EXECUTIVE SUMMARY

THE MEDICAL DEVICE INDUSTRY IN MASSACHUSETTS

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We benefit from medical devices throughout our lives, young and old, healthy and sick. Prenatal development is monitored by ultrasound devices. Sports injuries are diagnosed with MRI machines and fixed with arthroscopic tools. Heart blockages are cleared with angioplasties and drug-coated stents. Devices include the simple and mundane—eyeglasses and thermometers—and stretch to the boundaries of technology—laser scalpels, needles embedded with microprocessors, magnetic resonance imaging machines, and artificial hearts. All are products of the medical device industry.

THE MEDICAL DEVICE INDUSTRY IN MASSACHUSETTS

HOW IS THE MEDICAL DEVICE INDUSTRY DEFINED?

Medical devices have drastically reduced the invasiveness of surgical procedures, shortened recovery times, and lowered medical costs. This trend is continuing at a rapid pace, aided by advances in electronics and biotechnology. For diabetics, for example, internal pumps to monitor and deliver insulin are being developed and may be the closest thing yet to an artificial pancreas. Medical devices and biotechnology developments are becoming more complementary over time, as devices of increasing sophistication and miniaturization are used to deliver new pharmaceutical and biotechnological products. In the future, nano devices may be used to deliver biological agents directly to cancer cells.

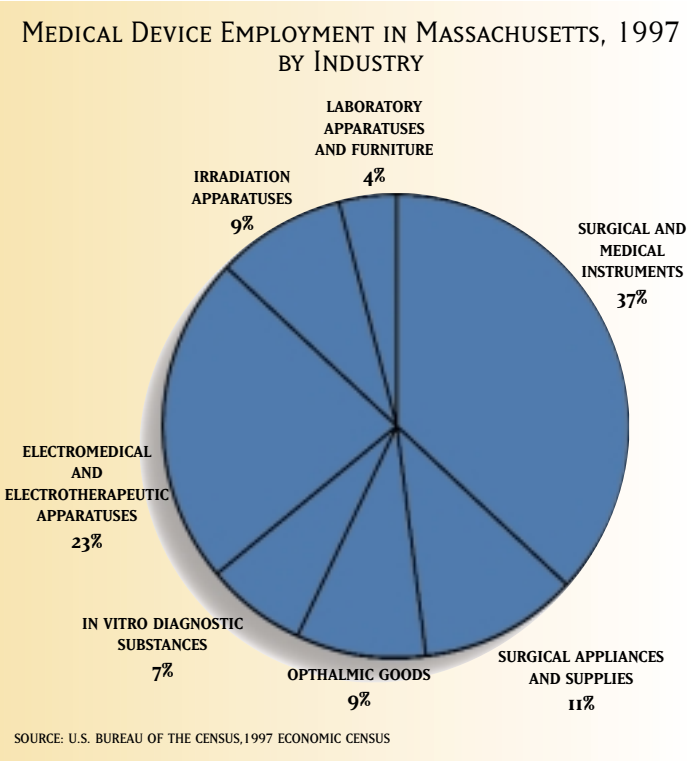
The field of medical devices is the larger part of a medical science sector that supports the health services sector. According to statistics from the 1997 Economic Census (Department of Commerce, 2000a), the medical science sector in Massachusetts was composed of three industry groups:

1. Medical devices consisted of 264 manufacturing establishments with 20,756 employees, a payroll of $989 million, and shipments of $4.0 billion.
2. Pharmaceuticals consisted of 57 manufacturing establishments with 5,612 employees, a payroll of $270 million, and shipments of $1.8 billion.
3. Biotechnology consisted of 282 research establishments with 9,311 employees, a payroll of $589 million, and shipments of $1.5 billion.

Altogether, the medical science sector consisted of 603 establishments with 35,679 workers, a payroll of over $1.8 billion, and shipments of $7.3 billion. This sector is therefore larger in size than several key high-technology sectors. It is larger than computers and office equipment or electronic components (including semiconductors), which had recent employment levels of 25,600 and 31,000, respectively.

OVERVIEW

Massachusetts medical devices contribute to the health and quality of life of persons here in the state and around the world, which may be why so many of the sector's industry executives, scientists, engineers, and production workers chose careers in this field. On a more mundane—but still important—level, the production of medical devices also contributes to the economic health and vitality of the Commonwealth. The purpose of the this report is to enumerate the ways in which the sector affects the state's economy, quantify these effects where possible, and explore current and future trends in the industry.



As a preview, the key findings of the report may be briefly summarized as follows:

- Massachusetts is a leading state in the production of medical devices.
- Medical device workers are more highly skilled, better educated, and better paid than workers in manufacturing as a whole—and in the economy overall.
- Production in Massachusetts is concentrated in surgical and medical instruments, and electromedical and electrotherapeutic instruments.
- Important linkages exist between medical device manufacturers and manufacturers of electronics, producers of precision metal components, and plastics manufacturers.
- Every dollar of output produced by medical suppliers is associated with another 45 cents of goods and services produced by other firms in Massachusetts, and every 100 jobs in medical devices is associated with an additional 79 jobs in the state.
- Employment and wages in medical devices have grown faster than in manufacturing as a whole.
- The aging of the population and growth in worldwide per capita incomes should provide a platform for stable and steady growth of the sector.
- Research, development, and improvements in technology, so vital to this sector, are supported in large part by the state's hospitals and by suppliers of venture capital.
- Federal government regulation by the FDA and the HCFA directly impact the sector's growth and profitability. Indirectly, they impact the quantity and quality of health care services available to the general population.
- In order to foster continued growth in medical devices and to keep Massachusetts in the forefront of the industry, state public policy should focus on providing quality public education, work on lowering the high cost of living in Massachusetts, promote Massachusetts as a place to do business, and develop a liaison with the industry.

MASSACHUSETTS MEDICAL DEVICES IN A NATIONAL CONTEXT: STATE RANKINGS

Using four measures of economic size and impact from the 1997 Economic Census—value of shipments, employment, payroll, and value added (labor plus overhead)—expressed in both absolute size and per capita terms, Minnesota and Massachusetts appear to be the two top states in the production of medical devices. Though Massachusetts does not rank first on any of the eight criteria, it ranks high on all.

In terms of sheer size, California and Illinois rank first and second, respectively, on all four measures. Massachusetts ranks third in value of shipments, fifth in employment, third in payroll, and fourth in value added. Minnesota ranks fourth in value of shipments, fourth in employment, fourth in payroll, and third in value added. New York ranks third in employment and fifth in payroll, and Florida ranks fifth in both value of shipments and value added. In terms of population and overall economic activity, California, Illinois, New York, and Florida are far larger than either Massachusetts or Minnesota, so their higher rankings on measures of absolute size do not indicate a higher concentration of medical device manufacturing. To rank states in terms of concentration of medical device activity, per capita comparisons are appropriate.

In terms of per capita measures, Minnesota ranks first on all four, whereas Massachusetts ranks third in value of shipments, employment, and value added, and second in payroll. Utah, with a small presence in terms of absolute size, ranks second in employment, fourth in value of shipments and value added, and third in payroll. Connecticut, roughly half the size of Massachusetts in absolute size, ranks second in value of shipments and value added, fourth in employment, and fifth in payroll. Illinois ranks fourth in payroll and fifth in employment, and Nebraska ranks fifth in value of shipments and value added.

One way to combine these criteria into a single comparison measure is to assign a rank score to each and form each state's total score as the sum of its rank scores on each category.[1] Using such a simple scheme, Minnesota and Massachusetts rank first and second, respectively, on the four per capita measures and tie for third on the four absolute size criteria. Combining all eight criteria, Massachusetts ranks second behind Minnesota, and ahead of California, Illinois, Connecticut, and Utah.

The thrust of these rankings is confirmed by conversations with industry executives in the Commonwealth. Minnesota and Massachusetts have similar agglomeration economies, with a favorable mix of higher education, medical, and high-tech industries.

