2.
Characteristics of the Medical Devices Industry

An initial invention, however dramatic, needs many refinements before it is of widespread use. In the commercialisation of technology, the tortoises who carry out these refinements often beat the hares.

—The Economist

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INTRODUCTION

In recent decades, the industry that manufactures medical devices has experienced continuous growth and change. As increased health insurance coverage has expanded purchasing power for medical care, the market for medical devices has grown correspondingly. Growth has occurred not only in the number of companies and employees working in the field, but also in the range of products developed and marketed. Throughout all facets of medical care—from diagnostic imaging and surgery to dentistry and optometry-devices unknown a generation or even a decade ago are now part of routine practice.

This chapter presents the most notable features of the medical devices industry. Besides the dynamic nature of the field, several themes emerge. One is great diversity, both in the medical devices that are marketed and in the companies that make them. Underlying the diversity in products is the high level of innovation. Another theme is that, more than in many other U.S. industries, small firms are particularly important in developing and producing medical devices. U.S. medical devices appear to be quite competitive internationally. Despite the diversity in companies and products, however, the concentration of production in medical devices is about the same as it is in a typical industry, i.e., a relatively small number of companies account for a sizable share of the market.

GROWTH IN THE MEDICAL DEVICES INDUSTRY

During the past 25 years, sales (value of shipments) of products in the five Standard Industrial Classification (SIC) codes representing medical devices have grown from less than $1 billion to more than $17 billion, an annual increase of more than 12 percent (table 1). The growth has been enormous, even when expressed in real dollars, which are intended to take account of price changes[1] (table 2). By 1982, sales in real dollars had reached six times the 1958 level, having risen at an average annual rate of 8 percent.

Growth in sales appears to have accelerated after 1963, a period which coincided with the early years after implementation of the Medicare and Medicaid programs in 1966. From 1966 to 1982, total U.S. expenditures on personal health care in real dollars grew at an average annual rate of 5 percent, and those of the Medicare program alone at 18.5 percent.

Although the start of Medicare and Medicaid was the most notable change, both private and public third parties have accounted for an increasing share of the growing expenditures on personal health care—from 35 percent in 1950 (12 percent private, 12 percent State and local, 10 percent Federal) to 51 percent in 1966 (25 percent private, 12 percent State and local, 13 percent Federal) and 69 percent in 1982 (28 percent private, 11 percent State and local, 29 percent Federal) (128). Although the exact relationship has not been documented, growth in health care expenditures expanded the market for products such as medical devices that are used in the course of delivering that care (see ch. 3).

[1]Like most price indexes, those of the Department of Commerce measure annual price changes in a market basket of devices that were specified in 1972 (369). A common problem with such indexes is their inability to take into account price changes associated with the introduction of new products and with changes in product quality. This problem is particularly acute for medical devices, which have experienced constant and dramatic change.

Table I.—Current Dollar Value of Shipments of Medical Devices by SIC Code, Selected Years 1958-83[a]

Year	Current dollar value of shipments (in millions)						Annual percentage change[b]					
	X-ray and electro-medical equipment (Sic 3693)	Surgical and medical instruments (Sic 3841)	Surgical appliances and supplies (Sic 3842)	Dental equipment and supplies (Sic 3843)	Ophthalmic goods (SIC 3851)	Total	X-ray and electro-medical equipment	Surgical and medical instruments	Surgical appliances and supplies	Dental equipment and supplies	Ophthalmic goods	Total
1983[c]	$5,500	$4,590	$6,140	$1,180	N A[d]	*$17,410*[e]	*21%*	*12%*	*90/₀*	*70/₀*	—	*13%*[e]
1982	*4,557*	*4,114*	*5,642*	*1,107*	*$1,358*	*16,778*	*42*	*30*	*19*	*-16*	*8*	*23*
1981	3,203	3,158	4,734	1,314	1,263	13,672	27	17	23	5	4	18
1980	2,527	2,697	3,861	1,252	1,212	11,549	10	14	14	17	8	13
1977	1,885	1,833	2,597	787	972	8,074	34	14	12	14	11	16
1972 ..., .	444	962	1,454	409	568	3,837	14	15	12	13	6	12
1967	233	475	838	221	426	2,193	13	14	9	11	12	11
1963. .	144	284	597	148	273	1,446	9	17	5	5	7	8
1958	95	130	462	116	194	997	–	—	—	—	—	—

[a]For a listing of products in the Standard industrial Classification (SIC) codes used, see table 7

[b]For inconsecutive years, the compound annual growth rate, the annual rate of growth that makes the present value compound forward to equal a specified future value, was calculated.

$$\%\Delta = [(FV/PV)^{1/N} - 1]\ 100, \text{ where}$$

%Δ = compound annual growth rate
FV = future value (the value at the end of N compounding periods)
PV = present value
N = total number of compounding periods

[c]Preliminary estimates.

[d]NA Indicates information not available.

[e]Total does not include shipments of ophthalmic goods.

SOURCES: U.S. Department of Commerce, Bureau of Industrial Economics, Capital, Energy, and Productivity Studies Division, Washington, DC, unpublished data, January 1984; P. Marcus, U.S. Department of Commerce, Washington, DC, personal communication, January 1984; U.S. Department of Commerce, Bureau of the Census, *1982 Census of Manufactures*, Preliminary Report Industry Series, MC82-I-36F-3(P), MC82-I-38B-1(P), MC82-I-38B-2(P), MC82-I-38B-3(P), MC82-I-38 B-4(P), 1984; and E. Arakaki, U.S. Department of Commerce, Washington, DC, personal communication, August 1984.

Table 2.–Real (1972) Dollar Value of Shipments of Medical Devices by SIC Code[a], Selected Years 1958=83

	Real (1972) dollar value of shipments (in millions)						Annual percentage change[b]					
Year	X-ray and electro-medical equipment (SIC 3693)	Surgical and medical instruments (sic 3841)	Surgical appliances and supplies (Sic 3842)	Dental equipment and supplies (Sic 3843)	Ophthalmic goods (SIC 3851)	Total	X-ray and electro-medical equipment	Surgical and medical instruments	Surgical appliances and supplies	Dental equipment and supplies	Ophthalmic goods	Total
1983[c]	$2,145	$2,050	$2,975	$540	N A[d]	$7,710'	150%	70%	70%	20%		9%[e]
1982	1,858	1,915	2,790	528	$757	7,848	35	21	19	-20	8	18
1981	1,374	1,587	2,337	659	704	6,661	14	6	16	-4	-4	9
1980	1,210	1,494	2,007	685	735	6,131	-1.7	5	7	7	1	4
1977	1,274	1,273	1,649	564	707	5,467	23	6	3	7	4	7
1972	444	962	1,454	409	568	3,837		11	10	12	3	9
1967	311	568	920	234	479	2,512	9	11	7	10	11	9
1963.	217	377	705	160	312	1,771	8	15	5	4	6	7
1958	150	184	549	130	231	1,244	—	—	—	—	—	—

[a]For a listing of products in the SIC categories used, see table 7
[b]For inconsecutive years the compound annual growth rate, the annual rate of growth that makes the present value compound forward to equal a specified future value. was calculated

$$\%\Delta = [(FV/PV)^{1/N} - 1] \ 100$$

where %Δ = compound annual growth rate
FV = future value (the value at the end of N compounding periods)
PV = present value
N = total number of compounding periods

[c]Preliminary estimates.
[d]NA indicates information not available.
[e]Total does not include shipments of ophthalmic goods.

SOURCES: U.S Department of Commerce, Bureau of Industrial Economics, Capital, Energy, and Productivity Studies Division, Washin gon, DC, unpublished data, January 1984; P. Marcus, U.S. Department of Commerce, Washington, DC, personal communication, January 1%34; M. Pavliscak, U.S. Department of Commerce, Washington, DC, personal communication, June 1984; and E. Arakaki, U.S. Department of Commerce, Washington, DC, personal communication, August 1984.

All segments of the medical devices industry have benefited from this growth, some more than others (tables 1 and 2). Most medical devices fall into one of five SIC codes of the Department of Commerce: 3693, X-ray, electromedical, and electrotherapeutics equipment; 3841, surgical and medical instruments; 3842, orthopedic, prosthetic, and surgical appliances and supplies; 3843, dental equipment and supplies; and 3851, ophthalmic goods.[2]

[2]The most comprehensive statistics on the medical devices industry come from the Census of Manufactures, which is conducted by the Bureau of the Census in the Department of Commerce. The data relate to domestic production by U.S. and foreign companies operating in the United States. A complete census is conducted every 5 years and an Annual Survey of a sample in intervening years. Products are categorized by Standard Industrial Classification (SIC) codes. Establishments are assigned to SIC "industries" on the basis of their primary line of business. A 1980 sample of 1,891 manufacturing establishments registered with the Bureau of Medical Devices in the Food and Drug Administration (FDA) fell into 162 SIC codes: 47 percent into the 5 major medical devices codes, which included an average of 177 establishments per code; 37 percent into 25 other SIC codes, each with 10 or more establishments; and 16 percent into 132 other SIC codes, each with fewer than 10 establishments (393). It can therefore be inferred that the establishments in the five medical devices codes account for a greater volume of medical devices production than those in other codes. Nevertheless, data by establishment from the five medical devices SIC codes exclude some establishments and perhaps some devices of multiproduct establishments whose primary products fall into other categories.

