinical investigations capable of gathering data to support premarket approval for Class 111 devices.

R&D Policies Related to Medical Devices

The present level of private R&D for medical devices appears to be generally adequate. If industrial R&D in medical devices responds to market opportunities, as it does in other fields, the greater demand for most medical devices because of health insurance would argue that medical devices R&D has been adequately stimulated.

From 1974 to 1980, R&D grew at an average annual rate of about 16 percent in medical devices companies, as compared with a rate of about 12 percent in industry as a whole. In 1980, company-sponsored R&D as a percentage of sales was greater in medical devices than in industry as a whole (2.9 percent compared with 1.6 percent). The percentage of company-sponsored R&D devoted to basic research differed only slightly in medical devices firms and in industry as a whole (3.7 percent compared with 4.1 percent).

Basic research has long been recognized as subject to underfunding by private companies. As research becomes more targeted to development of a commercializable device, however, the case for governmental involvement declines. Federal support has been lower for R&D conducted in medical devices companies than for industrial R&D as a whole. In 1980, the Federal Government funded less than 3 percent of the R&D conducted by medical devices firms, compared with 29 percent of that conducted by industry as a whole.

Under a new Federal program, the Small Business Innovation Research (SBIR) program, NIH and other Federal agencies with sizable R&D budgets must set aside a small percentage for R&D awards to small businesses. Although NIH funds for the SBIR program may come at least partly from funds that would otherwise have gone to basic research and nonprofit institutions, the redistributional implications of the program are not yet clear. The program's solicitation and selection methods merit attention as the funds devoted to this effort increase.

The Orphan Drug Act of 1983 (Public Law 97-414) charges the Federal Government to identify and promote orphan products, including both drugs and medical devices. Devices that are very valuable to potential users, especially in relation to their cost, and that are so costly that it would be unreasonable or inequitable to expect potential users to pay a price sufficient to cover production costs, are by definition worthy of support. However, it is difficult to distinguish between such orphan devices and devices that lack a sufficient market because they are not worthwhile.

Neither the Orphan Drug Act nor regulations have provided sound criteria for identifying orphan devices. By spreading payment across many people, third-party payment may render previous orphan devices and services affordable. Medicare coverage of dialysis for end-stage renal disease is an example. Expensive devices are usually covered by health insurance, and many of those not covered, including preventive and rehabilitative devices, may have a large enough market to permit sale at a sufficiently low price. But the problem of orphan devices may grow as third parties develop increasingly restrictive payment policies.

The Orphan Drug Act makes available to orphan drugs certain benefits (e.g., grants and contracts for clinical testing) that are not available to devices. It appears premature to extend the benefits of the Orphan Drug Act to devices until criteria are developed to distinguish orphan devices from those that are not worth their costs. However, an option would be for Congress to mandate that the Department of Health and Human Services develop criteria and methods for identifying orphan devices.

Regulation of the Providers of Medical Devices

Federal regulation of the providers of medical devices applies mainly to facilities, such as hospitals, but affects physicians indirectly. Such regulation has been undertaken to promote good quality medical care, to control rising costs by evaluating technology adoption and use, and to ensure access to care, including medical devices.

As a condition of receiving funds from Medicare, hospitals have periodically had to review the medical necessity of admissions, extended stays,

and professional services. The reviews performed by Professional Standards Review Organizations (PSROs) focused more on reducing overutilization of inpatient care and on containing costs than on reducing underuse or improving overall quality of care. The emphasis of PSRO review was consistent with the incentives of Medicare's cost-based reimbursement system, which encouraged admissions and days and use of technologies even if there were few benefits. The PSRO review program often led to reductions in admissions and lengths of stay, but when the costs of the program are taken into account, it is not clear that it saved Medicare costs.

Under Medicare's new DRG hospital payment system, hospitals continue to have financial incentives to increase admissions, but they also have incentives to reduce lengths of stay and technology use for inpatients. In order to be paid by Medicare, participating hospitals are required to contract by November 15, 1984, with utilization and quality control peer review organizations (PROS), which will monitor hospital admissions, lengths of stay, and use of technologies. The focus of the PRO review program has changed from that of the PSRO program to reflect the incentives of the new payment system. Like PSROs, PROS will review hospital admissions for overuse. In addition, however, PROS must specifically monitor cardiac pacemaker implantations and reimplantations for possible overuse. PROS will also be more concerned than PSROs were with reviewing short lengths of stay and eventually with underuse of ancillary services.