Why be concerned about how Massachusetts ranks in measures of medical device production relative to other states? The one-word answer is "exports." Over half the output of the Commonwealth's medical device industry is exported to other states or countries.[2] Because revenues from exports are ultimately received by Massachusetts workers and suppliers of capital to the state's medical device companies, industries that export support the state economy's health and growth. Given the agglomeration economies that are favorable to production of medical devices—that is, the state's concentration in higher education, teaching hospitals, precision production, and electronics—Massachusetts would be expected to rank high in measures of relative production volume, and it does.

Rankings of Top Five Medical Device States by Production Characteristic

Absolute Size					Per Capita			
Value of Shipments	Employment	Payroll	Value Added	Rank	Value of Shipments	Employment	Payroll	Value Added
CA	CA	CA	CA	1	MN	MN	MN	MN
IL	IL	IL	IL	2	CT	UT	MA	CT
MA	NY	MA	MN	3	MA	MA	UT	MA
MN	MN	MN	MA	4	UT	CT	IL	UT
FL	MA	NY	FL	5	NE	IL	CT	NE

Source: U.S. Bureau of the Census, 1997 Economic Census

BASIC CHARACTERISTICS OF THE MASSACHUSETTS AND U.S. MEDICAL DEVICE INDUSTRY

Number and Size of Establishments

According to the 1997 Economic Census, there were 264 manufacturing establishments in the state's medical device industry. These companies employed 20,800 workers, or 3.39 of every thousand residents. Nationally, there were 335,800 employees in 1997, or 1.26 per thousand residents. The industry is thus 2.7 times as concentrated in Massachusetts as in the nation overall. The value of shipments from the state's manufacturing facilities totaled $4.0 billion, with a payroll in 1997 of $1.0 billion.

Aggregate sales are dominated by a handful of large companies. In a 2000 Boston Business Journal survey of the largest 25 medical device employers in Massachusetts, 1999 sales ranged from $2.8 billion for Boston Scientific Corp., the largest company, to $2.5 million for UroMed Corp., the 24th-ranked company in terms of sales.

As of 1998, there were just over two dozen Massachusetts-headquartered, publicly held medical companies, with $3.2 billion in sales. Although the vast majority of companies are privately held and small by comparison (approximately half of these manufacturing establishments were small, employing fewer than 20 employees), they are critically important to the vitality and technological advancement of this industry. One indicator is the scale of venture capital funding, which is targeted to small start-ups. Over the four quarters ending in the third quarter of 2000, venture capital funding received by the state's medical device firms totaled $314 million (PriceWaterhouseCoopers, 2000). To illustrate its magnitude, this investment is roughly equal to the total research and development spending of the 26 Massachusetts-headquartered publicly held medical device companies in 1997 and is nearly twice the amount spent in 1997 on capital expenditures for all medical device manufacturing establishments in the state.

photo courtesy of Smith & Nephew, Inc., Endoscopy Division

Industrial Composition of the Medical Device Sector

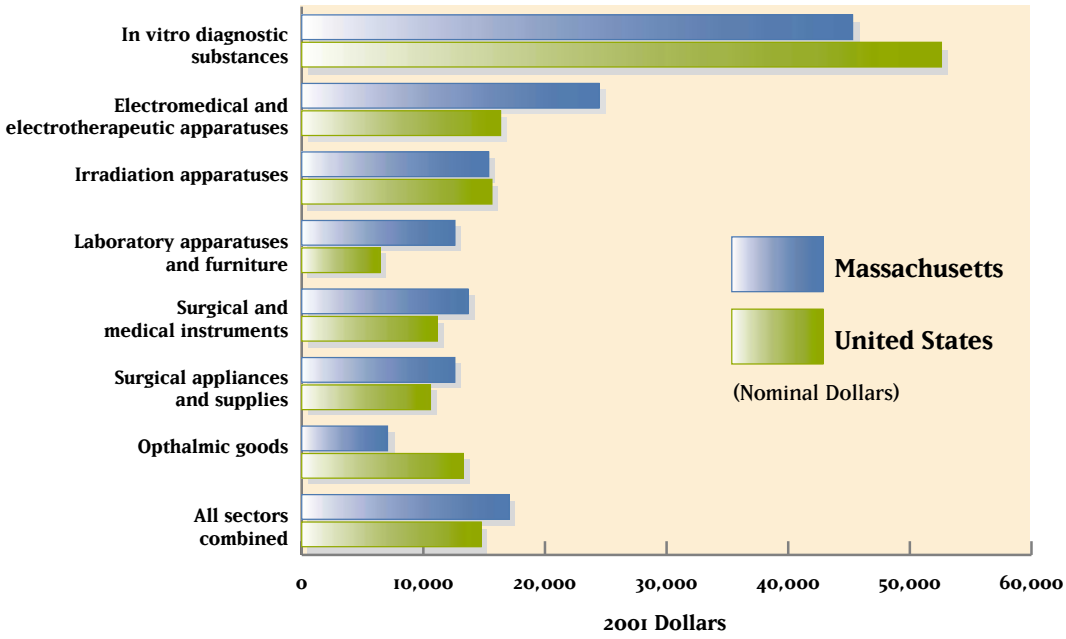
In Massachusetts, the largest industry in the medical device sector, with 37 percent of medical device employment, is surgical and medical instruments. The next largest, with 23 percent of employment, is electromedical and electrotherapeutic apparatuses. In contrast, these two industries comprise 31 percent and 16 percent of national medical device employment, respectively. The relative concentration of these two industries in Massachusetts reflects the state's comparative specialization in precision specialty production and electronics.

The distribution of employment in Massachusetts among the other medical device industries is 11 percent in surgical appliances and supplies, 9 percent in irradiation apparatuses, 9 percent in ophthalmic goods, 7 percent in in vitro diagnostic substances, and 4 percent in laboratory apparatuses and furniture. Relative to the nation as a whole, Massachusetts has a higher proportion of its employment in irradiation apparatuses and a lower proportion in surgical appliances and supplies and in vitro diagnostic substances.

Productivity

Another important industry characteristic is productivity. In conjunction with employment, productivity determines the sector's contribution to the economic product and income it generates. Whereas Massachusetts manufacturing overall is characterized by high productivity relative to the nation, medical devices is a high-productivity sector relative to manufacturing within Massachusetts. According to the 1997 Economic Census (U.S. Department of Commerce, 2000a), productivity in medical devices, measured by the value added per production worker hour,[3] exceeds that of overall manufacturing in Massachusetts by 52 percent, capital expenditures per worker in medical devices exceed those of overall manufacturing in Massachusetts by 26 percent, and the proportion of employees who hold non-

Capital Expenditures per Production Worker, United States versus Massachusetts, 1997



Source: U.S. Bureau of the Census 1997 Economic Census

production-related positions in medical devices exceeds that of overall manufacturing in Massachusetts by 51.6 percent to 38.4 percent.

Value added per production worker hour averaged $129 per worker hour for medical devices in Massachusetts in 1997 versus $115 per worker hour for the U.S. medical device sector. The higher overall productivity in the state partly reflects a relative concentration in higher productivity industries—value added in electromedical and electrotherapeutic apparatuses was $178 per worker hour, for example—but, in addition, the state's workers are more productive than the U.S. average in four of the sector's seven industries. Those industries in which Massachusetts is less productive than the national average—in vitro diagnostics substances, irradiation apparatuses, and ophthalmic goods—account for less than a quarter of employment in the industry.

These differences in productivity between Massachusetts and the nation as a whole may reflect the production of a different combination of products within each of the seven industries as well as different production technologies. In any case, higher productivity in Massachusetts is a common theme across all manufacturing. The state has a comparative advantage in producing products that require higher skills or more intensive use of engineering, and the area of medical devices is no exception (Clayton-Matthews, 1999). In the case of medical devices, higher productivity in Massachusetts versus the U.S. average is attained by higher capital expenditures per worker and a less intense use of production workers relative to non-production workers. Capital expenditures per worker are higher in Massachusetts relative to the nation as a whole in those medical device industries that have higher value added. Less intense use of production workers is probably associated with a more intense use of scientists and engineers (including computer-related engineers).[4] Five of the state's medical device industries have significantly lower proportions of their workforce in production than do their corresponding industries nationwide. For the two exceptions—electromedical and electrotherapeutic apparatuses and in vitro diagnostic substances—the Massachusetts and U.S. proportions are similar.

