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Estimates of Medical Device Spending in the United States

Prepared by
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June 2021

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Background

The role of medical technology in health care costs has long been a source of debate. It has been widely asserted that healthcare technology can be cost increasing, due to price and volume effects, both for medical technologies themselves and related services.[1] Other findings have suggested that benefits from spending on medical technologies can far exceed their costs, particularly when longer-term benefits are measured in terms of productivity and reduced disability.[2] Yet, surprisingly, very little analysis has been conducted on the direct costs to the health system of medical devices themselves.[3]

This study was engaged to: (1) develop estimates of medical device spending in the United States that are compatible and consistent with estimates of National Health Expenditures (NHE) developed by the Centers for Medicare & Medicaid Services (CMS); (2) compare our estimates of medical device expenditures to NHE estimates published by CMS; and (3) develop estimates of price changes for medical devices for comparison to standard indexes.[4]

Major Findings

Major findings of the study include:

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[1] Gerald Donahoe worked for the Bureau of Economic Analysis (BEA), U.S Department of Commerce, and later served as BEA's Chief of the National Income and Wealth Division and then became Associate Director for National Economic Accounts.

[2] See Fuchs, V.R., "Economics, Values and Health Care Reform," *The American Economic Review*, March 1996, Vol 86, No. 1, pp. 1 – 25, at 19.

[3] Chatterjee, A, King, J, Kubendran, S, DeVol, R, *Healthy Savings; Medical Technology and the Economic Burden of Disease*, Milken Institute, July 2014; Cutler, DM, McClellan, M., "Is Technological Change Worth It?" *Health Affairs* 20 (5), Sept./Oct. 2001, pp 11 – 29.

[4] A review of the literature for medical device related studies did not find a single, empirical study on systemic spending on all types of medical devices. See "Assessing the Impact of Medical Technology Innovations on Human Capital; Phase I Final Report (Part A): State- of-the-Science Literature Reviews", Prepared for the Institute for Medical Technology Innovation, available at: http://www.inhealth.org/MediaCenter/Duke_Final_Report_A___State_of_the_Science_Literature_Reviews.pdf January 31, 2006.

[5] This project was sponsored by the Advanced Medical Technology Association (AdvaMed) and is an update of earlier studies on the same subject. This study updates the estimates through 2019 and accounts for extensions and revisions in source data that have become available since early 2018.

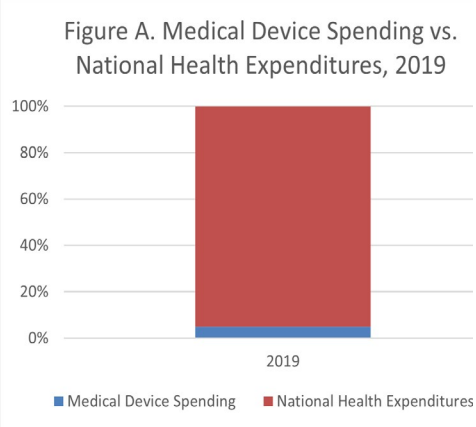
- In 2019, the latest year that can be studied using the Census Bureau data, spending on medical and in-vitro diagnostics totaled $199.1 billion, or 5.2 percent of total national health expenditures [Figure A and Figure 1 below].

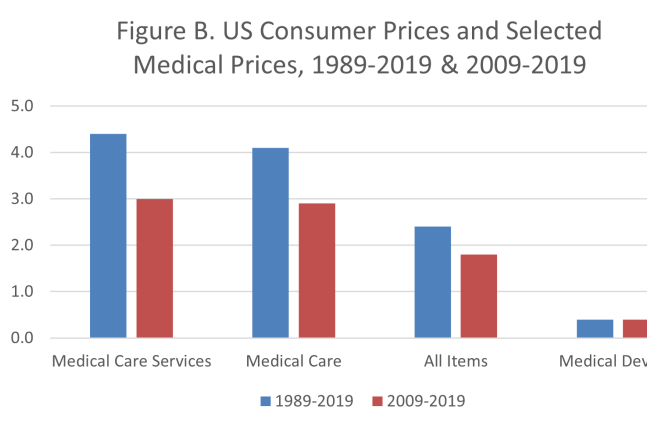
- Throughout the thirty-year period (1989-2019) examined by this study, device spending as a share of total national health expenditures varied somewhat from year-to-year. It started at 5.7 percent and ended at 5.2 percent with a range from 6.3 percent to 5.1 percent [Figure 2 below].