In addition, the FDA sample lists 47 establishments in SIC **2831,** biological (393). Diagnostic substances and other biological represent about 45 percent of all shipments in SIC **2831 (363),** but the data are not sufficiently detailed to permit separation of these medical devices products from other biologics, such as blood and vaccines.

SIC data on product shipments, however, include shipments of all medical devices, both those produced by establishments classified in the five medical devices codes and those classified in other codes (393).

In both current and real dollars, sales of products in SIC codes 3693, 3841, and 3842 are much greater than sales of dental equipment and supplies and ophthalmic goods. Not only are sales in these three codes the largest in absolute terms, but they have also experienced the highest rates of increase, especially since 1980. SIC 3842 (surgical appliances and supplies), the category with the greatest sales, has had the highest growth rates, followed closely by SIC 3693 (X-ray, electromedical, and electrotherapeutics equipment). The tremendous growth in SIC 3693 from 1972 to 1977 may be somewhat overstated; in 1977, products misclassified in other SIC codes, mainly 3841, were assigned to 3693 (393).

Increases in the number of companies (firms) and establishments (plants) have paralleled the increases in sales (see table 3). From 1963 to 1982, SIC 3693 (X-ray and electromedical equipment), with annual rates of about 7 and 8 percent respectively, experienced the greatest rate of increase in companies and establishments. During this period, the other four SIC codes had annual increases ranging from about 2 to 6 percent. In all five medical devices codes, firms entering a field have thus exceeded those exiting.

By 1982, employment in the establishments in the SIC medical devices codes had exceeded 200,000, a 68-percent increase over the 129,500 employed in 1972 (see table 4). SIC 3693 (X-ray and electromedical equipment) again had the greatest rates of increase, reflecting the huge growth in production and facilities during the decade.

Table 3.–Growth in Medical Device Companies, Establishments, and Employment by SIC Code[a], 1963-82

	1982 levels (number)			1963-1982 compound annual growth rate		
SIC industry segment	Companies	Establishments	Employment (thousands)	Companies	Establishments	Employment
Total	2,986	3,361	217.5	4.4%	4.0%	5.6%
SIC 3693: X-ray and electromedical equipment	205	260	49.2	7.1	8.2	11.5
SIC 3841: Surgical and medical instruments	767	858	57.4	5.9	5.8	7.3
SIC 3842: Surgical appliances and supplies	1,212	1,365	68.6	4.5	3.5	4.8
SIC 3843: Dental equipment and supplies	435	474	15.4	2.6	2.2	3.5
SIC 3851: Ophthalmic goods	367	404	26.9	3.0	3.0	1.5

[a]For a listing of products in the SIC categories used, see table 7.

SOURCES: U.S. Department of Commerce, Bureau of the Census, *1963* Census of Manufactures, *Industry Series,* MC63-I-36E and MC63-I-38A, 7982 Census of *Manufactures*, Preliminary Report Industry Series (Washington, DC: U.S. Government Printing Office, 1966 and 1984).

Table 4.—Number of Employees in the Medical Devices Industry by SIC Code[a], Selected Years 1958.83 (in thousands)

Year	X-ray and elect ro-medical equipment (SIC 3693)	Surgical and medical instruments (SIC 3841)	Surgical appliances and supplies (SIC 3842)	Dental equipment and supplies (SIC 3843)	Ophthalmic goods (SIC 3851)	Total
1983[b]	50.5	62.0	71.2	16.2	NA[c]	199.9[d]
1982	49.2	57.4	68.6	15.4	26.9	217.5
1981	41.5	54.6	64.9	17.4	26.4	204.8
1980	38.8	51.3	61.8	16.7	29.4	198.0
1977	30.9	43.2	53.9	16.3	30.0	174.3
1972, ...	12.1	34.5	43.9	12.4	26.6	129.5
1967 .....,	7.9	22.0	35.2	10.2	25.6	100.9
1963	6.2	15.1	28.3	8.0	20.3	77.9
1958	5.3	10.3	24.2	7.2	18.2	65.2

[a]For a listing of products in the SIC categories used, see table 7
[b]Preliminary estimates.
[c]NA indicates information not available.
[d]Total does not include employment in the ophthalmic goods industry.

SOURCES: U.S. Department of Commerce, Bureau of the Census, *Annual Survey of Manufactures,* Statistics for Industry Groups and Industries, for years 1958, 1983, 1987, 1972, 1977, and 1981; U S Department of Commerce, Bureau of Industrial Economics, 1984 *US. Industrial Outlook* (Washington, DC U S Government Printing Office, January 1984); and E Arakaki, Department of Commerce, Washington, DC, personal communication, August 1984.

In 1982, about 3,000 companies (firms) with 3,400 establishments (plants) were manufacturing products in the five medical devices SIC codes (table 3). Although this information is the most comprehensive and most recent available, it excludes multiproduct establishments with primary products in other codes. Changes in employment may be used as a proxy for changes in numbers of companies and establishments. In 1980, 4,300 establishments were registered with the Food and Drug Administration (FDA) as being engaged in manufacturing medical devices (197).[3]

Available information from the Internal Revenue Service (IRS) indicates that the profit rates of medical devices companies have exceeded those of many other manufacturing industries (table 5). The IRS category 3845 (optical, medical, and ophthalmic goods) includes some firms that do not produce medical devices (optical instrument and lenses firms) and excludes some that do (if their principal line of business lies in a different category). Nevertheless, this category contains substantial numbers of firms whose principal activity is producing medical devices (26). Sales of electrical medical devices may represent a small fraction—perhaps at the most 10 percent—of IRS category 3698 (other electrical equipment) (26). Annual profit rates for both of these IRS categories ranged from 10 to 18 percent (26), higher than the 9 to 11 percent in total manufacturing. In 1980, firms in IRS category 3845 (optical, medical, and ophthalmic goods), with 12.7-percent return on assets, were more profitable than firms in similar products such as other electrical equipment, chemicals and allied products, and electrical and electronic equipment.[4]

By any of these measures—sales, companies, establishments, employment, or profits—the growth of the medical devices industry has far exceeded that of many other industries (table 6). For example, from 1963 to 1982, the output of the total manufacturing sector grew at an annual rate of 2.7 percent and employment at a 0.5-percent rate. Even chemicals and related products, electrical and electronic equipment, and instruments and related products—sectors with products similar to medical devices—achieved much lower annual increases in output (from 4.3 to 5.6 percent annually) and in employment (from 1.4 to 2.9 percent annually).

[3]As explained in ch. 5, several entities besides medical devices manufacturers also register with FDA.

[4]According to data from Dun & Bradstreet, returns on assets (indicators of profits) for medical devices SIC codes have equaled or exceeded returns on assets in other fields (95). For example, from 1978 to 1980, returns on assets for SIC 3693 (X-ray, electromedical, and electrotherapeutics devices) ranged from 8.8 to 11.4 percent, compared with a range of 9.0 to 9.8 percent for the broader SIC category 36 (electrical and electronic machinery, equipment, and supplies)

Table 5.—Percent Return on Assets[a] for Medical Devices and Selected Industries by IRS Category, Selected Years 1963-80

Year	Optical, medical and ophthalmic goods[b] (IRS 3845)	Other electrical equipment (IRS 3698)	Total manufacturing (IRS 40)	Chemicals and allied products (IRS 17)	Electrical and electronic equipment (IRS 25)
1980	12.70/o	11 .0%0	10.50/0	11.29'0	9.6%
1977	14.5	11.2	10.6	12.5	10.5
1972	13.1	9.6	8.8	11.3	7.7
1967	17.9	13.6	10.2	12.8	11.4
1963	12.1	12.9	10.2	14,0	9.5

[a]Percent return on assets = $\frac{\text{Net income (less deficit) + interest paid}}{\text{Total assets}}$

Net income (less deficit) equals "total receipts less total deductions" less "Interest on State and local Government obligations" plus "constructive taxable income from related foreign corporations."

[b]The IRS minor industry 3845 (optical, medical and ophthalmic goods) includes firms that would declassified in SIC categories 383 (optical instrument and lenses), 364 (surgical, medical, and dental instruments and supplies), and 365 (ophthalmic goods).

[c]The IRS minor industry 3698 (other electrical equipment) includes firms that would declassified inSIC categories 361 (electric transmission and distribution equipment), 362 (electrical industrial apparatus), 364 (electric lighting and wiring equipment), and 369 (miscellaneous electrical machinery, equipment, and supplies).

SOURCES: U.S. Department of the Treasury, Internal Revenue Service, *Sourcebook of Statistics of Income*, for years 1963, 1967, 1972, 1977, and 1980; *Corporation Income Tax Returns*, statistics of income, for years 1963, 1967, 1972, 1977, and 1960; *A General Description of the Corporation Source Book*. publication 647, revised June 1983.