DEMOGRAPHIC CHARACTERISTICS OF MEDICAL DEVICE MANUFACTURING WORKERS[5]

Who works in the medical device industry, and what are the demographic and economic characteristics—gender, age, race, education, and occupation—of these workers? Does the industry provide good jobs at good wages? The answers to these questions for the nation as a whole are provided by the March Current

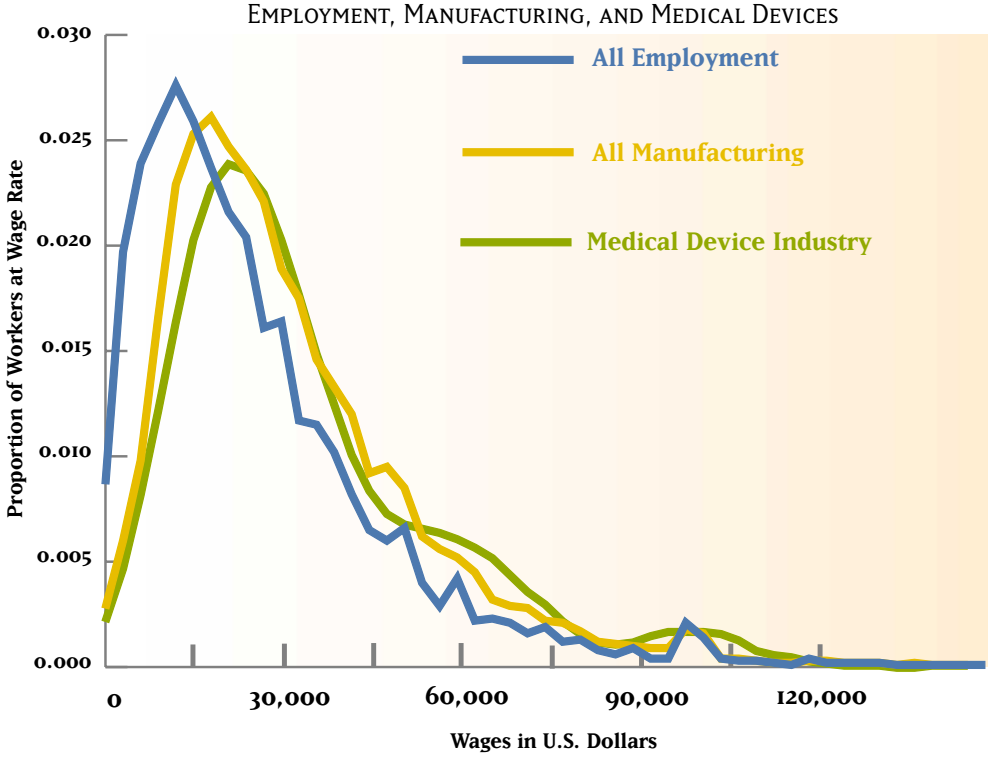
Population Surveys (CPS) for 1994 through 1998.

Occupation

The occupational distribution of medical device workers, like manufacturing, is weighted much more heavily than nonmanufacturing toward machine operators, assemblers, inspectors, and transportation and material-moving equipment occupations. Medical devices, however, employs a smaller proportion of its workers in these occupations than manufacturing overall, 42.6 percent versus 49.9 percent. Medical devices has 37.6 percent of its workforce in executive, administrative, managerial, professional specialty, and technical occupations, much higher than in manufacturing as a whole (25.5 percent) and substantially higher than in all jobs (27.5 percent). This concentration of employment in occupations requiring higher levels of education is associated, as discussed later, with higher levels of educational attainment and higher wages and salaries. The proportion of medical device workers in sales occupations is somewhat higher than in the rest of manufacturing, 5.3 percent versus 3.9 percent. This difference reflects the more intense marketing effort required relative to most other manufacturing industries, because medical device products need to be marketed to individual physicians.

Sales jobs in medical devices, and in manufacturing in general, cannot be compared with the broad sales category for all workers, which make up 14.3 percent of all jobs; the overwhelming majority of jobs in the broader category are in retail sales establishments and are quite different in both character and skill from sales jobs in manufacturing. The proportion of medical device workers in clerical occupations, 10.8 percent, is about the same as in manufacturing overall, 10.0 percent, and less than in the overall economy, 13.1 percent. Not surprisingly, the medical device industry, like manufacturing, employs very few workers classified in service occupations.

U.S. Annual Wage Distribution for All Employment, Manufacturing, and Medical Devices



Source: U.S. Bureau of the Census Current Population Surveys 1994-1998

Education

The proportion of medical device workers who have college educations is substantially higher than that for other manufacturing workers and for all other workers. Just over half, 50.7 percent, of all workers have at least some college education. The proportion of all manufacturing workers with at least some college education is lower, at 44.1 percent, but in medical devices, it is higher, at 57.1 percent. Furthermore, the proportion of workers who have college degrees is higher in medical devices than in the economy as a whole: 9.2 percent of medical device workers have associate's degrees, 18.4 percent have bachelor of arts or bachelor of science degrees, and 12.0 percent have professional or graduate degrees. The corresponding figures for all workers are, respectively, 7.8, 15.8, and 6.3 percent.

Employment Wages, Salaries, and Benefits

Not surprisingly, wages and salaries in medical devices are higher than in the economy as a whole and in manufacturing as a whole. Median annual wages of medical device workers were $30,000 during 1994–1998, according to the CPS, versus $28,000 in manufacturing and $21,243 for all workers.[6] Even though manufacturing workers on the whole have a lower level of educational attainment than all workers, they are generally paid better, which is true at every level of educational attainment. For college-educated medical device workers, this premium is even greater. A medical device worker with an associate's degree earned an average annual salary of $41,145 in 1994–1998, versus $36,916 in all manufacturing and $30,470 in all jobs. A medical device worker with a bachelor's degree earned on average $66,292 per year versus $54,012 in all manufacturing and $44,307 in all jobs; a medical device worker with a professional or graduate degree earned on average $85,101 per year versus $77,477 in all manufacturing and $70,704 in all jobs. These premiums probably reflect the value of specific job training for those with a high school education or less and higher market valuations for degrees related to medical device research and development for those with a college education. Many medical device workers earn salaries that are quite high. One in twenty earned more than $100,000 per year in the 1994–1998 period.

Medical device employers also gave their workers better benefits than employers in manufacturing as a whole. In the 1994–1998 period, 75 percent of medical device workers had employer- or union-provided health insurance versus 71.3 percent of all manufacturing workers and 50.1 percent of all workers. Pension and retirement benefits were also more common in medical device firms, with 62.8 percent of employees participating in employer or union plans versus 57.3 percent of all manufacturing employees and 36.7 percent of all employees.