- Over the full period, medical device spending increased at an average annual rate of 5.8 percent compared to 6.1 percent for overall national health expenditures.

- Prices for medical devices have actually grown far more slowly than the Medical Consumer Price Index or even the overall Consumer Price Index [Figure 3 below]. Over the period from 2009 to 2019, medical device prices have increased at an average annual rate of only 0.4 percent, compared to 2.9 percent for the MC-CPI and 1.8 percent for the CPI [Figure B]. This relatively slow rate of price increase suggests the industry is highly price competitive.

- Consistent with these differences in price trends, medical device spending increased at an annual rate of only 3.1 percent from 2009 to 2019 in nominal dollars, considerably lower than the increase 4.3 percent in aggregate national health accounts.



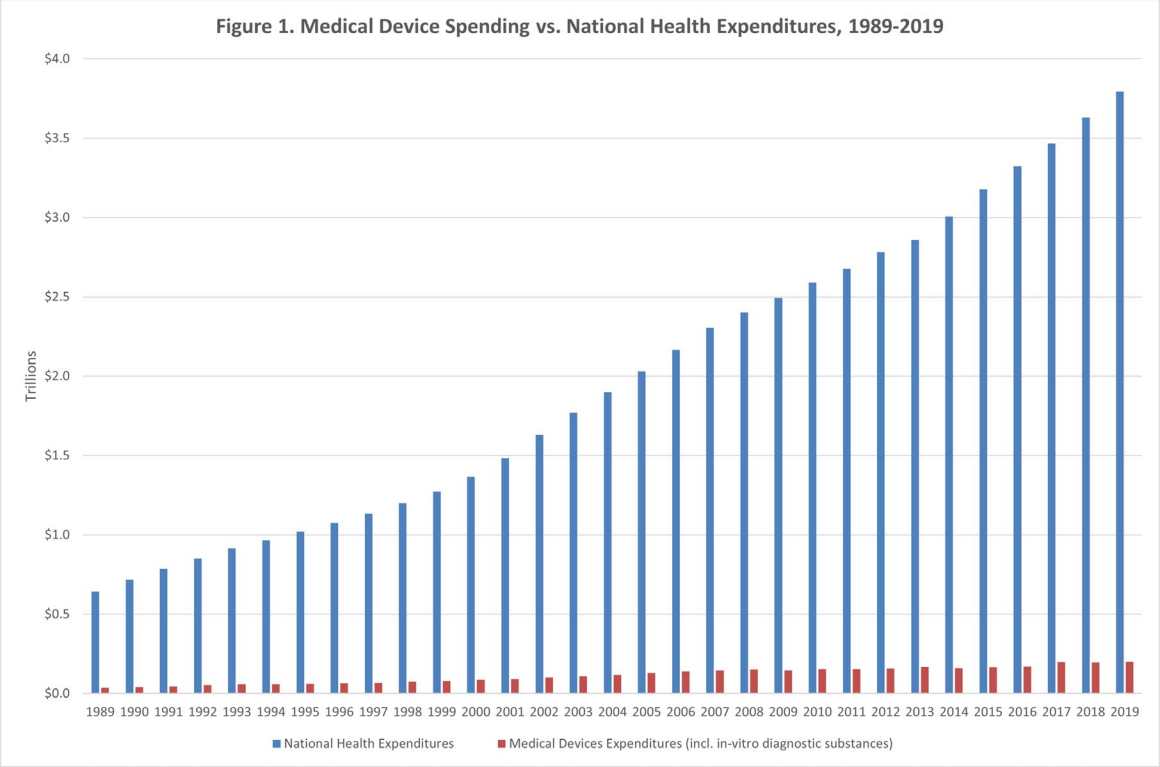


Study Overview

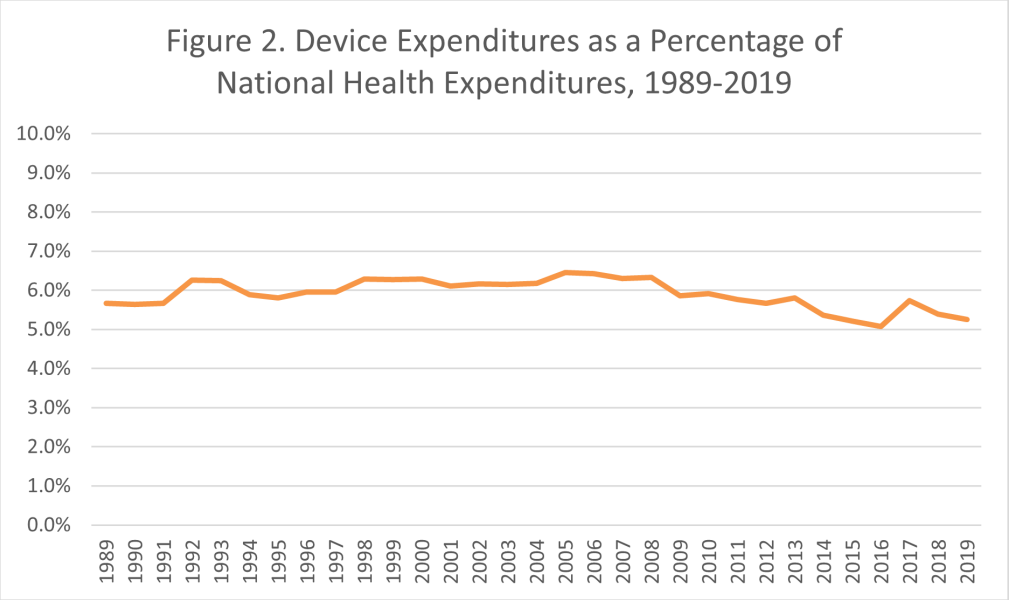
Changes in medical practice due to medical technology encompass a variety of factors. These factors include: (1) development of new medical procedures; (2) improvements in existing procedures; (3) increases in the number of procedures performed because of increased safety, effectiveness, or convenience; (4) development of new pharmaceutical products; and (5) the development and use of new and improved medical devices and diagnostics. The focus of this study is on medical devices and diagnostics, the contribution of the cost of these products to national health expenditures, and the overall price trends of these products compared to other medical products and to the Consumer Price Index (CPI).