Table 6.—Growth in the Output and Employment of Selected Industries, 1963=82

Industrial sector	1963-82 compound annual growth rate: Output	Employment
Total manufacturing	2.7%	0.5%
Chemicals and allied products	4.3	1.4
Electrical and electronic equipment . . .	5.6	1.5
Instruments and related products	5.6	2.9

SOURCES: U.S. Department of Commerce, Bureau of Industrial Economics, 1984 *U.S. Industrial Outlook* (Washington, DC: U.S. Government Printing Office, January 1984); and V. Kettering, U.S. Department of Commerce, Bureau of Industrial Economics, Washington, DC, personal communication, February 1984.

The Department of Commerce has ranked several of the medical devices SIC codes in the top 50 codes whose growth in 1984 is predicted to exceed their 1972-81 peak: 3842, orthopedic, prosthetic, and surgical appliances and supplies, as 9th; 3693, X-ray, electromedical, and electrotherapeutic equipment, as 11th; 3841, surgical and medical instruments, as 13th; 2831, biological products, as 24th; and 3843, dental equipment and supplies, as 47th (369).

DIVERSITY IN PRODUCTS

The devices included in the five major SIC codes illustrate the wide range of products, not only across codes but within each code as well (table 7). SIC 3842 encompasses disposable supplies such as surgical drapes and adult diapers as well as wheelchairs and prostheses. And together the different codes include pacemakers, hospital furniture, and materials for dentures.

Table 8 presents 1982 sales of selected medical devices to U.S. hospitals. These data are national estimates that IMS America, Ltd., has compiled for OTA from the purchases of a sample of hospitals. Because the IMS data include only devices that are purchased frequently enough to permit statistical estimation, many expensive devices that are rarely purchased by individual hospitals, such as computed tomography (CT) scanners, do not appear.

Almost half of personal health care expenditures in the United States relate to hospital care (128), and hospitals-use devices more intensively than other health care settings. Thus, the data in table 8 give some indication of the size of the mar-

Table 7.—Products in the Medical Devices Industry by SIC Code[a]

SIC code/products
3693—X-ray, electromedical, and electrotherapeutics apparatus
Irradiation (ionizing radiation) equipment, including X-ray, beta ray, gamma ray, and nuclear (medical, dental, industrial, and scientific)
Medical X-ray equipment:
Diagnostic
Therapeutic
Dental X-ray equipment
Industrial and scientific X-ray equipment, excluding gamma and beta ray equipment
X-ray equipment accessories
X-ray tubes (sold separately)
Parts for X-ray equipment (sold separately)
All other ionizing radiation equipment, including gamma and beta ray equipment, excluding accelerators, cyclotrons, etc.
Irradiation (ionizing radiation) equipment, including X-ray, beta ray, gamma ray, and nuclear (medical, dental, industrial, and scientific), n.s.k.
Electromedical equipment, including diagnostic, therapeutic, and patient monitoring, but excluding ionizing radiation equipment
Diagnostic:
Electrocardiograph (ECG)
Electroencephalograph (EEG)
Electromyograph (EMC)
Ultrasonic scanning devices
Automated blood and body fluid analyzers
Audiological equipment
Endoscopic equipment (bronchoscope, cystoscope, proctosigmoidoscope, colonoscope, etc.)
Respiratory analysis equipment
All other diagnostic equipment
Therapeutic:
Pacemakers
Defibrillators
Electrosurgical equipment
Diathermy apparatus (short wave and microwave)
Dialyzers
Ultrasonic therapeutic equipment
All other therapeutic equipment
Patient monitoring:
Intensive care/coronary care units, including component modules such as temperature, blood pressure, and pulse
Perinatal monitoring
Respiratory monitoring
All other patient monitoring equipment
Surgical support systems:
Heart-lung machines, excluding iron lungs
Blood-flow systems
All other surgical support systems
Parts and accessories for diagnostic, therapeutic, monitoring, and surgical support systems (sold separately)
Electromedical equipment, including diagnostic, therapeutic, and patient monitoring, but excluding ionizing radiation equipment, n.s.k.
X-ray, electromedical and electrotherapeutics apparatus, n.s.k., typically for establishments with more than 5 employees
X-ray, electromedical and electrotherapeutics apparatus, n.s.k., typically for establishments with less than 5 employees
3641-Surgical and medical instruments and apparatus
Surgical instruments, including suture needles, and eye, ear, nose, and throat instruments
Orthopedic instruments, such as bone drills and bone plates, excluding eye, ear, nose, and throat instruments
Diagnostic apparatus:
Metabolism and blood pressure
Optical diagnostic
Other
Syringes:
Other than hypodermic
Hypodermic:
Uniquely designed for prebilling
Other
Hypodermic needles
Anesthesia apparatus, instruments, and parts
Oxygen tents
Veterinary instruments
Blood transfusion and intravenous equipment
Blood donor kits
Mechanical therapy appliances and parts thereof
Other surgical and medical instruments
Surgical and medical instruments, n.s.k.
Hospital furniture, excluding beds and chairs
Operating room furniture, including tables, cases, cabinets, etc.
Patient room furniture, including cabinets, overbed tables, desks, dressers, etc., but excluding beds and chairs
Other hospital furniture, excluding operating and patient room furniture, beds, and instruments, but including cases, tables, bassinets, chart racks, backrests, etc.
Hospital furniture, n.s.k.
Surgical and medical instruments, n.s.k. typically for establishments with 5 employees or more
Surgical and medical instruments, n.s.k., typically for establishments with less than 5 employees
3642-Surgical appliances and supplies
Surgical, orthopedic, and prosthetic appliances and supplies
Orthopedic appliances (braces), including parts
Sterilizers (hospital and surgical), excluding dental sterilizers
Surgical dressings:
Bandages, elastic
Bandages, other, including muslin, plaster of paris, etc. but excluding self-adhering bandages
Adhesive plaster, medicated and nonmedicated, including self-adhering bandages
Gauze (absorbent and packing)
Cotton, including cotton balls (sterile and nonsterile)
Other surgical dressings, including sponges, compresses, pads, etc.
Disposable surgical drapes, including O/B and O/R packs
Disposable incontinent pads, bed pads, and adult diapers
Sterile surgical sutures:
Absorbable
Nonabsorbable
Artificial limbs (prosthetic), including parts
Elastic stockings

Table 7.—Products in the Medical Devices Industry by SIC Code—continued

SIC code/products
Elastic braces, suspensories, and other elastic supports
Arch supports and other foot appliances
Corn remover pads, bunion pads, etc.
Breathing devices, excluding anesthetic apparatus but including incubators, respirators, resuscitators, inhalators, etc.
Surgical corsets
Crutches, canes, and other walking assistance devices
Splints and trusses
Wheel chairs
Other surgical orthopedic, and prosthetic appliances and supplies
Surgical, orthopedic, and prosthetic appliances and supplies, n.s.k.
Personal industrial safety devices
Respiratory protection equipment, including gas masks, abrasive masks, canister masks, etc.
Eye and face protection devices, including face shields, hoods, and welding helmets and masks, but excluding industrial goggles and eye protectors
Protective clothing, except shoes
First aid snake bite and burn kits, both household and industrial types
Other personal safety devices
Personal industrial safety devices, n.s.k.
Hearing aids, electronic:
Hearing aids, electronic
Surgical appliances and supplies, n.s.k., typically for establishments with 5 employees or more
Surgical appliances and supplies, n.s.k., typically for establishments with less than 5 employees
3843-Dental equipment and supplies
Dental metals:
Precious
Nonprecious
Dental alloys for amalgams
Teeth, excluding dentures:
Porcelain
Other, including resinous and plastic
Denture-base materials
Dental chairs
Instrument delivery systems (dental units)
Dental hand pieces
Other dental professional equipment, except X-ray
Dental laboratory equipment, including furnaces, casting machines, lathes, benches, polishing units, flasks, blowpipes, presses, etc.
Dental hand instruments (forceps and pliers, brosches, cutting instruments, etc.)
Burs, diamond points, abrasive points, wheels, disks, and similar tools for use with hand pieces
Dental cements and other non-metallic filling materials
Waxes, dental gypsums, and other consumable supplies
Other dental products including sterilizers, but excluding X-ray equipment
Dental equipment and supplies, n.s.k., typically for establishments with 5 employees or more
Dental equipment and supplies, n.s.k., typically for establishments with less than 5 employees
3851-Ophthalmic goods
Ophthalmic fronts and temples
Fronts, finished (with or without decoration), and temples:
Gold filled fronts (full rimmed, semirimless, or rimless)
Aluminum and other base metal fronts
Plastic fronts
Combination fronts
Temples, all types
Ophthalmic fronts and temples, n.s.k.
Glass ophthalmic focus lenses
Single vision lenses (ground and polished and moulded blanks)
Multifocal lenses:
Bifocals
Trifocals and double segments
Glass ophthalmic focus lenses, n.s.k.
Plastic ophthalmic focus lenses
Single vision lenses
Multifocal lenses
Plastic ophthalmic focus lenses, n.s.k.
Contact lenses
Conventional (hard)
soft
Contact lenses, n.s.k.
Other ophthalmic goods, n.e.c.
Centers, oxfords, parts, trims, etc.
Ophthalmic spectacles and eyeglasses (frames and mountings of all types when sold with corrective lenses inserted, with or without decoration)
Industrial goggles, eye protectors, welding circles and plates, mountings, and parts
Sun or glare glasses and sungoggles, ready-made
Nonfocus fashion tinted lenses, plastic and glass
Other ophthalmic goods and accessories (sunglass frames, single readers and magnifiers, holders, gas mask inserts, etc.)
All other ophthalmic goods, n.s.k.
Ophthalmic goods, n.s.k., typically for establishments with 5 employees or more
Ophthalmic goods, n.s.k., typically for establishments with less than 5 employees

[a]n.e.c.—Not elsewhere classified.

n.s.k.—Not specified in kind.