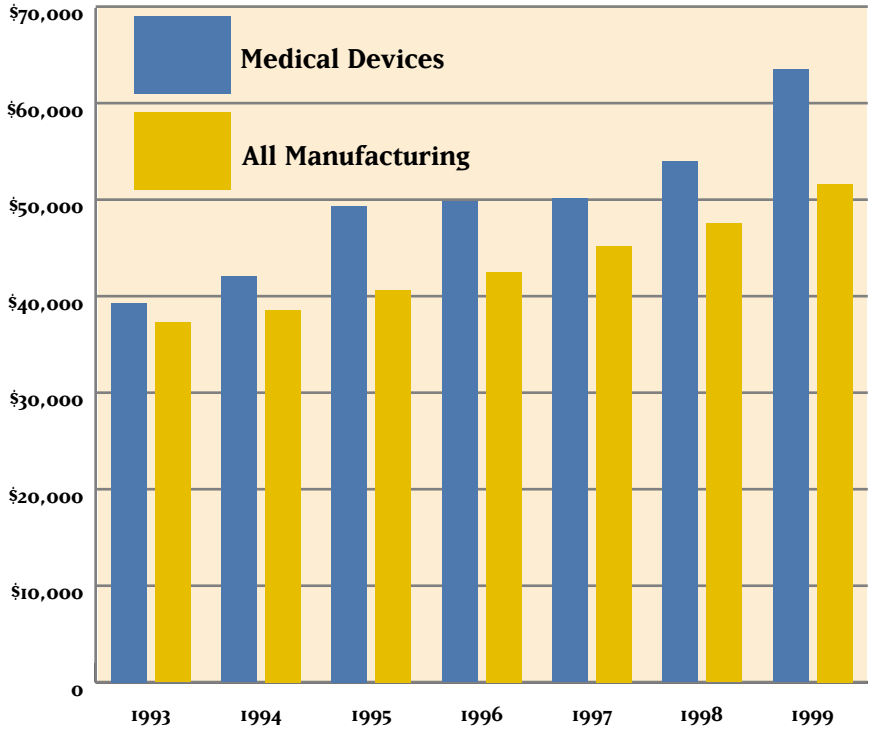
Age, Gender, Race, and Ethnicity

The age distribution of medical device workers is much like that of manufacturing, which in turn is just slightly older than of the nation's workforce as a whole. The median age of medical device workers is 39, with half of workers (i.e., the interquartile spread) between the ages of 32 and 48. This median is the same as in manufacturing as a whole and is slightly older than for all workers, where the median age is 37, and where half of all workers are between 27 and 47 years of age.

The gender distribution in medical devices is more equal than in other manufacturing and is much like that of overall employment. In medical devices, 46.5 percent of workers are women, versus 33.0 percent in all manufacturing and 45.5 percent for all workers.

The racial and ethnic composition of workers in the U.S. medical device industry is different from the rest of manufacturing and the overall workforce in two respects. Although the composition of workers in manufacturing is much like that of the rest of the economy, there are

Massachusetts Annual Wages in Medical Devices and Manufacturing, by Year



Source: Massachusetts Division of Employment and Training, ES-202

proportionately fewer black non-Hispanics and more Asian Americans in the medical device industry. This difference may be related to the industry's concentration in specific metropolitan areas with higher concentrations of Asian Americans and lower concentrations of African Americans than in the nation as a whole.

THE ECONOMIC IMPACT OF MEDICAL DEVICES ON THE MASSACHUSETTS ECONOMY: INDUSTRY LINKAGES[7]

Massachusetts purchasers bought medical devices worth $1.57 billion in 1998 (all dollar figures in this section are in 1992 dollars), of which $1.342 billion, or 85 percent, were purchased from Massachusetts producers. Massachusetts medical device manufacturers sold another $1.441 billion worth of devices to the rest of the United States and worldwide, so the industry exported more than half its output of $2.784 billion. Value added generated by the medical device industry in 1998 was $1.529 billion. This figure represents the contribution of medical devices to the gross state product for 1998.

The economic impact of the medical device industry can be understood by tracing the purchases required to produce its output. For Massachusetts medical devices, the breakdown of purchases is materials, 45 percent; labor, 21 percent; and overhead, 34 percent. The last two components form what economists call value added. Every dollar of a representative firm's output consists of 45 cents' worth of materials and services purchased from other firms plus 55 cents of value that is added by the firm's own production process. This 55 cents is paid out as wages and salaries, benefits, rents, business taxes, profits to investors, depreciation accounts, and research and development.

Of the 45 cents' worth of materials and services purchased from other firms required to produce a dollar of output in medical devices, 22 cents represents purchases from suppliers in the state and 23 cents from suppliers outside the state. Only the former has an economic effect on Massachusetts; the latter represents imports of materials or components from other states and countries.

Industry Linkages: Suppliers

Every $1 million of medical device output requires purchases of $88,900 from the electronic components and accessories industry. Of this amount, $23,600 is from suppliers located in Massachusetts and $66,300 is from out-of-state suppliers. In terms of cost, the electronic components industry is the number one supplier to the medical device industry. Even though only 25 percent of electronic component inputs are purchased from in-state suppliers, this proportion is many times the Commonwealth's electronic components companies' share of the national/international market in electronics, illustrating two important and related aspects of the linkages in the economy. First, medical device manufacturers, some of whom are primarily "testing and assembly" producers, often prefer using local suppliers because it allows greater control and management over their inputs. Such control is very important for products that are specialized, have high value added, or are in early stages of production and testing. Second, linkage is an aspect of the state's agglomeration economy in which the confluence of supplying and purchasing industries in geographic proximity allow more efficient—that is, cheaper—production than would otherwise be the case.

Every dollar of medical device output is associated with, or connected to, an additional 45 cents of output of Massachusetts firms, and every 100 jobs in medical devices is associated with another 79 jobs in Massachusetts.

The close connection between the medical device and electronics industries also adds an element of stability to the electronics industry and therefore to the Massachusetts economy. Most of the output of the electronics industry goes to the supply of consumer electronics and business investment goods, each of which operates on its own cycle of ebbs and flows in demand. The medical device industry adds another important source of demand, thus diversifying the sales base for the electronics industry. Moreover, the long-term outlook for

medical devices is for strong and relatively steady growth, as demand for health services worldwide expands with an aging population and growth in worldwide incomes.

Next in importance is the medical equipment industry itself. For every $1 million of medical devices produced, manufacturers in the state purchase $47,800 of products from other medical device firms. Furthermore, all but $4,300 of these purchases are made from establishments located within the state. Wholesale trade markups of $39,600 constitute the next largest expenditure, and again, most go to in-state suppliers. Other important suppliers include plastics, metal products, transportation and communications services, and real estate.

Purchases of material and service inputs total $450,800 for every $1 million of output, $218,800 from suppliers situated in Massachusetts, and $232,000 imported from suppliers outside Massachusetts. Labor costs total $206,800, and overhead/profit components total $342,400.

Industry Linkages: Customers

Due to intermediate goods production in the medical device industry, the top purchaser is the medical equipment industry itself. Not surprisingly, the health sector is the other major customer of medical devices. For every $1 million of services provided by hospitals, hospitals buy $28,120 worth of medical equipment, instruments, and supplies; for every $1 million of services they provide, health practitioners purchase $25,050 of goods from medical device companies. For nursing and personal care facilities, $11,100 in medical devices are purchased per $1 million of services provided; for ophthalmic goods producers, $19,160; and for health services not elsewhere classified, $46,090. Other sectors are relatively small purchasers of medical device equipment and supplies.

THE ECONOMIC IMPACT OF MEDICAL DEVICES ON THE MASSACHUSETTS ECONOMY: THE MULTIPLIER

The economic effects of the medical device industry go beyond the initial purchases of that industry itself. They extend directly to firms that supply medical device firms, to firms that produce the consumer goods and services purchased by the workers, and to owners of these firms. The ratio of these initial, direct, and induced effects to the initial purchases is the economic impact multiplier. The output and employment multipliers for medical devices in Massachusetts are 1.45 and 1.79, respectively.

These multipliers mean that every dollar of medical device output is associated with, or connected to, an additional 45 cents of output of Massachusetts firms, and every 100 jobs in medical devices is associated with another 79 jobs in Massachusetts. Applying these multipliers to the 1997 value of shipments of $3.996 billion and employment of 20,756 from the 1997 Economic Census, the total effect of the medical device industry on the state's 1997 economy was approximately $5.8 billion and 37,000 jobs. In other words, the industry is associated with that much economic activity in Massachusetts.

That statistic, however, does not mean that every additional dollar of output in medical devices adds $1.45 to total output or that every additional 100 jobs in the sector add 179 jobs to the Commonwealth, at least not in the short term. The expansion in medical devices in the short term comes at some expense to other sectors by bidding material and service inputs and labor away from other sectors of the economy. Even in the long term, the economic impact is somewhat less than these multipliers suggest, because the supply of usable real estate for manufacturing is not unlimited. Nor is there any guarantee that even if the real estate were developed, additional workers would come. The long-term impact multipliers, however, are probably close to 1.45 for output and 1.79 for employment. Even in the short term, there is some additional effect beyond a dollar-for-dollar change in aggregate output for a change in medical devices because of the agglomeration economies already noted. A significant capacity of plastics and metal fabrication

photo courtesy of Smith & Nephew, Inc., Endoscopy Division

manufacturing, for example, would not exist in the Commonwealth in the absence of a medical device industry.