In this study, we have attempted to estimate the cost of medical devices and the contribution of these products to increases in national health expenditures. We include in-vitro diagnostics in the definition of medical devices, as discussed in the Methodological Appendix below. We attempted to use the same methodological rigor in estimating medical device spending as is used by CMS in compiling estimates of the major categories of national health care spending. As described in the Methodological Appendix, we began our analysis by selecting categories from the North American Industry Classification System (NAICS). We then measured expenditures as manufacturers' shipments plus imports minus exports and added margins for wholesale and retail trade, using Economic Census data and annual survey data. Price changes were measured using appropriate Producer Price Indexes and margin rates and incorporating a Fisher Index formula.

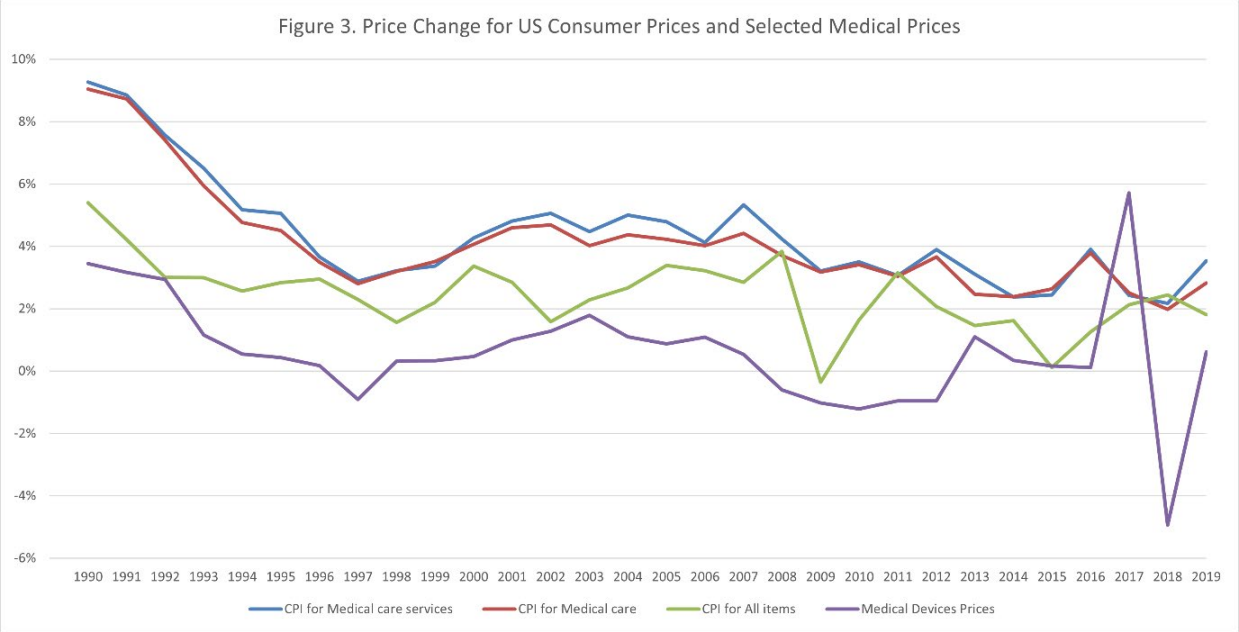
The major findings of our study are amplified in Figures 1 through 4 below: Medical device spending has been a relatively small and constant share of national health expenditures. In 2019, spending on medical devices and in-vitro diagnostics totaled $199.1 billion, or 5.2 percent of total national health expenditures [Figure 1].