SOURCE: U.S. Department of Commerce, Bureau of the Census, *Annual Survey of Manufactures,* Statistics for Industry Groups and Industries, 1977,

Table 8.–Sales of Selected Medical Devices to Hospitals by SIC Code, 1982

SIC code/product	Sales to hospitals (thousands of dollars)
X-ray and electromedical equipment (SIC 3693)	
X-ray supplies	$ 777,366
Radiological catheters and guide wire	135,878
Pacemakers and other cardiovascular products	***499,999***
Electrosurgical supplies	***48,552***
Surgical and medical instruments (SIC 3841)	
Surgeons' needles	4,310
Blood collection supplies	57,845
Thermometers	31,426
Surgical instruments	294,284
Syringes and needles	331,054
Catheters, tubes, and allied products	235,445
Diagnostic instruments	69,549
Surgical appliances and supplies (SIC 3842)	286,635
Ostomy products	13,842
Surgical packs and parts	174,123
Maternity products	26,869
Dialysis supplies	97,677
Cardiopulmonary supplies	71,176
Sponges	174,768
Bandages, dressings and elastic	172,303
Orthopedic supplies	302,283
Parenteral supplies	701,106
Urological products	198,970
Sterilizer supplies	88,846
Cast room supplies	39,836
Disposable kits and trays	258,317
Respiratory therapy	245,890
Garments, textiles, and gloves	592,254
Ophthalmic goods (SIC 3851)	
Ophthalmic-related products	83,649
Other	
Solutions	***872,985***
Medical supplies	***420,702***
Chemicals and soaps	***153,946***
Paper products	***113,738***
Gases	***109,933***
Underpads	***55,259***
Identification supplies	***31,517***
Elastic goods	***24,932***
Rubber goods	***7,281***
Total	$7,804,545

SOURCE: IMS America, Ltd. Rockville, MD, unpublished data, 1983.

ket for different devices. The highest sales to hospitals are of disposable or nondurable items, such as X-ray supplies and garments, textiles, and gloves. For many of the devices with high sales volumes, hospitals account for only a portion of the overall market. For example, parenteral supplies (for feeding through the bloodstream rather than the alimentary canal) are increasingly used in home health care (see ch. 3) and X-ray supplies are also purchased by independent diagnostic centers and private offices.

Nondurable products are even more prominent among the medical devices in a physician's office. Table 9 lists the medical devices in an office of two internists practicing in an urban setting. Although the office contains basic medical furniture and equipment, most of the products predisposed of after one use.

CHARACTERISTICS OF MEDICAL DEVICES MANUFACTURERS

As indicated by table 3, the number of device companies is almost as large as the number of establishments, with an average of 1.13 establishments per company. This relationship implies that the mode in the medical devices industry is a company with one plant, although larger companies are likely to have multiple plants. This pattern appears to be similiar to that in other industries. For industries in which the four leading firms accounted for between 40 and 64 percent of market sales, a situation similar to that in the medical devices industry, the four leaders in 1963

Table 9.—Medical Devices in an Internist's Office

Medical fixtures:
(examining tables and other fixtures used for medical purposes)
Examination rooms (2)
2 exam tables with stirrups and storage drawers
2 scales
1 treatment cabinet (large)
1 instrument cabinet (small)
1 eyechart
Laboratory
1 X-ray view box
1 test tube rack
1 sedimentation tube rack

Medical office supplies:
1 hanging medical record cabinet (7 tiers)
Manila chart folders
Printed forms for charts
Prescription blanks
Color-coded medical record stickers

Diagnostic supplies:
Cover slides
Urinalysis plastic cups
Wipes for urinalysis clean catch
Table paper
Drapes
Paper tape
Bili lab stix (dip-urinalysis)
K-Y jelly
Pregnancy test kit (urinary chorionic gonadotrophins (UCG)-Beta slide)
Sedimentation tubes, cotton plug
Stains (Gran's iodine-safranin, etc.)
Throat culture plates (oxblood 5%0)
Discs for throat cultures (Taxo A)
Uricults
Hemoccult slides (single and triple)
Electrocardiograph (EKG) -mounting paper, electro pads & electrode cream
Sani vaginal specs size (S)
Sani vaginal specs size (M)
Anoscopes
Cards for tuberculosis test
Sclavotest purified protein derivative (PPD) tuberculosis test
Patient gowns (cloth)
Cloth tape measures
Thermometers
Gonococcus culture plates
Blood drawing tubes
Alcohol wipes
Sterile swabs
Swabs
Baggies
Cervi scrapes
Fixative spray for Pap slides
Slides (wet mount for Pap)
Cardboard containers for Pap slides
Culturettes
Gloves (reed Tru-touch)
Request slips for tests

Therapeutic supplies:
Gauzes
Syringes
Peroxide
Alcohol
Betadine scrub
Cidex 7 (long life)
Drug samples
Bandaids

Diagnostic equipment:
Examination rooms (2)
2 wall model Baumanometer blood pressure instruments (3 cuffs)
1 EKG machine
2 Burton exam lamps
2 otoscope/ophthalmoscope desk units
Laboratory
1 centrifuge (provided on load by lab)
1 microscope
1 incubator

Therapeutic equipment:
Instruments (minor surgical--i.e., scissors, scalpels, tweezers, etc.)

SOURCE: R. Berenson, Washington, DC, personal communication, January 1984.

averaged 4.7 establishments per company and the next four, 2.4 establishments per company; but the remaining firms averaged only 1.08 establishments per company (274).

In 1977, medical devices establishments averaged 54 employees, about the same as the 53 employees per establishment for all manufacturing (362). Within the medical devices field, SIC 3693 (X-ray and electromedical equipment) had the largest average size establishment with 127 employees, and SIC 3843 (dental equipment) had the smallest with 30 employees (table 10).

Despite the growth that has occurred in medical devices in recent years, there have not been major increases in the average size of an establishment. In fact, for all of the major medical devices SIC codes except X-ray and electromedical equipment and dental equipment, average employee size fell from 1972 to 1977; for SIC 3693 (X-ray and electromedical equipment), it rose from 116 to 127 employees per establishment, and for SIC 3843 (dental equipment), it rose from 29 to 30 employees per establishment (362). From these statistics, one may infer that, with the possible exception of X-ray and electromedical equip-

Table 10.–Size of Employment in Medical Devices Establishments by SIC Code, 1977

SIC industry segment	Number of establishments by employee size				Percentage of all establishments by employee size				Average number of employees per establishment
	1-19	20-99	100-499	> 500	1-19	20-99	100-499	>500	
SIC 3693: X-ray and electro medical equipment	117	55	55	16	4890	230/₀	230/₀	7%	127
SIC 3841: Surgical and medical instruments.	412	147	72	19	63	23	11	3	66
SIC 3842: Surgical appliances and supplies	832	213	86	22	72	18	7	2	46
SIC 3843: Dental equipment and supplies	431	85	***30***	***4***	***78***	***15***	***5***	1	30
SIC 3851: Ophthalmic goods	479	98	50		76	15	8	1	47
Total	2,271	598	293	68	70%	19%	9%	2%	54

SOURCE: U.S. Department of Commerce, Bureau of the Census, 1977 *Census of Manufactures, Industry Series, MC 774-38B* and MC 77-I-36F (Washington, DC: U.S. Government Printing Office, June 1980).

ment, growth has occurred through increases in the numbers rather than in the size of establishments.

Although small establishments dominate in number, they account for a much smaller fraction of total shipments in each SIC code (table 11), and these patterns have been extremely stable since 1963 (393). The extremes are again represented by X-ray and electromedical equipment and dental equipment. Among manufacturers of X-ray and electromedical equipment in 1977, establishments with fewer than **50** employees sold only 5 percent of all shipments, but those with **250** or more employees sold 71 percent of all shipments. In the dental equipment field, establishments with fewer than **50** employees sold 21 percent and those with 250 or more employees sold 46 percent of all shipments (393).