CURRENT AND FUTURE TRENDS

The Commonwealth's medical device industry is growing rapidly. Employment, wages, productivity, and foreign exports in this industry have been growing faster than manufacturing as a whole in Massachusetts, and medical device wages and foreign exports have been growing faster recently in Massachusetts than in the nation.

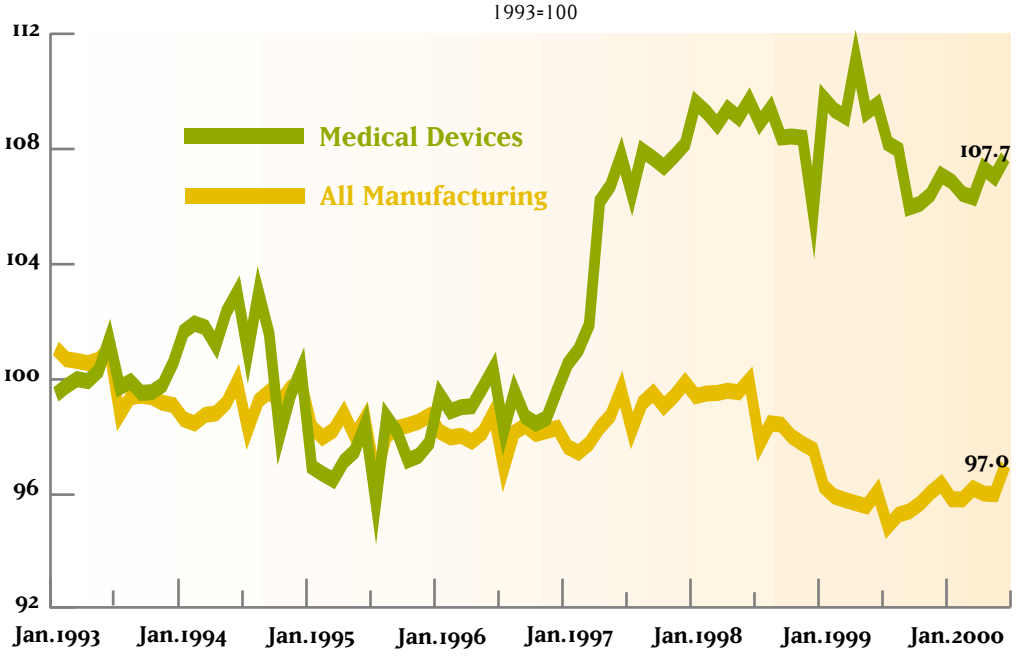
Employment[8]

Since 1993, medical device employment in Massachusetts has been up and down, but with an upward trend. In 1993 and 1994, there were about 16,000 jobs in the medical device industry. During the national and regional slowdown in 1995, employment declined to 15,500. In 1997, employment rose sharply and has since been in the 17,000 to 17,500 range. The strength of the industry is apparent when compared with overall trends in Massachusetts manufacturing employment.

In 1997, aggregate manufacturing employment rose, but it rose faster in medical instruments. Between January 1997 and June 1998, the date of the most recent peak in statewide manufacturing employment, total manufacturing jobs expanded by 2.4 percent, whereas medical device jobs increased 9.1 percent. Then the effects of the Asian financial crisis were felt. Statewide manufacturing employment fell sharply through June 1999 and has remained roughly level since then. In June 2000, overall manufacturing employment was 2.9 percent below its June 1998 peak. The fall in medical device employment, however, was less severe. As of June 2000, employment was only 1.8 percent lower than in June 1998.

Medical device employment trends in Massachusetts and in the United States were similar from 1997 to 1999. Annual average employment grew by 2.6 percent in Massachusetts and by 3.0 percent in the nation as a whole.

MASSACHUSETTS EMPLOYMENT INDEXES,
MEDICAL DEVICES VERSUS ALL MANUFACTURING
1993=100



SOURCE: MASSACHUSETTS DIVISION OF EMPLOYMENT AND TRAINING, ES-202

Wages and Implied Productivity[9]

Employment trends are perhaps the most publicly visible signs of trends in the size of the sector, but they are not the most important. Given productivity growth, even declining employment may be associated with substantial increases in output and earnings generated by that employment. Although there are no reliable data on annual output or productivity measures for medical devices, data are available on a regular basis for wages. Since 1993, total wages paid in Massachusetts medical devices grew every year, rising from $624.8 million in 1993 to

$1,096.5 million in 1999, a 75 percent increase. This growth reflects both increased employment and increased productivity. Because relationships between wages, value added, and output tend to change very slowly over time, this measure is a good proxy for the growth in output during this time. The best proxy for productivity growth available from these data is obtained from the trend in total wages per worker. Average annual wages rose from $39,300 per worker in 1993 to $63,500 per worker in 1999, an annual average growth of 8.3 percent. From 1993 to 1999, average annual wages per worker in all Massachusetts manufacturing grew at the slower annual average rate of 5.6 percent by year, suggesting that productivity in medical devices grew faster than in manufacturing as a whole.

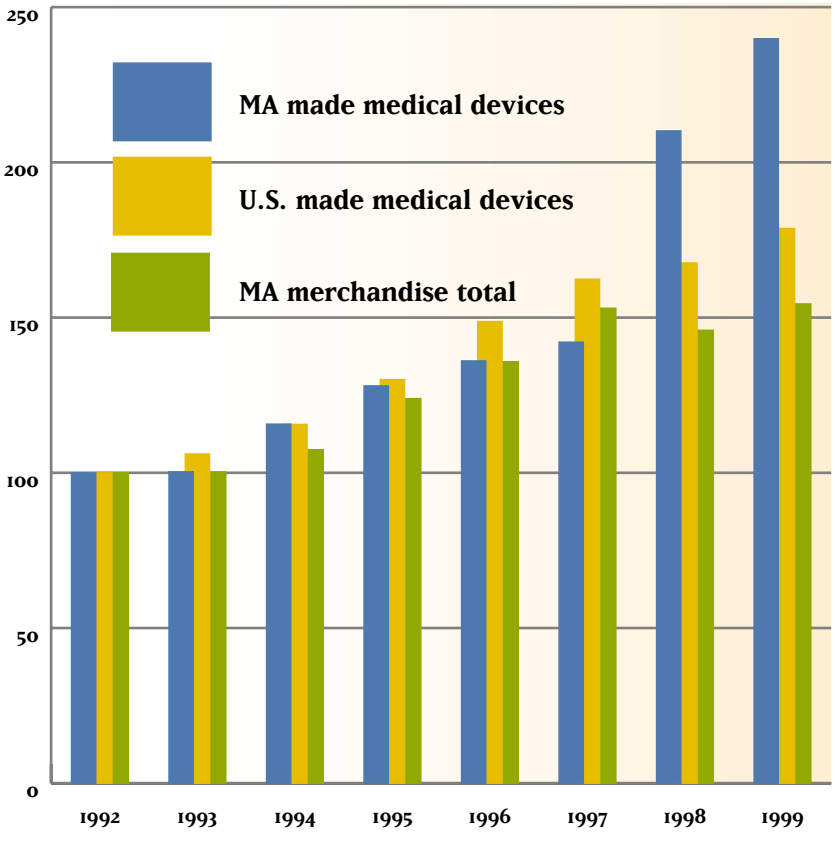
From 1997 to 1999, wages per worker in medical devices rose faster in Massachusetts than in the United States as a whole, at an annual average rate of 12.6 percent versus 6.7 percent, suggesting that productivity growth in Massachusetts may have been higher than in the nation.

Exports

In Massachusetts, the growth in medical device exports to foreign countries has been rapid. Europe has been the chief destination of exports, with demand driven by high incomes relative to most of the rest of the world, but growth in East Asia is accelerating from a much smaller per capita base. As incomes rise in East Asia, the market should expand dramatically.

Medical device exports to foreign countries from Massachusetts manufacturers grew by 42 percent from 1992 to 1997 and then exploded, growing by 69 percent from 1997 to 1999 (U.S. Department of Commerce, 2000b). This 140 percent growth in exports from 1992 to 1998 far exceeded medical device export growth from the nation as a whole over the same period (79 percent) and growth of total Massachusetts merchandise exports over the same period (54 percent).