Throughout the thirty-year period (1989-2019) examined by this study, device spending as a share of total national health expenditures varied somewhat from year-to-year [Figure 2]. It started at 5.7 percent and ended at 5.2 percent, with a range from 6.3 percent to 5.1 percent.

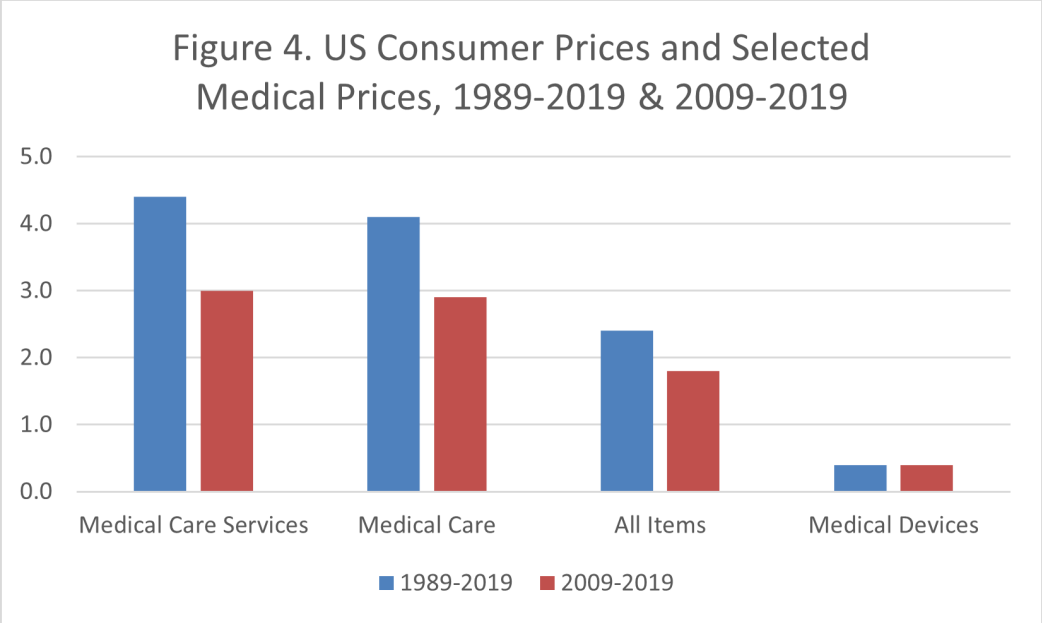


Medical device price changes have been consistently low over the period from 1989 to 2019 [Figure 3].



Medical device prices have increased at an average annual rate of 0.4 percent, compared to the Consumer Price Index (CPI) increase of 2.4 percent, the Medical Care Consumer Price Index (MC-CPI) increase of 4.1 percent, and the Medical Care Services Consumer

Price Index (MCS-CPI) increase of 4.4 percent [Figure 4]. The most recent 10-year period reveals a similar pattern. For the 10-year period ending in 2019, the average annual increase in the medical device prices was also 0.4 percent, compared to the CPI increase of 1.8 percent, the MC-CPI increase of 2.9 percent, and the MCS-CPI increase of 3.0 percent.



Conclusion

During much of the thirty-year period 1989 to 2019, a significant driver of changed medical practice has been the development of new medical devices—from stents to implantable defibrillators to artificial hips and knees to new imaging modalities to new diagnostic tests and new surgical tools. In view of the conventional wisdom about the role of medical technology in driving up costs, it is surprising that the cost of medical devices has risen little as a share of total national health expenditures. It is also striking that, unlike most other areas of medicine, the prices of medical devices have actually grown more slowly than both the MC-CPI and the CPI as a whole.