There is some evidence that larger medical devices establishments have higher profit rates than smaller ones. One indicator of profits is the difference between the cost of manufacturing a product and the price for which it is sold. Price-

Table il.–Market Share of Value of Medical Devices Shipments by Establishment Size, 1977, 1972, and 1963

SIC industry segment	Total number of establishments	Percentage of market share of establishments by employee size			
		1-49	50-99	100-249	> 250
SIC 3693: ***X-ray and electromedical equipment***					
1977	243	*5%*	*50/₀*	*19%*	*71%*
1972	104	*7*	*4*	20	*69*
1963	58	*6*	11	23	*60*
sic 3841: ***Surgical and medical instruments***					
1977	***650***	12	9	17	62
1972	***506***	11	11	21	57
1963	***294***	15	11	24	39
SIC 3842: ***Surgical appliances and supplies***					
1977	1,153	13	8	16	63
1972	873	12	6	13	69
1963	704	12	8	11	69
SIC 3843: ***Dental equipment and supplies***					
1977	***550***	21	8	25	46
1972	***429***	22	14	24	39
1963	***316***	23	20	21	36
SIC 3851: Ophthalmic goods					
1977	***634***	***15***	***5***	***17***	***63***
1972	***494***	***12***	***7***	***17***	***64***
1963	***229***	***9***	***14***	***12***	***65***

SOURCES: U.S. Department of Commerce, Bureau of the Census, *Census of Manufactures, Industry Series,* for years 1963, 1972, and 1977, as cited in Arthur Young & Co., *A Profile of the Medical Technology Industry and Governmental Policies,* final report, vol. 1, June 30, 1961.

cost margins have been calculated for medical devices establishments with data from the Census of Manufactures (table 12). According to these 1977 data, price-cost margins were highest for the largest establishments. In only two of the five codes, however, did the smallest sized establishments have the lowest margins. A serious problem with these figures is that they overstate profits because they exclude costs such as research and development, advertising, and depreciation (18).

Small companies in the medical devices field have a greater share of industry output than in manufacturing generally (26). Companies with one establishment account for 21 percent of all sales of medical instruments and supplies and 31 percent of optical and ophthalmic goods, but only 16 percent of all manufacturing.[5] Companies with fewer than 250 employees account for 25 percent of all sales of medical instruments and supplies and 32 percent of optical and ophthalmic goods as compared with 18 percent of all manufacturing.

The role of small firms in medical instruments and supplies is comparable to that of those in electronic components in terms of number of establishments or total receipts. If firm size is defined by number of employees, small medical instrument and supply firms with fewer than 250 employees account for a larger share of sales than firms of a similar size in the electronic components industry.

[5]These data are compiled on the basis of companies rather than establishments. The category optical and ophthalmic goods includes products such as telescopes and other optical equipment and hence is broader than medical devices (26).

Table 12.—Price-Cost Margins[a] of Medical Devices Establishments by Employee Size, 1977

		Margins of establishments by employee size			
SIC industry segment	Total	1-49	50-99	100-249	> 250
SIC ***3693:*** X-ray and electromedical equipment	0.406	0.374	0.275	0.398	0.422
SIC 3641: Surgical and medical instruments	0.394	0.326	0.360	0.368	0.420
SIC 3842: Surgical appliances and supplies	0.374	0.307	0.322	0.355	0.400
SIC 3843: Dental equipment and supplies	0.325	0.283	0.360	0.274	0.366
SIC 3851: Ophthalmic goods	0.352	0.350	0.297	0.351	0.357

[a]Price-cost margins are calculated from Bureau of the Census data as follows:

$$\text{Price-cost margin} = \frac{\text{Value added} - \text{Payroll}}{\text{Value of shipments}}$$

"Value added" is the value of shipments minus materials, supplies, energy and certain other input costs. It is defined by the Census on an establishment basis. Price-cost margins are just one measure of profitability; each different measure has advantages as well as disadvantages. Limitations of the price-cost margins are: 1) the margins are overstated proxies of profitability since the Census does not provide directly comparable estimates of non-plant costs such as advertising, central office costs, R&D, and plant depreciation, and 2) the margins are conceptually inadequate because they fail to account for the industry's capital intensity.

SOURCE: U.S. Department of Commerce, Bureau of the Census, 1977 *Census of Manufactures, Industry Series,* as cited in Arthur Young & Co., *A Profile of the Medical Technology Industry and Governmental Policies,* final report, vol. 1, Washington, DC, June 30, 1981.

CONCENTRATION IN THE MEDICAL DEVICES INDUSTRY

The extent to which sales are concentrated among a few companies is a measure of the competitiveness of an industry. Despite the large number of companies, especially small ones, concentration in the five medical devices SIC codes is similar to that in other manufacturing industries. In 1977, the four leading firms accounted for 32 to 45 percent of the sales in the medical devices SIC codes (table 13). By comparison, in 43 percent of all U.S. manufacturing industries during 1972, the four leading firms had 40 percent or more of the total market (274). In the five medical devices codes, the share of the four or eight leading firms has been continually declining since

Table 13.–Market Share of Value of Medical Devices Shipments by Leading Companies, 1977 and 1963

SIC industry segment	Total number of companies	Percentage of market share: 4 leading companies	Percentage of market share: 8 leading companies
X-ray and electromedical equipment (SIC 3693)			
1977	***212***	*32%*	*51%*
1963	*56*	*67*	*79*
Surgical and medical instruments (SIC 3841)			
1977	***575***	***32***	***48***
1963	***256***	***47***	***58***
Surgical appliances and supplies (SIC 3842)			
1977	***1,017***	***38***	***49***
1963	***525***	***49***	***58***
Dental equipment and supplies (SIC 3843)			
1977	***507***	***33***	***46***
1963	***267***	***37***	***50***
Ophthalmic goods (SIC 3851)			
1977	***593***	***45***	***56***
1963	***211***	***53***	***62***

SOURCES: U.S. Department of Commerce, Bureau of the Census, Certsus *of Manufactures, Industry* Series, foryears 1963 and 1977, as cited in U.S. Departmentof Health and Human Services, Food andDrugAdministration, Office of Planning and Evaluation, *Baseline* Data *on the Availability of Medical Devices and /n-Vitro Diagnostic* Products, OPE Study 54, Washington, DC, 1980.

1963, with the possible exception of SIC 3841(surgical and medical instruments), whose ratio increased slightly from 1972 to 1977.

As one would expect, the field appears to be much more concentrated at the level of more specific products. The 1977 Census of Manufactures reported the number of companies with shipments of $100,000 or more for each product line. SIC 3693 (electromedical equipment) had four product types with only one manufacturer, and SIC 3842 (surgical appliances and supplies) had one product with a single manufacturer (393). The products in the other SIC codes, which varied in their level of detail, all had more than one manufacturer, although the numbers were sometimes small.

Data from IMS America on sales to hospitals indicate that a small number of companies have a large share of the market for specific devices (table 14). For sutures, the four leading companies accounted for 99.9 percent of all sales. Market shares over 96 percent were also held by the four leading firms in surgeons' needles, blood collection supplies, and ostomy products (for discharge of intestinal contents or urine through an artificial opening). The lowest market shares of the four leaders, which were still substantial were 43 percent for garments, textiles, and gloves and 45 percent for respiratory therapy devices. Several companies have large market shares across a range of products. As shown in table 15, American Hospital Supply Corp. is one of eight leading firms in 21 of the 28 product categories listed in table 14, and Johnson &Johnson is one in 14.

Prices for products in SIC medical devices codes have increased at rates comparable to those in other manufacturing industries. Available indexes measure price changes in a given market basket of products and do not incorporate new products or changes in old ones, a serious deficiency for the innovative medical devices field. From 1972 to 1982, product prices rose at an annual rate of 9.5 percent for SIC 3693 (X-ray and electromedical equipment), 8 percent for SIC 3841 (surgical and medical instruments), 7.3 percent for SIC 3842 (surgical appliances and supplies), 7.7 percent for SIC 3843 (dental equipment and supplies), and 5.9 for SIC 3851 (ophthalmic goods) (369, 375). During that time, product prices increased at an annual rate of 9.2 percent for all manufacturing industries and 6.7 percent for the electrical and electronic equipment industry.