EXPORTS TO FOREIGN COUNTRIES, INDEXES OF GROWTH
1992=100



SOURCE: U.S. DEPARTMENT OF COMMERCE

Trends in Products, Markets, and Technology[10]

Many trends in medical device applications and demographics favor continued growth of the industry. Some of these trends—for example, the increasing importance of electronics; the confluence of devices, pharmaceuticals, and biotechnology; and the development of new treatments in such areas as the central nervous system—are especially suited to the state's strengths relative to other regions of the country. These trends bode well for Massachusetts emerging as the dominant player in the medical device industry in the coming decades.

The following illustrate the range of trends in products, markets, and technologies in the medical device sector:

- The aging of the baby boom generation should increase demand for med-

ical procedures that use medical devices. The boost in demand will be supported by the sheer number of older Americans, their willingness to spend on health services, and their wealth to support such spending.

- Worldwide growth in economic output and per capita incomes will support increased demand for medical devices, because per capita expenditures on health services should rise with per capita income. This increase in demand favors medical devices made in the United States, because the U.S. Food and Drug Administration (FDA) approval process is widely viewed as the gold standard in establishing a product's safety and effectiveness. These trends are becoming evident in export growth to Europe and (even more) rapidly rising exports to Asia.
- With the aid of medical devices, the trend in surgery is for faster and less invasive procedures that result in less trauma, fewer complications, and shorter recovery times. Thus, efficiency and cost saving in the provision of medical services is tied to increased use and development of medical devices. For example, the typical recovery time for many arthroscopy surgeries has been reduced from five or six weeks to one week.
- Medical devices will increasingly be involved in delivering pharmaceutical products. Recent examples of this trend include (1) the coating of stents with medicines that retard the formation of scar tissue around these stents, (2) the development of needles and pumps that regulate the delivery of insulin in diabetes patients, and (3) the use of silicon skin patches to facilitate the delivery of a wide range of pharmaceuticals.
- Another related trend is in the composition of products that are implanted or used to attach, stitch, staple, or otherwise fix internal parts of the body. The use of metal and other materials for these products is shifting toward bioabsorbable products and to genomic products that trigger the body to repair itself.
- The previous two trends are examples of a more general trend coined "hybrid" technologies. This trend in technology is being mirrored in the industrial organization of the industry, with partnerships between instrument makers and biotechnology firms and, increasingly, with the formation of hybrid firms through mergers and acquisitions.
- The market for cardiology applications continues to grow, but the next big wave is in the neural radiology market. In the 1970s and 1980s, new technology in medical devices focused on the heart; in the early part of the twenty-first century, the focus will be on the brain and central nervous system. Massachusetts should benefit from this trend, especially because MIT has established a new center devoted exclusively to brain research.
- Testing for in vitro and other devices is moving closer to the patient. In the past, such devices were used primarily in the lab. Today, they are frequently used at the hospital bedside. In the future, they will be used more frequently in the physician's office and in the patient's home.
- Reflecting the trend toward direct use by patients, marketing is also increasingly aimed directly at the ultimate consumer. Two examples of devices being marketed directly are home glucose testing devices and defibrillators.
- Electronics are becoming increasingly important. Trends in increased computing power and the smaller size of electronic components are resulting in medical devices that are smaller, mechanically simpler, and therefore more reliable and more powerful in what they can do. This trend plays into one of the state's comparative advantages, because Massachusetts is more concentrated in electromedical equipment than is the nation as a whole.
- There is more manufacturing of products that are produced in high volume outside Massachusetts and outside the country. This trend is common to all manufacturing, not just medical devices. Such products are at the mature end of the product cycle. Typically, these products have large markets, price competition is fierce (and therefore profit margins are low), the production process is fully developed and standardized, and significant cost savings can be achieved by exploiting low-cost labor. The type of manufacturing that remains—and is growing—in Massachusetts involves high research and development

expenditures, prototyping, product design, technical support, and large marketing expenditures. These characteristics are typical of products in the beginning stages of the product cycle.

- Two other manufacturing trends are (1) an increasing reliance on metal injection molding to replace complex metal parts and (2) new data systems being used not only to track inventories and the manufacturing process but also customers' inventories so that, for example, hospitals can maintain a stock of devices for their physicians more efficiently.

VENTURE CAPITAL

By financing the development of new technologies in start-up firms, venture capital funding plays a crucial role in the growth of the medical device industry. In the four-quarter period ending in the third quarter of 2000, Massachusetts firms received a total of $314 million in venture capital financing.[11]

The medical device sector competes with other technology-related sectors for venture capital funding, principally information technology (IT) and biotechnology. The total supply of venture capital funds depends in part on investors' perceptions of the likelihood of successful "liquidity events" such as initial public offerings (IPOs) or acquisitions in which investors recoup their initial outlay plus a substantial profit.

Nationally, the medical device industry received 2.3 percent of all venture capital funding in the four-quarter period ending in the third quarter of 2000 (the most recent period for which data are available). The share of all venture capital funds going to medical device companies is roughly equivalent to that received by biotechnology firms, but well below that received by firms in the IT sector. The relative unattractiveness of medical device companies compared with IT is largely due to the longer time to a liquidity event, especially an IPO outcome, because FDA approval to market a device and Health Care and Financing Administration (HCFA) reimbursement approval needed to make the device profitable are time-consuming processes. The time to profitability of IT ventures is perceived to be much shorter. Medical devices, however, compares favorably with biotechnology on this score, especially if a device can be registered with the FDA as a 510(k) device. A 510(k) device can usually be brought to market quickly, without the need for clinical trials. (See discussion on FDA regulation, page 15.)

The competition of venture capital funds is also affected by the size of the expected return and the risk of a return. By their nature, venture capital investments are risky. The expectation is that many, if not most, ventures will fail to be profitable, but those that are will be profitable enough to compensate for failed ventures. Relative to biotechnology, medical devices are perceived to be less risky, but successes are perceived to be less profitable. The risk advantage derives from the small probability, in pharmaceuticals, of discovering a safe and effective drug relative to the probability, in medical devices, of developing a safe and effective instrument. On the other hand, the payoff to a successful drug is enormous relative to the payoff to a successful device, because once the drug or device is approved for marketing, the marginal costs of producing a drug are typically very small relative to those of producing a medical device.

Massachusetts receives roughly 10 percent of the total supply of venture capital funds for medical devices in the United States, although the amount can vary markedly in the short run. For the four-quarter period ending in the third quarter of 2000, the state received 19.5 percent of all U.S. venture capital funding for medical devices. That figure, however, is inflated by the remarkably successful first quarter of 2000, when Massachusetts medical device companies received $163.3 million, nearly half of the U.S. total. In the next two quarters, Massachusetts companies received $30.9 million and $46.2 million, representing 9.2 percent and 8.7 percent of the U.S. total.

In the amount of venture capital funding it receives, how does Massachusetts fare relative to other areas? In terms of the share of national venture capital financing, the state does well. Its share of national venture capital funding for medical devices, roughly 10 percent, exceeds

what would be expected based on medical device industry measures, such as the share of national shipments, value added, or employment, which is approximately 6 to 7 percent. On the other hand, venture capital funding is concentrated in a handful of regions, including Silicon Valley, New England, San Diego, the Midwest, and the Southeast. Although New England and Massachusetts typically rank second or third, Massachusetts falls far behind Silicon Valley in the share of funds it receives.

THE ROLE OF HOSPITALS AND UNIVERSITIES[12]

Teaching hospitals and universities play an arguably more important role in the growth of the medical device sector than venture capital does. More research is done in these institutions than in private industry, often resulting in the licensing of technology to medical device firms and occasionally in the formation of start-up companies or joint ventures with existing companies. Massachusetts hospitals and universities license and form ventures with companies around the world, but roughly 30 to 40 percent of the deals are with in-state partners.