Methodological Appendix

Definition of "Medical Devices"

In measuring economic activity, such as the nation's production or national health expenditures, it is necessary to clearly define the boundary of the activity being measured.[5] To develop a clear "device boundary," we initially adopted a working definition based on a standard dictionary definition of "device," something "made, particularly for a working purpose; an invention or contrivance, especially a mechanical or electrical one."

However, this "device boundary" definition would have eliminated In-vitro diagnostic substances (NAICS 325413) because these commodities are considered "substances" rather than devices. We therefore then examined items classified as medical devices under the Federal Food, Drug and Cosmetic Act, and listed in the regulations administered by the Food and Drug Administration (FDA). Based on the FDA regulatory definitions, we decided to include in-vitro diagnostic substances and equipment.

To further determine the "device boundary," we used manufacturing categories in the North American Industry Classification System (NAICS) because the data from which the estimates were developed are from the federal government statistical system, and that system is currently based on NAICS for industry and product data. This constraint further narrowed the medical boundary's economic activity universe to the nine categories shown below with their NAICS codes.

334510—Electromedical and electrotherapeutic apparatus
334517—Irradiation apparatus
339111—Laboratory apparatus and furniture*
339112—Surgical and medical instruments
339113—Surgical apparatus and supplies
339114—Dental equipment and supplies*
339115—Ophthalmic goods
339116—Dental laboratories*
* *These categories are not included in the study, as discussed below.*

[6] For example, both the National Health Expenditure Accounts published by the Centers for Medicare and Medicaid Services and the "System of Health Accounts" of the Organization for Economic Co-operation and Development exclude food manufacturing and fitness services from the health universe even though both are important for health.

Devices such as computers and automobiles that are used by the health services industry as well as by many other industries were not included in this initial list because the health services industry devices cannot be distinguished from the larger categories as defined by NAICS.

Dental equipment and supplies (NAICS 339114) and dental laboratories (NAICS 339116) were excluded from the "device boundary," either because complete corresponding data were unavailable for all elements of the analysis (in the case of dental laboratories), or because dental care and related expenses are typically financed through different healthcare insurance mechanisms than the other products considered in the analysis.

We decided to exclude Laboratory apparatus and furniture (NAICS 339111) because the apparatus portion was largely non-medical, and no data were available to allocate the total. In 2012, there were about 670 thousand medical establishments in the United States, but most were offices of doctors and other practitioners, and these offices generally did not contain labs. Only about six thousand of the 670 thousand establishments were medical labs, but there were about 25 thousand food-processing establishments, many with quality assurance labs, and nearly five thousand institutions of higher learning, many of which have labs.

We believe that some types of hospital furniture should be classified as medical devices, to the extent they are regulated by the FDA. For example, operating room furniture and hospital beds appear to fit both the dictionary and regulatory definitions of medical devices. Unfortunately, lack of separate data prevented us from including this category. Shipments of hospital beds are available for the entire period covered by the estimates, but separate codes are not available for imports and exports.

Methodology

The general methodology involved measuring implied consumption (or expenditures) as manufacturers' shipments plus imports minus exports. This is sometimes known as a "commodity-flow" procedure. In earlier updates of these studies, we had removed expenditures of manufactures shipments, imports, and exports from some of the categories: Irradiation equipment used for non-medical uses; personal industrial safety devices and protective clothing (from Surgical apparatus and supplies); and antiglare glasses and related goods (such as non-prescription reading glasses) from Ophthalmic goods. Because non-medical data on these categories for shipments are no longer available from the Census Bureau, we decided not to continue these adjustments. This change increased the level of medical device spending by nearly seven percent for earlier

years through 2009. From 2010 to 2016, the levels are lower than in the preceding estimates, reflecting largely to higher exports which are a subtraction.

Finally, we had intended to eliminate some double counting in the manufacturers' shipments data caused by recording a shipment when shipped by a parts manufacturer and then recording the value a second time when embodied in the shipment of an assembled device. For example, Census Bureau data indicate that about five percent of the output of irradiation apparatus consists of X-ray tubes sold separately. But some of these sales (perhaps most of them) may be used as replacement tubes for existing machinery. Also, the Input-Output Tables prepared by the Bureau of Economic Analysis (BEA) indicate that about one percent of the output of electromedical and electrotherapeutic apparatus was purchased and used by that same industry. Unfortunately, sufficient data were not available to systematically eliminate such double counting for this study.