The lower rate of price increase in ophthalmic goods is consistent with the case of contact lenses. From 1971 to 1982, the list price of soft contact lenses fell 50 percent, a result of competition among fitters as well as among producers of the lenses (275). The mature hard lens sector, which exhibits little evidence of economies of scale in production, has few dominant firms and has been highly price-competitive for several years. In the

Table 14.—Leading Companies' Market Share of Hospital Sales of Medical Devices, 1982[a]

SIC code/product	Sales to hospitals (thousands of dollars)	Percent market share: 4 leading companies	Percent market share: 8 leading companies
X-ray and electromedical equipment (SIC *3693*)			
X-ray supplies	$77,366	89.3%	98.2%
Radiological catheters and guide wire	135,878	85.3	92.8
Pacemakers and other cardiovascular products	499,999	73.7	88.9
Electrosurgical supplies	48,552	58.9	82.6
Surgical and medical instruments (SIC 3841)			
Surgeons' needles	4,310	96.5	99.6
Blood collection supplies	57,845	96.4	99.1
Thermometers	31,426	78.8	92.3
Surgical instruments	294,284	68.1	81.2
Syringes and needles	331,054	65.7	80.9
Catheters, tubes and allied products	235,445	60.8	81.6
Diagnostic instruments	69,549	59.5	77.8
Surgical appliances and supplies (SIC 3842)			
Sutures	286,635	99.9	100.0
Ostomy products	13,842	97.9	99.6
Surgical packs and parts	174,123	84.1	95.1
Maternity products	26,869	82.3	91.8
Dialysis supplies	97,677	81.5	93.3
Cardiopulmonary supplies	71,176	79.4	98.0
Sponges	174,768	78.9	88.4
Bandages, dressings and elastic	172,303	77.3	87.5
Orthopedic supplies	302,283	74.5	83.8
Parenteral supplies	701,106	72.6	91.9
Urological products	198,970	71.7	86,8
Sterilizer supplies	88,846	71.4	83,5
Cast room supplies	39,836	62,2	78.6
Disposable kits and trays	258,317	46.7	63.1
Respiratory therapy	245,890	45.1	67.4
Garments, textiles, and gloves	592,254	43.7	61.1
Ophthalmic goods (SIC 3851)			
Ophthalmic-related products	83,649	67.9	93.3

[a]IMS America's Hospital Supply Index also has nine other categories that are not included here: elastic goods, identification supplies, solutions, chemicals and soaps, gases, medical supplies, paper products, rubber goods, and underpads.

SOURCE: IMS America, Ltd., Rockville, MD, unpublished data, 1983.

Table 15.—Eight Leading Companies in Hospital Sales of Medical Devices in Three or More Product Categories, 1982[a]

Company	Number of product categories in which company is one of eight leading companies	Company	Number of product categories in which company is one of eight leading companies
American Hospital Supply Corp.	21	Brunswick Corp.	4
Johnson & Johnson	14	Lilly	4
Colgate-Palmolive	8	Cordis/Cordis Dow.	3
Baxter-Travenol	7	Dart Industries	3
Bard, C.R.	6	Independent Lab	3
Pfizer	6	Kimberly-Clark	3
Abbott	5	Professional Med. P.	3
Bristol-Myers	5	Squibb	3
Minnesota 3M Labs	5	Terumo-America Inc.	3
Becton Dickinson	4	Warner-Lambert	3

[a]Out of the 28 product categories listed in table 14.

SOURCE: IMS America, Ltd. Rockville, MD, unpublished data, 1983.

Box A.—Changes in the Clinical Laboratory

In the 1950s, I saw the marvelous technique of Folin-Wu, which was used in those days in order to determine the patient's blood glucose level, or as it is more colloquially known, the blood sugar. This entailed the mixing of various chemicals in such a fashion as to cause after 45 minutes of smelly boiling, the development of a blue color whose intensity was an indication of the amount of sugar which was present in the patient's blood. It should be remembered that prior to this test, presence of glucose in the patient's urine was determined by tasting the urine and in fact, as is generally known, the term diabetes mellitus means sweet tasting and derives from the physician's diagnosis of excess sugar in the patient's system by the test of urine tasting. I suspect that in some parts of the world, Folin-Wu sugars are still being performed because they are cheap, work, and require only a basic knowledge of chemistry and simple laboratory equipment. This is in contrast to the methods which we now employ, which involve a sophisticated enzymatic reduction method. . . . In days past, the determination of the Folin-Wu sugar on 10 patients would entail a full morning's work for the skilled laboratory technologist in the pathology laboratory. Today, we can perform 150 glucose tests in 1 hour using the skills of a well-trained and educated high school graduate. The cost per test now is on the order of a few pennies and the cost per test 20 years ago was considered to be inexpensive at $5.00 . . .

The clinical diagnostic laboratory or Department of Laboratory Medicine is routinely accepted today as a vital component of modern health care. As recently as 30 years ago, however, that was not the case. What is now called a Department of Laboratory Medicine, or in some centers, clinical pathology, was then part and parcel of the Department of Pathology. There were no commercial clinical laboratories to speak of and you could count the number of manufacturers of capital laboratory goods on the fingers of one hand. If a physician wanted to know the quantity of sugar in the patient's blood, the test required about an hour and a half of preparation, boiling, and manipulation before an approximation could be given of the amount of glucose in the patient's blood—-and in fact, we weren't measuring glucose; we measured reducing substances, that is, all of the sugar-like materials that were in the patient's blood. For that matter, there were very few constituents that we were able to chemically approximate just 30 years ago, . . .

Diagnostic biochemistry really began to flower in the 1950s and early 1960s when various enzymatic methods were discovered for the determination of specific sugars, such as glucose, and other determinations were developed for uric acid, urea nitrogen rather than the gross determination of nonprotein nitrogen, total protein, calcium and phosphorus, and other constituencies which appear to be useful in the daily management of patients who were ill and under stress. . . .

In mid-1950, Dr. Skeggs at Western Reserve University had a rather ingenious idea, He automated, for the first time in the clinical Laboratory, the mixing, sampling and reading of the constituents in the patient's blood when he automated the blood sugar using the continuous-flow autoanalyzer. That first single-channel autoanalyzer was sold in 1957 by the Technicon Company. . . . With the invention and mass sale in the early 1960s of the single-channel autoanalyzer, it suddenly became possible to perform a series of tests virtually without regard for the cost of labor . . .

In *1965,* I recall being a first-year resident in pathology and witnessing the chief of the department bringing back the first SMA 12 in Pittsburgh to our hospital in his station wagon. We set it upon saw-horses. He and the administrator agreed that the instrument would not only provide 12 tests to the institution on every patient (at great savings) but would also provide a charge to the institution in *1965* dollars of $20.00 per evaluation. That is comparable in 1984 dollars to $65.34 .. .

It should also be pointed out that these instruments all used large quantities of reagants as did the continuous flow technology. This of course put the capital vendors into the reagent and parts business in a big way. In those days we did not have the microchemical procedures that later evolved in the mid-1970s, and have been extrapolated in the past few years to virtually all of the automated equipment which is used in the laboratory. Even if the cost of running these instruments was high and the purchase costs were large, when compared to the then available manual testing methods that were in vogue, these new instruments were a quantum leap forward in efficiency, quality, and quantity of data base. . . .

Where we had in the mid-1950s and early 1960s the rare professional medical technologist performing reducing substances on the patient's blood manually at the rate of six tests per hour, by 1983 we had one registered medical technologist supervising the production of one machine which has the capability of performing 1,$00 individual tests per hour. Where them was virtually no capital equipment cost to do the few sugars in 1960, the capital equipment cost in order to process the 2,300 samples per hour is on the order of $400,000.

[1]Excerpted from a paper prepared for OTA by Lupovich (199).

younger soft lens sector, the four leading firms control almost 70 percent of the market, but new firms have entered and the concentration level has declined steadily during the past 5 years.

There is some evidence that merger activity in the medical devices field accelerated during the latter part of the 1970s. Respondents to a survey in 1981 said that only 4 percent of their companies had been acquired by another firm, merged with another firm, or acquired another firm from 1972 to 1975, but 23 percent answered affirmatively for 1976 to 1980 (197). By 1982, 100 of the 140 firms belonging to the Pharmaceutical Manufacturers Association produced diagnostic products and other medical devices, accounting for an estimated 60 percent of all such sales (244).

INNOVATION IN MEDICAL DEVICES

A hallmark of the medical devices field has been the introduction of new products and the refinement of old ones. Some innovations affect ordinary devices that are used frequently, such as assembled surgical trays for operating rooms (2). Others represent the application of sophisticated technology to medical uses, such as nuclear magnetic resonance imaging. [6]This rapid innovation in medical devices has certainly underlain much of the growth in firms and sales in recent decades.

Although innovation in medical devices has not been precisely documented, striking evidence is provided by the changes in medical practice that have resulted from new medical devices. In boxes A and B, respectively, a pathologist and an ophthalmologist relate certain changes in clinical laboratories and ophthalmology that have been linked to innovations in devices. Innovative devices have been the basis for tremendous changes in clinical laboratory procedures. Compared to a generation ago, clinical laboratory tests can now be performed more accurately and quickly as well as with fewer, less skilled personnel and at lower cost .

The pace of innovation in ophthalmology described in box B is greater than one might expect from the relative growth of the SIC code 3851 (ophthalmic goods). However, many of the new or refined medical devices used in ophthalmology are surgical instruments or electromedical equipment, which appear in other SIC codes. Similar innovations have taken place in other areas of medicine, such as digital subtraction angiography and CT scanning in diagnostic imaging and pacemakers and materials for hip joints in surgery.

Patents are frequently used as a measure of innovative activity in an industry. Such data have limitations since not all inventions are patented, several patents may pertain to a single invention, and the propensity to patent is greater in some fields than in others.

