Estimates of Medical Device Spending in the United States

Prepared by
Gerald Donahoe and Guy King, F.S.A., M.A.A.A.

June 2014

Estimates of Medical Device Spending in the United States

Prepared by
Gerald Donahoe and Guy King, F.S.A., M.A.A.A.
June 2014

Summary

Medical devices make up a relatively small and constant share of national health expenditures. In 2011, the latest year that can be studied using Census Bureau data, spending on medical devices and in-vitro diagnostics totaled $159.4 billion, or 5.9 percent of total national health expenditures (NHE) (Figure 1).[1]

Throughout the 23-year period (1989-2011) examined by this study, device spending as a share of total national health expenditures did vary by year, but increased only from 5.3 percent to 5.9 percent. Virtually all of this growth in medical device spending as a share of NHE took place between 1989 and 1992. Since 1992 the share of medical device spending as a percent of NHE has been essentially flat at about 6.0 percent. Over the full period, medical device spending increased at an average annual rate of 7.2 percent compared to 6.7 percent for overall national health expenditures. Since 1992, however, medical device spending has increased at a rate of 6.1 percent annually compared to 6.2 percent for NHE.

While medical device spending has grown at about the same rate as national health expenditures overall, prices for medical devices have actually grown far more slowly than the Medical Consumer Price Index or even the overall Consumer Price Index. Over the period from 1989 to 2011, medical device prices have increased at an average annual rate of only 1.0 percent, compared to 4.6 percent for the MC-CPI and 2.7 percent for the CPI. This relatively slow rate of price increase suggests the industry is highly price competitive.

Background

The authors were engaged to: (1) develop estimates of medical device spending in the United States that are compatible and consistent with estimates of National Health Expenditures 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.[2] This paper is an update of earlier studies by the authors on the same subject. This study updates the data through 2011 and takes into account extensions and revisions in source data that have occurred since the earlier papers were written.

Mr. Donahoe was primarily responsible for developing the estimates of medical device spending and price changes. Mr. King was primarily responsible for analyzing the estimates and putting them in context.

[1] The release of data from the Census Bureau's 2012 Economic Census has been delayed until late 2014 or early 2015.

[2] This project was sponsored by the Advanced Medical Technology Association.

History and Overview

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.[3] 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.[4] Yet, surprisingly, very little analysis has been conducted on the direct costs to the health system of medical devices themselves.[5]

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).

Major Findings

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 diagnostic devices 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. Our study reveals the following major findings:

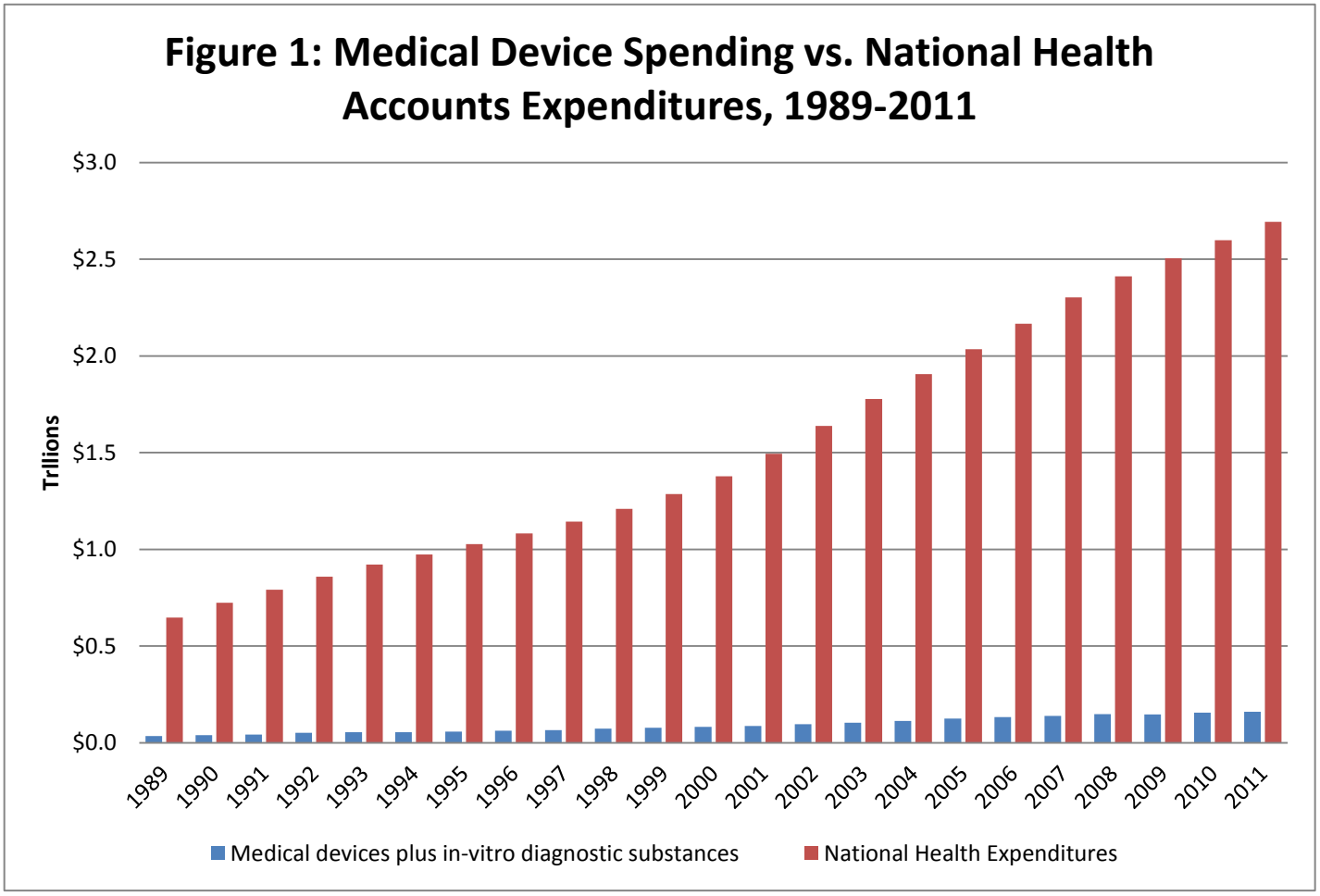
[3] See Fuchs, V.R., "Economics, Values and Health Care Reform," *The American Economic Review*, March 1996,Vol 86, No. 1, pp. 1 – 25, at 19.