Although aggregate figures for the effect on the medical device industry are not available, the order of magnitude can be inferred from a couple of examples. The University of Massachusetts receives approximately $200 million in research money annually, more than half of which goes to the UMass Medical Center. The university's Office of Commercial Ventures and Intellectual Property had license revenues of $4 million to $5 million in 2000, and such revenues have been rising at double-digit rates since the office was started in 1995. Roughly three-quarters of these revenues are medical related, and somewhat more than 10 percent are due directly to medical devices.

Universities attribute the rapid growth in the licensing of sponsored research to the Bayh-Dole Act, passed in the 1980s. This legislation allows universities to own the intellectual property created by faculty and research personnel.

Universities attribute the rapid growth in the licensing of sponsored research to the Bayh-Dole Act, passed in the 1980s. This legislation allows universities to own the intellectual property created by faculty and research personnel. Other countries are beginning to emulate this model, an indication of the policy's success in increasing the volume of university-sponsored research.

In another example, Massachusetts General Hospital does $250 million in research annually, with a significant portion related to medical device research in lasers, imaging devices such as MRIs, and other radiology applications. Much of this research is performed in the hospital's Center for Minimally Invasive Technologies. Medical device–related licensing revenues are running at about $2 million per year. The role of such research in other teaching hospitals is similar, although the scale is less than at Mass General or Brigham and Women's, which rank first and second, respectively, in the volume of research performed by Massachusetts hospitals.

GOVERNMENT REGULATION

Medical device manufacturers are subject to regulation from two federal government regulatory bodies, the FDA and the HCFA. These two agencies effectively control whether or not a device may be marketed and, if so, whether or not it will be profitable. The FDA requires that a device be proven to be both safe and effective. Before allowing a device to be reimbursable under federal health programs, including Medicare and Medicaid, the HCFA conducts an additional assessment of effectiveness and requires the device be cost effective.

The Food and Drug Administration (FDA)

Prior to 1976, there was little regulation of medical devices, and new device could be brought to the market rapidly. In May 1976, the FDA promulgated regulations that classified any product currently on the market as a class I, II, or III device. Class I and class II devices were assumed to be safe and effective. Class III devices might require some data in the future to demonstrate safety and effectiveness. Devices in all three classes are called "old" devices.

In 1990, following several years of negotiation in Congress, the Safe Medical Devices Act (SMDA) was

passed, which dramatically increased the federal government's role in regulating the introduction of new devices to the market. At the time, the industry was concerned that the regulations were too complex, that the FDA was understaffed, and that the FDA would not be able to apply the regulations consistently (Olsen, 1993).

Today, when a company wants to bring a new device to the market, it must notify the FDA 90 days prior to marketing. The FDA then determines whether or not the device is new or if it can be considered substantially equivalent to an "old" device.

510(k) Submissions

If the claim is that a device is substantially equivalent to an "old" one, the FDA may require a demonstration of that equivalence. Applications claiming equivalence to an old device are called 510(k) submissions. If a company needs to demonstrate equivalence to an old device, data on clinical human experience are filed in compliance with investigational device exemption (IDE) regulations for investigations performed in the United States. A company must wait for the FDA to issue an order finding substantial equivalence before it can put its device on the market. This route to the market is relatively short, even for most class III devices, unless the FDA calls for safety and effectiveness data for that device.

Premarket Approval Submissions

If the device is new and is not substantially equivalent to an existing product, or if the device is a class III device and the FDA requires a safety and effectiveness demonstration, the company must file a premarket approval (PMA) application. Generally, the company must conduct clinical trials (that comply with IDE regulations if that trial is conducted in the United States). The FDA will approve the PMA application if it is reasonably assured that the device is safe and effective for its intended purpose.

The FDA has wide latitude in its requirements. Almost all PMA routes to bringing a product to market require a clinical study. In recent years, the agency has become more inclined to require randomized control designs, which have resulted in larger clinical trials, more follow-up time, and a longer demonstration period. The FDA can also ban certain medical devices or intervene in the market to restrain use of medical devices it later finds to pose unreasonable risks to the public health.

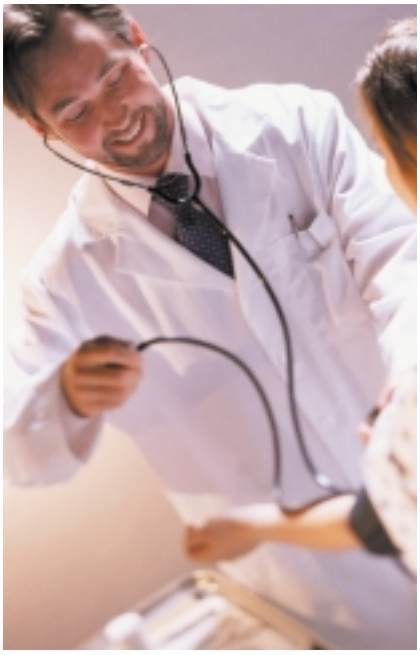
Industry's Perception of FDA Regulation[13]

During the first five or so years of the SMDA, the relationship between the FDA and the medical device industry was adversarial. Since about a year prior to passage of the FDA Modernization Act (FDAMA) and under the new leadership of Dr. Jane Henney, head of the FDA, and Dr. David Feigel, the new director of the Center of Device and Radiological Health (CDRH), the center with whom the devices industry deals, the industry's perception of the FDA has improved markedly. Today the FDA seems open to suggestions from the industry and willing to work with them. It is now easier to use the 510(k) route to bring a device to market, substantially reducing the wait.

Medical device manufacturers agree with the goals of the FDA to provide the public assurance that devices will be safe and effective. The regulatory structure, however, lengthens the product development cycle for "new" products by several years. This process encourages the development of products that can pass as "old" under existing guidelines. Ultimately, that strategy may not be in the best interests of the public, because the opportunity cost of that route is to forgo work on a device that could radically improve the treatment of some disease.

Health Care and Financing Administration (HCFA)

Until about 1995, the major issues involved product approval from the FDA; now the big issue is getting paid for products. Almost all medical devices are marketed to hospitals, doctors, and other health care providers, who are reimbursed by third-party payers, primarily Medicare or Medicaid programs, managed health care providers, and private insurers. These third-party payers add a third criterion for marketability over and above the safety and effectiveness criteria of the FDA: cost effectiveness. In the cost-containment environment that has prevailed since the tightening of Medicare regulations in the 1997 Balanced



Budget Act, the medical device industry perceives an increasingly difficult time in getting approval for reimbursement.

Because of Medicare's predominant role in insuring the vast majority of patients who ultimately receive the services of medical devices, the HCFA plays a paramount role in reimbursement. Private payers usually follow the lead of the HCFA in determining whether or not to approve reimbursement for a device's use.

Industry's Perception of HCFA Regulation[14]

The HCFA is perceived to view technology as a driver of costs rather than a saver of costs. The HCFA's approach to reimbursement coding and classification has been a deep, dark secret. It has also been characterized as a black box. In some cases, due to cumbersome coverage, coding, and payment procedures, the HCFA's reimbursement processes delay the introduction of new medical products from two to five years.

A new procedure that uses a new device may cost more in the short run but save money in the long run because it is more effective, has fewer side effects, has faster recovery times, or requires fewer health care services in the future than what is available today. The HCFA, however, fails to take these long-run savings into account when considering cost effectiveness. Part of the problem is that efficacy review and financial review take place in two different offices within the HCFA, and these offices do not communicate effectively with one another.

The medical device community seems satisfied with the efforts of the Commonwealth's congressional delegation in addressing the problems of federal regulation. Senator Edward M. Kennedy was particularly instrumental in the passage of the FDAMA.

One welcome development has been the recent implementation of a policy that allows reimbursement for clinical trial costs equal to what costs would have been reimbursed had the patient not been in the clinical trial. This new policy substantially reduces the costs of clinical trials.

POLICY CONSIDERATIONS

The following policy recommendations were suggested by industry executives or are more or less logical implications of their suggestions. Most of these recommendations deal with state policy; the main federal policy issues, involving the FDA and the HCFA, were discussed earlier.