The number of patents granted by the U.S. Patent Office grew modestly through the 1970s. From 1968 to 1979, almost 22,000 applications were filed for medical devices patents that were subsequently issued (table 16), representing 2 percent of all patents (381). Compared with all U.S. patents over the same period of time (see app. D, table D-2): 1) while all patents have remained essentially constant, medical devices patents increased moderately; and 2) while foreign-origin medical devices patents as a percent of total medical devices patents increased from 20 to 30 percent over the 1970s, foreign-origin patents for all U.S.-issued patents increased from about 30 to 40 percent. Individuals owned 37 percent of the medical devices patents, compared with 22 percent of all patents, an observation suggesting the important role of individuals in the medical devices field. Table 17 provides information on patenting activity in specific medical device fields (see app. D for further information on patents). Electrical systems and diagnostic equipment using radiation, for example, accounted for about 6 percent of all medical devices patents. Strength in this area is consistent with the rapid growth in sales, firms, and employment that has characterized the related segment of the medical devices industry (X-ray,

[6]See the separately published OTA case study on nuclear magnetic resonance imaging by Steinberg and Cohen (291).

Box B.—How Ophthalmology Has Changed During My Career[1]

Ophthalmology is practiced mostly in private offices, the majority of the work being primary care with attendant high-volume, low-disease rates, and the remainder at a tertiary level with great technical sophistication and high-risk, high-reward surgery. Here is a description of ophthalmological technology when I began my residency in 1956, and how it then changed. . . .

Measuring the refractive state of the eye is usually accomplished in two stages: objective and subjective. When I entered ophthalmology, the objective phase was almost invariably performed by the practitioner's using a small hand instrument called a retinoscope. In a darkened room, with the patient gazing at a distant small light source that would not encourage accommodation, the examiner peering through a sight-hole of the instrument along the axis of a light beam entering the patient's pupil, is able to gauge the nature of the optical system of the eye by the character of the small amount of light reflecting back from the patient's retina. . . .

Objective testing has changed significantly during my career. There are now nearly 20 optical-electronic devices commercially available for performing retinoscopy or some other very closely allied objective test. These can all be operated by technicians who need not have any skills in the traditional methods of refraction. . . .

Early in the 1950s, most sharp cutting instruments were still made of nonstainless steel, were hand-sharpened, and were used repeatedly. The cornea is extremely tough tissue to cut, and instruments for opening the cornea to begin cataract surgery presented a particularly difficult problem. If the point of such an instrument is only slightly dull, the surgeon must push it harder, and then it is likely to enter the eye in a rush. A great improvement has been made in recent years with the introduction of disposable blades. Each of these blades is very sharp, but, more important, they are predictable. The amount of force required to use them is always the same, and the surgeon knows what to expect.

Another important advance in ophthalmic instrumentation for surgery has been the development of better needles for suturing the ocular tissues. In the early 1950s, the needles were hand-honed, used repeatedly, and had eyes that required threading, like ordinary sewing needles. Placing sutures in the cornea with these needles did not **allow** great precision in apposition of the wound edges. Disposable needles swaged onto the ends of the suture made a great advance. By the late 1950s, the new generation of very sharp disposable swaged-on needles made placement of sutures a qualitatively different procedure. . . .

The next great changes in cataract surgery came about as the result of increased we of magnification. During the 1950s and 1960s, the operating microscope was a feature of every well-equipped ophthalmic operating room. However, the instrument was used primarily for corneal transplants, where a higher level of precision of technique was clearly advantageous. The microscope improved in response to the demands of the surgeons, and with improvements in the operating microscope the surgeons demanded finer and finer needles and sutures. . . . During the decade of the **1970s,** the operating microscope became the standard for modern corneal and cataract surgery, and today it would be difficult to defend this type of surgery without the use of a first-class operating microscope. A good operating microscope today costs from $30,000 to $60,000 or $70,000, and with photographic and other optional attachments the price can go significantly higher. . . .

The first truly successful intraocular lens (IOL) implants were made of one rigid piece of plastic (methyl methacrylate) placed in the anterior chamber of the eye, under the vault of the cornea, and in front of the iris. . . . These lenses are still in use, but are falling into disfavor because the pressure of the lens against the tissues holding it causes disturbances that can be serious. . . . There was a great wave of enthusiasm for iris-supported lenses, but this began to wane about 2 or 3 years ago, when the reports of bad long-term results began to accumulate. . . . The next shift in IOL implants has been toward placing the IOL in the posterior chamber, the place behind the iris from which the patient's own natural lens has been removed . . . surgeons' choosing to put IOLs in the posterior chamber **has** revived the extracapsular operation, which leaves the posterior capsule in place to support the IOL.

From the moment that lasers appeared in our culture, it was obvious that their use in the eye was reasonable, because of the optical transparency of many of the ocular tissues. Sophisticated and very expensive machines are available from a number of companies that allow the ophthalmologist to deliver sufficient laser light to tiny areas of ocular tissue to create destructive burns. Carefully controlled, these burns can do many beneficial things. Without opening the globe, the laser can seal holes in the retina by creating "spot welds," thus avoiding the necessity for a full-blown retinal detachment operation. Areas of abnormal vessel growth can be treated to coagulate the vessels and to prevent hemorrhage or exudation of fluid from the vessels which might otherwise be very destructive. Within the last several years, the laser has developed a widespread use in the treatment of diabetic disease of the retina, diabetic retinopathy. . . .

The Neodymium YAG (yttrium aluminum garnet) laser creates invisible radiation in the infrared range, and has been used for 15 years or more by industry and the military. It can deliver very large amounts of power to a very small area, and is not dependent on the color of the tissue for the delivery of its energy. . . . Approximately 40 percent of patients who have extracapsular surgery will develop sufficient opacification of the posterior capsule so that a secondary procedure is required to create a clear pupil through which the patient can obtain good vision.

Until the introduction of the YAG laser, the only way to treat this opacification was by introducing a small cutting needle or knife into the eye at a second surgical procedure, and slitting the membrane. Posterior capsulotomy is safe, but it does involve re-entering the eye, and that is always to be avoided if possible. The YAG laser can deliver its energy to the posterior capsule and can easily cut holes in the posterior capsule, when no other available laser can do that. This procedure can be done in the office with the patient sitting at the slit lamp which has been adapted to guide the laser light into the eye. It is easy for the surgeon and the patient. The entire procedure frequently does not take five minutes. However, the laser may cost in the neighborhood of $80,000, and the procedure is remunerated at the same rate as a surgical capsulotomy, which has been classically remunerated at the high rates that are afforded for intraocular surgery. There has, as a result, been a rush to purchase YAG lasers, and surgeons who have busy practices may acquire them in their private offices.

[1]Excerpted from a paper prepared for OTA by Safir (267).

Table 16.—U.S. and Foreign Medical Devices Patents Granted by U.S. Patent Office by Application Date, 1968-79

	Number			Annual percentage change		
Year	Total	United States	Foreign	Total	United States	Foreign
1979a	2,142	1,488	654	5.3%	2.0%	13.5%
1978a	*2,035*	*1,459*	*676*	*-4.8*	*-7.0*	14
1977	2,137	1,569	568	3.8	1.6	107
1976	2,058	1,545	513	3.2	0.1	13,7
1975	*1,994*	*1,543*	*451*	--0.5	1.8	-5.8
1974	1,995	1,516	479	6.6	4.0	15,7
1973	1,871	1,457	414	9.4	8.1	14,0
1972	1,711	1,348	363	4.0	-1.0	28,3
1971	1,645	1,362	283	6.1	8.2	-2.7
1970	1,550	1,259	291	9.1	9.2	8.6
1969	1,421	1,153	268	12,7	9.9	26.4
1968	1,261	1,049	212	---	--	--
Total	21,820	16,748	5072			

[a]The average pendency (the delay between the filing of a patent application and its subsequent issuance as a patent) is currently longer than 2 years. It is estimated that 2 to 5 percent of 1978 applications and 1 percent of the 1978 applications were still pending in June 1983.

SOURCE: U.S. Department of Health and Human Services, Food and Drug Administration, Office of Economic Analysis, Rockville, MD, compilation of published data from the U.S. Patent and Trademark Office, December 1983.

Table 17.—U.S. and Foreign Medical Devices Patents Granted by U.S. Patent Office by Source and Selected Categories, 1968-79

Category	Total number of U.S. and foreign patents[a]	Percentage of total[b]			
		Corporations	U.S. Government	Universities	Individuals
Diagnostic equipment	3,037	56%	4%	3%	37%
Respiratory methods	1,042	55	2	[c]	43
Electrical systems	723	68	1	2	29
Implantable artificial body members	1,236	48	4	4	44
Dialysis and blood filters	440	68	4	2	26
Kinesitherapy equipment	1,015	32	1	1	66
Orthopedic devices	590	21	1	1	76
Bandages and trusses	1,880	46	1	1	52
Mediators	2,502	61	1	1	37
Instruments	2,290	49	1	1	49
Dental equipment	1,509	33	[c]	1	66
Ophthalmic equipment	1,110	59	1	1	39
Miscellaneous, including incubators, hearing aids, receptors, and baths	2,525	58	2	1	39

[a] Includes patents granted (as of June 1983) on applications filed from 1968–79. The average pendency (i.e., the delay between the filing of a patent application and its subsequent issuance as a patent) is currently longer than 2 years. It is estimated that 2 to 5 percent of the 1979 applications and 1 percent of the 1978 applications were still pending in June 1983. One patent may be included in more than one category.
[b] Percentages may not add up to 100 percent because of rounding.
[c] Less than 1 percent.