Manufacturers' Shipments

The most detailed shipments data are available from the Economic Censuses conducted by the Census Bureau in years ending in "2" and "7." Somewhat less detail is available from the Annual Survey of Manufacturers (ASM) for other years. Shipments data used are "product shipments" in contrast to "industry shipments." Product shipments are recorded on a "wherever made basis." In other words, they include products made in industries primarily engaged in a specific activity as well as the same products made in industries primarily engaged in other types of manufacturing. The 1997, 2002, 2007, 2012 and 2017 Economic Censuses were tabulated using NAICS, and the earlier Censuses were tabulated using the Standard Industrial Classification (SIC) codes. The Census Bureau website provided bridge tables linking the NAICS and SIC codes.

Imports and Exports

Imports and exports are tabulated by the Census Bureau from Customs and other documents and were pulled from the website maintained by the United States International Trade Commission (ITC).

Import values used are the C.I.F. (cost, insurance, and freight) values. This represents the landed value of the merchandise at the first port of arrival in the United States. For this study we used "General imports" rather than "Imports for consumption." Imports for consumption exclude imports that enter free trade zones and bonded warehouses, and they include merchandise that leaves free trade zones and custom warehouses. However, Census Bureau studies have shown that the values leaving these entities can be severely misstated because of rules governing duties. As a practical matter, the differences are not

large for the categories included in this study. Separate data on import duties were not available.

Exports are valued at the F.A.S. (free alongside ship) value. This is the value of exports at the U.S. seaport, airport, or border port of export, based on the transaction price, including inland freight, insurance, and other charges incurred in placing the merchandise alongside the carrier at the U.S. port of exportation. The value, as defined, excludes the cost of loading the merchandise aboard the exporting carrier and also excludes freight, insurance, and any charges or transportation costs beyond the port of exportation.

"Total exports" rather than "Domestic exports" were used for this study. Total exports include "reexports;" we decided to include these amounts because the re-exports are also reflected in the import data. The differences between total and domestic exports can be significant. For 2009, total exports for NAICS category 339112 were $12.2 billion, compared with domestic exports of $10.0 billion. Imports and exports were tabulated based on both NAICS categories (for 1996 forward) and SIC categories (for earlier years). In addition, a number of codes from the "Harmonized Tariff System" (HST) were tabulated to develop estimates needed to reconcile NAICS with the SIC.

HST codes were linked to NAICS codes via files on the Census Bureau website; these files were sorted by NAICS and then examined for the HST match-ups using long titles available on the files. Some additional HST codes were identified using the "Search" capability on the website.

Margins

Margins comprise the difference between the manufacturers' prices and the purchasers' prices. Margins include the transportation costs, taxes included in the final purchase prices (that are not included in the manufacturers' prices), and the value added in the wholesaling and retailing of medical devices. Margins must be accounted for to show the full value of medical devices used in the economy. The most important margins for medical devices are wholesale and retail margins and these have been developed largely from data published in the Economic Census.[6]

Census data through 1997 classified wholesalers into three groups: merchant wholesalers

[7] Margins are used extensively in the Input-Output Tables for the United States published by BEA—see the "Use Table" for Economic Census years, 1987, 1992, 1997, 2002 and 2007. BEA estimates transportation margins and retail sales taxes and import duties in addition to the margins used in this study. However, the methodology for assigning margins to commodities in the Input-Output Tables is tenuous at the detailed level used in our study.

(i.e., intermediaries in goods distribution between manufacturing or importing), retailers, or final users. These businesses purchase goods, hold goods in inventory, take title to the goods, and sell the goods. A second group—agents, brokers, and commission merchants—do not take title to the goods in which they deal, but instead provide a service of bringing buyers and sellers together and receive a commission for this service. (Both of these general types may deal in both types of these activities, but they are classified by their dominant economic activity.) The third group, manufacturers' sales branches and offices, tend to provide the same service as other wholesalers.

In the Economic Census for Wholesale Trade for these years, data on "Gross margins" were used to measure the margins, or value added, by merchant wholesalers, and data on commissions were used to measure the margins of agents, brokers, and commission agents. Both of these groups sell goods "on own account" (the primary function for merchant wholesalers) as well as "on the account of others" (the primary function for agents and brokers). We assumed that the margin rate for the primary function (own account or account of others) applies to all the sales of that group. For manufacturers' sales branches and offices, "Operating expenses" were used as the measure of margins.