Medical devices have been most directly regulated through provider regulation by the State certificate-of-need (CON) laws passed in response to the National Health Planning and Resources Development Act of 1974 (Public Law 93-641). These regulations sought to reduce expensive duplication of technology and to ensure access to facilities. By 1983, all States except one (Louisiana) had passed CON laws, but only 23 were in compliance with Federal requirements in 1984. Because of uncertainty about the future of the Federal health planning program, the current continuing resolution stipulates that noncomplying States are not to be penalized.

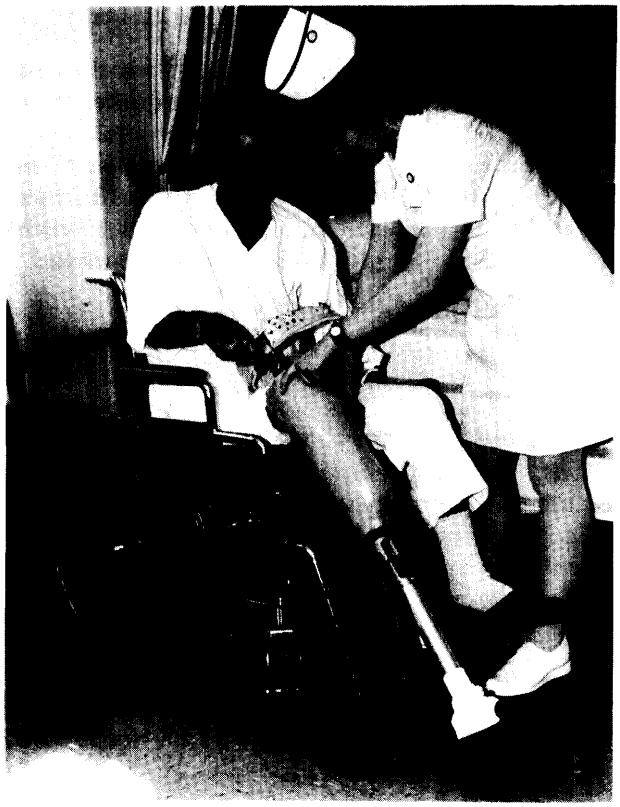

Photo credit: U.S. Veterans Administration

The VA Prosthetics Center was involved in developing most of the prosthetic limbs and fitting techniques used today.

Institutions such as hospitals, nursing homes, kidney disease treatment centers, and ambulatory surgical centers are required to obtain a CON from a State or State planning agency for capital expenditures that exceed a minimum threshold, substantially change bed capacity, or substantially change services. Medical research institutions and health maintenance organizations (HMOs) are given special consideration. Although State laws may cover investments in other locations, only nine States cover equipment purchases for physicians' offices. Few devices have been expensive enough to meet the threshold for CON review, which is now $600,000 for capital expenditures, $250,000 for annual operating costs from a change in services, and $400,000 for major medical equipment. Under the higher limits that have been proposed, fewer devices would come under review.

Evidence on the effect of CON laws on the adoption of medical devices has been inconclusive. Early studies indicated that numbers of hospital beds fell, but investment and assets per bed, which relate to devices, rose. This result is consistent with the CON emphasis on bed supply and the high thresholds for review. There is no indication that CON has controlled medical costs. This finding is not surprising, because a CON agency has no limit on the annual capital expenditures that it may approve and does not consider operating costs, total costs, or use of devices and other technologies. The program was also charged with often-conflicting goals of controlling cost and assuring access, and relied on consensus among decisionmakers with different interests. It is possible, however, that CON procedures may have deterred applications and purchases.

The different incentives for hospitals under DRG payment have implications for CON laws. Some of the change depends on how capital expenses are handled under the DRG system. Under DRG payment, hospitals themselves may increasingly have financial incentives to adopt cost-reducing devices and to examine carefully cost-raising ones. And DRG payment has strengthened the incentive for providers to locate and use equipment and facilities outside of the more constrained inpatient setting in such sites as ambulatory diagnostic centers or physician offices.

Several approaches could be taken to deal with the shortcomings of the CON process. Congress could expand the scope of CON regulation to cover purchases of equipment in all locations, or it could place a limit on the annual level of capital expenditures that CON agencies could approve. Alternatively, Congress could eliminate the CON requirement from the National Health Planning Act.

Veterans Administration Policies Regarding Medical Devices

With 172 medical centers, an annual budget of about $1.3 billion for equipment and supplies, and an R&D budget of almost $160 million, the VA has the potential to exert substantial influence in the market for medical devices, especially the market for rehabilitative devices.