- **Promote Massachusetts as a place for high-tech precision manufacturing, such as the manufacture of medical devices.** Other states promote their products. There is a need to offset the lingering perception that Massachusetts is not friendly toward business. It is also not widely known that in some areas of the state, the cost of doing business is competitive with alternative desirable locations in the South and West.
- **Develop a formal liaison between the industry and the state's legislative and executive branches.** Such a relationship could provide a conduit of information between the medical device community and the government to inform the Commonwealth's policy makers about issues pertinent to the industry's health and competitiveness relative to other states. For example, how do tax provisions that affect the industry, such as the research and development and investment tax credits, compare with those of Minnesota, California, Connecticut, Illinois, Utah, and so on?
- **Improve the quality of K–12 education and the community college system.** Massachusetts cannot compete in the production of high-volume standardized "commodities" that rely on low-paid labor to be cost effective. Rather, the state's comparative advantage in manufacturing lies in precision production that requires highly skilled production workers. Such production in turn requires, at a minimum, a good base in mathematics and good communications skills for many production positions and specialized technical training for other positions.

- **Implement more liberal and longer carryover provisions for business tax credits.** Carryover provisions are important for start-ups, which are usually not profitable for five to ten years, especially given the long time to bring new products to market in light of FDA and HCFA hurdles. Under existing tax codes, most carryovers would expire before the firm becomes profitable.
- **Expand the state's research and development tax credit to expenses involved in prototype manufacturing.** Small contract manufacturers have to do a lot of preliminary manufacturing: prototyping the manufacturing process and making alterations to the product and the way it is produced. Often, the production of thousands of units is needed to determine how to produce the product reliably and cost effectively. These expenditures are like research and development costs, but they are not allowed under the Commonwealth's current research and development tax credit guidelines.
- **The high cost of living, especially housing, is an obstacle to growth.** The only consolation is that the cost of living in California is also high. Other regions of medical device activity such as Florida, Minneapolis, and Deerfield, Illinois (home to Baxter Healthcare Corporation, one of the nation's largest medical device companies), however, have a much lower cost of living. While not immediately apparent, the high cost of housing in Massachusetts is partially a result of disparities between municipalities in the quality of their public schools. Massachusetts has some excellent public K–12 systems, but the quality of each school system depends on the individual community. Not surprisingly, housing costs in communities with excellent school systems are astronomical. Improvements in the K–12 system can have a positive effect on housing in addition to educational improvement per se. By making more communities attractive to families with children, medical device companies will find it easier to recruit workers from other regions. In addition, it is more likely that such families will stay in Massachusetts rather than move to another region of the country in search of more affordable housing.
- **Encourage consistent foreign trade regulations.** Obtain transparency and equity for how foreign governments regulate and approve medical devices. Different regulations across countries result in extra expense and time to market. The European Union Device Directive to bring consistency to member countries' approval processes is a helpful approach.
- **Encourage health care reform.** There are some calls for fundamental reform in health care and the way it is financed through the current insurance and managed care system. Without offering specific solutions, one problem is that the incentive for health care providers is to minimize short-run rather than long-run health care costs because the current provider may not be the insurer in the long run. This problem is exacerbated by a system that is essentially private until age 65, at which time the primary insurer changes to Medicare. Other perceptions are that cost containment has gone too far and that forced reductions in manufacturing costs might affect the "safety and effectiveness" of medical devices.

CONCLUSION

Massachusetts medical devices form the largest part of the state's vibrant medical science sector, which also includes pharmaceuticals and biotechnology. Massachusetts is one of the leading states in the production of medical devices, providing good jobs that employ high-paid scientists, engineers, and production workers. Through its economic links with electronics, metal and plastics manufacturers, hospitals, and financial institutions, the medical device sector comprises an important part of the state's high-technology economic base. The long-term outlook for the sector is one of continued growth, supported by growing worldwide demand for health services, and the state's comparative advantage in the development of new technologies. In order to ensure the future success of the medical device sector—and the state's economy as a whole—Massachusetts public policy should focus on providing quality public education, lowering the cost of living in the state (especially housing costs), promoting Massachusetts as a place to do business, and developing an information-sharing liaison with the industry. §

Endnotes

1 For each criterion, first place was assigned five points, second was assigned four points, and so on through one point for fifth place.

2 According to the Regional Economic Models Inc. Massachusetts economic accounts for 1998, exports of the medical device industry (SICs 384 and 385) were estimated to be 1,441 million ($92) and output was estimated to be 2,784 million ($92), for an export to output ratio of .5176. Here, exports refer to sales to the rest of the United States and the world.

3 A firm's value added represents the increase in market value over the cost of materials that occurs as a result of work done at the establishment. We use production worker hours in the denominator of the productivity measure, rather than total worker hours, for two reasons. First, hours for non-production workers are not available. Second, leaving non-production hours out of the denominator essentially treats non-production workers like capital, which is perhaps a better way to analyze the production technology in medical devices.

4 The Economic Census defines production workers as those workers engaged in activities closely associated with production operations at the establishment. Workers excluded from this classification are many, if not most, scientists and engineers engaged in research, development, and product design.

5 The source of the information in this section is the March Current Population Survey (CPS) for the years 1995 to 1999 (U.S. Department of Commerce, 1995–1999). The basic monthly survey is the source of the official national and state resident employment series and is the primary source of the official unemployment rate. The basic monthly survey includes, for each sample individual, information on gender, age, race, and educational attainment. In March of each year, the U.S. Census Bureau asks a set of supplementary questions of each sample individual. These questions ask about the person's income in the prior year by source of income; employment experience in the prior year, including weeks and hours worked; and the industry and occupation of the individual's "major" employer, the employer for whom the person worked the longest in the prior year. The CPS definition of medical devices includes the Standard Industrial Codes (SICs) 384, 385, and 3827 (optical instruments and lenses). This last sector is relatively small, so the CPS definition is close to the sector definition of this study. Unfortunately, the sample sizes are too small to estimate demographic characteristics for Massachusetts medical device workers, so the data are limited to a description of all U.S. medical device workers. Even so, to get a large enough sample for statistical reliability, the analysis here is based on a pooled sample of the last five March CPSs. The sample of 961 medical device workers gives a picture of the workforce for this sector for the calendar years 1994–1998. These workers are compared with the CPS-derived characteristics of manufacturing workers, and of all workers, for the same period. The CPS provides weights to inflate the sample to population totals. The tabulations given use these weights, divided by five, so that totals represent average U.S. population totals for 1994–1998.

6 Annual wages are calculated as follows. For each sample individual, the CPS reports earnings in the prior year from the primary employer (i.e., the employer for whom the individual worked the longest in the prior year) as well as weeks worked last year and number of employers in the prior year. (If the person worked for more than one employer at the same time, only one employer is counted.) For purposes of calculating annual wages, the sample was restricted to those individuals who worked for a single employer in the prior year. Annual earnings were calculated as earnings received from the primary employer divided by weeks worked times 52.

7 The source of information for this section is from Regional Economic Models Inc.'s regional model for Massachusetts (Regional Economic Models Inc., 2000).

8 The sources of information for this section are the state and national data from the "covered" payroll employment series, ES-202 (Division of Employment and Training, 1993–2001, and the U.S. Bureau of Labor Statistics, 2001). The ES-202 provides a time series of employment and wages from 1993 to 1999 for Massachusetts and from 1997 to 1999 for the United States as a whole for the medical device sector defined as SICs 384 and 385. Employment for the medical device sector as measured by the ES-202 is different from that as measured by the 1997 Economic Census, because these two sources use different classification systems for coding industries. The SIC system used for ES-202 data is in the process of being replaced by the new NAICS system, which was used for the 1997 Economic Census.

9 The sources of information for this section are Division of Employment and Training, 1993–2001, and the U.S. Bureau of Labor Statistics, 2001.

10 The sources of information for this section are interviews with executives from medical device companies or related businesses.

11 The data on venture capital in this section are from PriceWaterhouseCoopers's quarterly surveys on venture capital investments (PriceWaterhouseCoopers, 2000).

12 The sources of information for this section are interviews with executives from medical device companies or related businesses.

13 The views expressed in this section are those of executives of medical device and related businesses who were interviewed by the author.

14 The views expressed in this section are those of executives of medical device and related businesses who were interviewed by the author.

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