The full set of wholesale trade data as described was available for 1992, 1997, 2012 and 2017. For 1987, no margins for merchant wholesalers were available; so operating expenditures were substituted. Data for manufacturers' sales branches and offices were also not available, so their sales and expenses were extrapolated back using merchant wholesalers. For 2002, 2007, 2012 and 2017 Census data incorporated agents and brokers into merchant wholesalers.

Two wholesale trade "kind of business" categories were identified for purposes of this study. Surgical, medical and hospital supplies" (NAICS 4234501; part of SIC 5047) was assumed to be the outlet for manufacturing NAICS codes 334510, 334517, 339112, and 339113. We assumed that these categories shared the margin in proportion to their shipments, exports, and imports. The other category was Ophthalmic goods (NAICS 421460; SIC 5048).

The Wholesale Census also provided data on the share of sales to retail establishments and to export. The first percentage was used in conjunction with retail margin rates to estimate the retail margin. The retail margin rates were from the Census Bureau's Annual Retail Trade Survey (data for "Health and personal care stores," NAICS 446 for 1993 forward and "General merchandise," SIC 452, for earlier years). The export share was used to allocate margins to exports.

Margin rates were interpolated linearly between Census years and the 2017 values were repeated for subsequent years. Economic Census data for 2017 are incorporated in this update for the first time.

Note that the export estimates described above were considered to already contain the margins. Thus, the calculation of expenditures at purchasers' prices was the sum of manufacturers' shipments and imports plus their margins less exports. Exports at producers' value were calculated by subtracting the export margin. The measure called "Shipments margins" in this study is the portion of the margin allocated to domestically consumed shipments. The example below illustrates this calculation:

Total manufacturers' shipments (producer price)		10
Exports (adjusted to producers' price)		3
Of which:		
Exports at port value	*4*	
Less export margin	*1*	
Imports at port of entry price		4
Manufacturer shipments margin		3
Import margin		2
Expenditures (10-3+4+3+2)		**16**

Medical device price changes were measured using two sets of price data:

(1) The Producer Price Index (PPI), which is published by the Bureau of Labor Statistics. The individual PPIs are available for 6-digit NAICS categories and are based on various time periods depending upon when the indexes began. All of the indexes were rebased to the year 2000. The PPIs are applied to shipments and imports at producers' prices. The assumption underlying this procedure was that imports are competitive with shipments so that the PPIs are applicable to both (because exports are a subtraction, their prices do not affect the calculations).[7]

(2) Margin rates which were calculated by dividing the margins estimated as described above by, respectively, the shipments, imports, and exports to which they applied. Price indexes were then derived by rebasing the margin rates to the year 2000.

[8] The Bureau of Labor Statistics also publishes data on import and export prices, but they are not available at the 6-digit NAICS level.

As mentioned earlier, price changes were measured using a Fisher Index formula. This construct involves averaging the component price changes using expenditure weights for each pair of consecutive years rather than using the weights for a single "base" year, which tends to introduce bias for periods distant from the base year.

Reliability of the Data and Caveats

The major data sources used in this study are of very high quality. The Economic Censuses (manufacturing shipments and wholesale trade data) are nearly complete counts. The ASM (annual shipments data) is a high-quality probability sample. The import and export data cover all consignments above about $2,000 in value with sampling for small-value consignments. However, sampling errors are only part of the errors of measurement. The Census Bureau points this out in several of their publications:

> "All surveys and censuses are subject to non-sampling errors. Non-sampling errors can be attributed to many sources: inability to obtain information about all of the companies in the sample; inability or unwillingness on the part of respondents to provide correct information; response errors; definition difficulties; differences in the interpretation of questions; mistakes in recording or coding the data; and other errors of collection, response, coverage, and estimation for nonresponse."[8]

In addition, combining and blending source data, the process used in this study, can introduce errors. This study assumes that all of the margins in the wholesale trade industries selected were conduits for the categories of manufacturing, imports, and exports for the medical devices covered. Most retail and wholesale kinds of business deal in several categories of goods. It is likely that goods from other than the medical device industries pass through the wholesale outlets covered. But it is also true that some medical devices pass through other kinds of wholesale business.

[9] U.S. Census Bureau, *Annual Capital Expenditures*, 1999, page C-4.