Rehabilitation R&D in the VA is intended to improve the quality of life and to further the independence of physically disabled veterans. The program has stressed developing practical devices and increasing the availability of new devices on the market, especially in prosthetics, sensory aids, and devices related to spinal cord injuries. In the past, the VA Prosthetics Center was involved in developing most of the prosthetic limbs and fitting techniques used today and in demonstrating uses of electric wheelchairs, which were then adopted by manufacturers. In recent years, funding has shifted toward intramural projects, such as rehabilitation R&D centers, which are affiliated with leading engineering schools. Adjusted for inflation, VA funds committed to R&D in rehabilitative devices have been stable or declining.

Responsibility for testing and evaluating medical devices is divided among several VA organizational units. Despite the opportunity that the VA system presents to test devices under actual conditions of use, problems of coordination among units and of adherence to evaluation protocols have hampered field testing of rehabilitative devices at VA medical centers.

The Testing and Evaluation Staff in Hines, IL, is responsible for testing nonrehabilitative devices, mainly standard stock items and smaller medical equipment. These evaluations, which are aimed at validating manufacturers' claims, consist mainly of consumer research efforts. Although VA regulations prohibit explicit comparison of different products, some evaluations of classes of devices have been attempted. These evaluations are used by purchasers of devices inside and outside of the VA system.

Through the VA Marketing Center in Hines, which manages and negotiates the VA's national purchasing contracts, the VA has a substantial position in the markets for medical equipment and supplies. Procurement by the VA Marketing Center has accounted for 5 to 10 percent of the national sales of X-ray, nuclear diagnostic, hemodialysis, and patient monitoring equipment. And the VA has enhanced its market leverage by con-

tracting for the U.S. Public Health Service, the Department of Defense, and other Government agencies. The VA's market power has allowed the VA to obtain favorable prices on medical supplies through its centralized procurement channels.

VA medical centers purchase about 34 percent of their supplies through centralized procurement programs run by the VA or the General Services Administration. However, the medical centers have increasingly made purchases on the open market rather than through central supply channels, their open market purchases having risen from 10 percent of total purchases in the early 1960s to 39 percent in 1982. The VA medical centers' reduced use of central purchasing prevents the VA from taking advantage of lower prices available through greater device standardization and volume purchases.

The patterns of adoption and use of devices by the VA health system are conflicting. Some types of major medical equipment, such as CT scanners, may have been adopted by the VA less than warranted because of political pressures to contain costs. On the other hand, by statute, the provision of prosthetic devices to eligible veterans is unlimited. The VA's plan to set the budgets of medical centers on the basis of DRGs may distribute funds more rationally. This DRG system bears monitoring as it is implemented for issues of quality assurance and treatment of capital expenses.

Congressional options to improve VA policies towards medical devices could focus on specific areas, such as increasing research for longer term development of rehabilitative devices and expanding field testing of rehabilitative devices. Congress could also require the VA to move in the direction of undertaking more comparative evaluations of devices and increasing centralized procurement to take advantage of lower prices.

Conclusions

Since the purpose of the Medical Device Amendments of 1976 is to protect public health and safety, assessment of the law and potential changes in the act or its implementation cannot proceed without systematic information on the hazards associated with device use. Such information is now lacking. Available evidence indicates that the medical devices industry has not been systematically affected by regulation of marketing by FDA, insofar as companies have continued to be profitable and innovative and to enter the field. However, small manufacturers of contact lenses have had particular problems.

The medical devices industry has responded to incentives in the market, especially those from payment policies. As a result, the market has generally rewarded attention to technological sophistication but not to price or cost-consciousness and has fostered the development of devices used in acute care rather than in prevention and rehabilitation. Medicare's new method of paying hospitals on the basis of DRGs has the potential for cost containment and efficiency by providing incentives for providers, and hence manufacturers, to become more cost conscious.

At the same time, Medicare's DRG payment system raises important concerns: assurance of quality of care when providers have a financial incentive to minimize the use of technologies including devices, and possible inefficiencies if devices are purchased and used in locations less financially constrained than hospitals. The appropriate role of the CON program is tied to how capital expenses are handled under the DRG payment system. In any case, issues of access to devices for low-income and sparsely populated areas will remain. And as health insurance coverage and payment become more constrained, the concept of orphan devices may require more precise definition. The VA has the potential to use its leverage in the market, especially for rehabilitative devices, to channel development and commercialization into orphan devices with substantial social need and worth.