SOURCE: U.S. Department of Health and Human Services, Food and Drug Administration, Office of Economic Analysis, compilation of unpublished data from the U.S. Patent and Trademark Office, December 1983

electromedical, and electrotherapeutics equipment, SIC code 3693). Considerable activity also occurred in dialysis and blood filters, whose use has been covered by Medicare since 1972 (see ch. 3), and in diagnostic and implantable cardiovascular devices (see ch. 5).

Both large and small firms play a role in the innovation of medical devices, as they do in other sectors of the U.S. economy (274). There is no exact information, however, on the dynamic relationship between large and small medical device companies. It has been suggested that small firms introduce innovative devices and, after proving their commercial potential, merge or are acquired by larger, more stable companies (18). It is also possible that larger companies and establishments benefit from economies of scale, while the smaller ones specialize in products or functions that are not so dependent on scale (393).

INTERNATIONAL COMPETITIVENESS OF U.S. MEDICAL DEVICES

The United States has commanded a strong position in the foreign trade of medical devices. During the past decade, the surplus of U.S. medical devices exports over imports grew steadily until 1982. In 1983, the surplus fell from over $1 billion in 1982 to about $800 million (table 18). The $2.3 billion of medical devices exported in 1982 represented 17 percent of total sales (22,368). From 1978 to 1981, U.S. exports of medical devices grew about 19 percent a year, a substantial amount even though it does not allow for the 9 percent U.S. inflation rate at that time (219).[7]

U.S. foreign trade in medical devices contrasts with U.S. total merchandise trade, which has run a deficit (imports exceeded exports) for all but 2 years (1975 and 1976) since 1973 (358). The U.S.

[7] See app. H on consensus standards related to international trade and app. I on governmental regulation of foreign trade in medical devices by six countries.

Table 18.–U.S. Exports and Imports of Medical Devices by SIC Code, 1979-83

SIC code	Millions of dollars					Percent change
	1979	1980	1981	1982	1983a	1982-83
X-ray and electromedical equipment (SIC 3693)						
Exports	$ 717	$ 839	$1,006	$1,026	$1,065	3.8%
Imports	275	312	388	487	670	37.6
Surplus (deficit)	442	527	618	539	395	—
Surgical and medical instruments (SIC 3841)						
Exports	410	485	566	605	585	-3.3
Imports	146	174	195	222	255	14.9
Surplus (deficit)	264	311	371	383	330	—
Surgical appliances and supplies (SIC 3842)						
Exports	258	309	356	375	395	5.3
Imports	105	94	95	108	110	1.9
Surplus (deficit)	153	215	261	267	285	—
Dental equipment and supplies (SIC 3843)						
Exports	101	127	140	143	155	8.4
Imports	42	41	50	50	55	10.0
Surplus (deficit)	59	86	90	93	100	—
Ophthalmic goods (SIC 3851)						
Exports	99	114	123	113	110	-2.7
Imports	245	278	300	342	452	32.2
Surplus (deficit)	(146)	(164)	(177)	(299)	(342)	—
Total five SIC sectors						
Exports	$1,585	$1,874	$2,191	$2,262	$2,310	2.1%
Imports	$ 813	$ 899	$1,028	$1,209	$1,542	27.5%
Surplus (deficit)	$ 772	$ 975	$1,163	$1,053	$ 768	—

[a]Estimated

SOURCES: W.C. Bandy, U.S. Departmentof Commerce, Bureau of Industrial Economics, Washington, DC, personal communication, January 1983; E. Arakaki, U.S. Department of Commerce, Washington, DC, personal communication, February 1984; U.S. Department of Commerce, Bureau of Industrial Economics, 1984 U.S. *Industrial Outlook*, Washington, DC, January 1984.

position in medical devices is especially noteworthy because the growing strength of the dollar during the last decade increased the relative price of U.S. exports as it decreased the price of U.S. imports. That phenomenon did erode the U.S. surplus in 1983. The surplus in medical devices trade has also persisted during the recent recession, despite the reduced buying power of our major trading partners.

In 1983, the European Economic Community was the outlet for 37 percent of U.S. exports of medical devices, but Canada (14 percent) and Japan (10 percent) were the major individual purchasers.[8] The European Economic Community also provided more than half of U.S. imports, with West Germany (32 percent) and Japan (18 percent) the largest single sources (369).

Although U.S. production is greater in other categories of medical devices, SIC 3693 (X-ray and electromedical equipment) leads exports, with $1 billion or almost 50 percent of all U.S. foreign sales of medical devices. Domestic production in this category is heavily tied to export: 30 percent of electromedical equipment and 24 percent of X-ray equipment in 1983 were sold overseas (369). As a result, sales of these devices are more dependent on fluctuations in exchange rates.

Electromedical equipment, with exports that grew almost 25 percent annually from 1978 to 1981, accounts for most of the trade surplus in SIC 3693 (219). Although it is common that the U.S. share of the world market for a product declines overtime as other countries enter the field and U.S. growth falls behind a faster growing world market, this situation has not occurred with electromedical equipment. The U.S. share of the world market increased from 35 percent in 1975 to 47 percent in 1979 (219). Patient monitoring systems and other diagnostic electromedical apparatus have accounted for the majority of these exports (371,372). In 1981, Japan, Canada, the Netherlands, West Germany, and France purchased almost half of U.S. exports in this subcategory.

Trade in X-ray products has been less favorable. In1982, exports only slightly exceeded imports. A deficit of $175 million was expected for 1983,

[8]These figures relate to SIC codes 3841, 3842, 3843, and 3693 but exclude SIC code 3851 (ophthalmic goods),

with imports accounting for 33 percent of U.S. consumption of all X-ray products (369). About 40 percent of all X-ray products imported during 1981 and 1982 were X-ray apparatus and parts from West Germany (373,374).

Although SIC 3841 (surgical and medical instruments) showed a trade surplus in 1983, its position deteriorated from 1982: exports fell 3 percent and imports grew 15 percent. About 15 percent of the surgical and medical instruments produced in the United States during 1983 were exported, but only 7 percent of U.S. consumption came from imports. Exports of surgical and medical instruments indicate the untapped potential of markets other than our traditional trading partners. From 1978 to 1981, exports to Canada (17 percent) and the European Economic Community grew about 12 percent per annum. Exports to the Middle East (10 percent) and Latin America (18 percent), however, grew nearly 30 percent per annum (219,371).

SIC 3842 (surgical appliances and supplies), the largest medical devices category in sales, has the least relative involvement in foreign trade: only 7 percent of production is exported, and 2 percent of U.S. consumption is imported (369). From 1982 to 1983, exports experienced a 5-percent increase, and imports rose almost 2 percent. Both West Germany and Japan had sizable increases in their exports to the United States.

Exports of devices in SIC 3843 (dental equipment and supplies), representing 12 percent of production, increased 8 percent from 1982 to 1983. Imports, only about 5 percent of U.S. consumption, came mainly from West Germany and Japan (369).

SIC 3851 (ophthalmic goods) is the only medical devices code that has had a persistent trade deficit. Half of the imports consist of frames and mountings for eyeglasses, which are supplied primarily by France, Italy, Japan, and Hong Kong. Sunglasses, 38 percent of ophthalmic imports in 1981, came mainly from Japan and Hong Kong (373). Unlike most products in the other medical devices codes, ophthalmic goods are usually chosen and used by consumers rather than by medical providers. To the extent that use is discretionary or postponable, sales would be expected to be more sensitive to changes in price and general economic conditions. That reduced exports in sunglasses accounted for most of the fall in exports from 1981 to 1982 fits this pattern.

CONCLUSIONS

The medical devices industry can be characterized as a field that has undergone enormous growth in companies, establishments, employment, new products, and foreign trade. By all of these measures, the experience of the medical devices industry has exceeded that of manufacturing as a whole and of similar manufacturing sectors. Growth in medical devices has apparently occurred more by the addition of new companies than by the expansion of old ones, an indication that any barriers to entering the industry are not prohibitive. Both small and large firms have important positions in this industry. Small companies are responsible for a greater percentage of sales in the medical devices industry than in other industries. But large companies have accounted for the majority of sales, and a small number of firms have a considerable share of the market, especially in specific product lines.

There are, however, disquieting aspects to the situation. This phenomenal growth has occurred in a market where there is a consensus that technology, including medical devices, has sometimes been used excessively (168,266,346). Policy initiatives, both public and private, are now under way to improve the situation, chiefly by changing the way that medical providers are paid. In addition, Federal policy regarding premarket approval of devices is under review. It is therefore timely to analyze the likely effects on the medical devices industry of these and other policies, a task that is undertaken in the remainder of this report.