Tables

National Health Expenditure vs. Medical Devices

Year	National Health Expenditures (Billions of dollars)	Medical Device Expenditures (Billions of dollars)	Medical Devices as a Share of NHE
1989	642.2	36.4	5.7%
1990	718.8	40.6	5.6%
1991	786.1	44.6	5.7%
1992	852.4	53.3	6.3%
1993	915.1	57.1	6.2%
1994	966.0	56.8	5.9%
1995	1020.6	59.3	5.8%
1996	1074.0	64.0	6.0%
1997	1133.4	67.5	6.0%
1998	1198.9	75.3	6.3%
1999	1273.6	80.0	6.3%
2000	1365.6	85.8	6.3%
2001	1482.9	90.6	6.1%
2002	1630.6	100.5	6.2%
2003	1769.8	108.9	6.2%
2004	1899.5	117.3	6.2%
2005	2029.5	131.0	6.5%
2006	2166.3	139.1	6.4%
2007	2305.2	145.1	6.3%
2008	2402.5	152.0	6.3%
2009	2492.8	146.1	5.9%
2010	2589.7	153.1	5.9%
2011	2676.4	154.2	5.8%
2012	2783.1	157.6	5.7%
2013	2859.5	166.2	5.8%
2014	3008.3	161.5	5.4%
2015	3177.7	165.7	5.2%
2016	3324.5	168.7	5.1%
2017	3465.9	198.8	5.7%
2018	3629.7	195.5	5.4%
2019	3795.4	199.1	5.2%

National Health Expenditures vs. Medical Devices (Percent Change from Preceding Year)

Year	National Health Expenditures	Medical Devices Expenditures
1990	11.9%	11.6%
1991	9.4%	9.9%
1992	8.4%	19.7%
1993	7.4%	7.1%
1994	5.6%	-0.6%
1995	5.7%	4.4%
1996	5.2%	7.9%
1997	5.5%	5.5%
1998	5.8%	11.5%
1999	6.2%	6.2%
2000	7.2%	7.3%
2001	8.6%	5.5%
2002	10.0%	11.0%
2003	8.5%	8.4%
2004	7.3%	7.7%
2005	6.8%	11.7%
2006	6.7%	6.2%
2007	6.4%	4.3%
2008	4.2%	4.7%
2009	3.8%	-3.9%
2010	3.9%	4.8%
2011	3.3%	0.8%
2012	4.0%	2.2%
2013	2.7%	5.4%
2014	5.2%	-2.8%
2015	5.6%	2.5%
2016	4.6%	1.8%
2017	4.3%	17.9%
2018	4.7%	-1.7%
2019	4.6%	1.9%

Price Change for US Consumer Prices and Selected Medical Prices (Percent Change from Preceding Year)

Year	CPI For Medical care services	CPI for Medical care	CPI for All Items	Medical Devices Prices
1990	9.3%	9.0%	5.4%	3.4%
1991	8.9%	8.7%	4.2%	3.2%
1992	7.6%	7.4%	3.0%	2.9%
1993	6.5%	5.9%	3.0%	1.2%
1994	5.2%	4.8%	2.6%	0.5%
1995	5.1%	4.5%	2.8%	0.4%
1996	3.7%	3.5%	3.0%	0.2%
1997	2.9%	2.8%	2.3%	-0.9%
1998	3.2%	3.2%	1.6%	0.3%
1999	3.4%	3.5%	2.2%	0.3%
2000	4.3%	4.1%	3.4%	0.5%
2001	4.8%	4.6%	2.8%	1.0%
2002	5.1%	4.7%	1.6%	1.3%
2003	4.5%	4.0%	2.3%	1.8%
2004	5.0%	4.4%	2.7%	1.1%
2005	4.8%	4.2%	3.4%	0.9%
2006	4.1%	4.0%	3.2%	1.1%
2007	5.3%	4.4%	2.8%	0.5%
2008	4.2%	3.7%	3.8%	-0.6%
2009	3.2%	3.2%	-0.4%	-1.0%
2010	3.5%	3.4%	1.6%	-1.2%
2011	3.1%	3.0%	3.2%	-1.0%
2012	3.9%	3.7%	2.1%	-1.0%
2013	3.1%	2.5%	1.5%	1.1%
2014	2.4%	2.4%	1.6%	0.3%
2015	2.4%	2.6%	0.1%	0.2%
2016	3.9%	3.8%	1.3%	0.1%
2017	2.4%	2.5%	2.1%	5.7%
2018	2.2%	2.0%	2.4%	-4.9%
2019	3.5%	2.8%	1.8%	0.6%