[4] Cutler, DM, McClellan, M., "Is Technological Change Worth It?" *Health Affairs* 20 (5), Sept./Oct. 2001, pp 11 – 29.

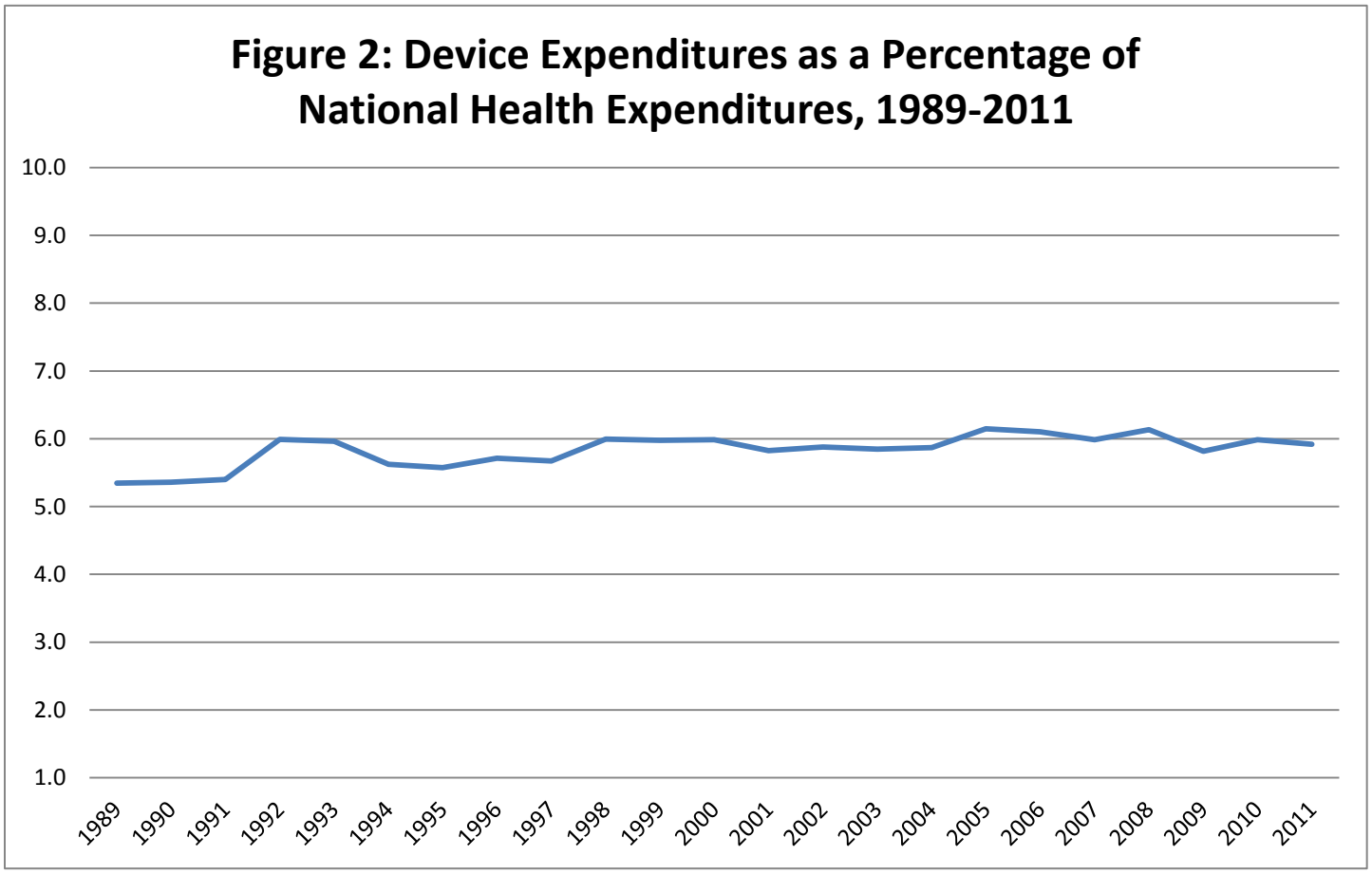
[5] A review of the literature for medical device related studies did not find a single, empirical study on systemic spending on all types of medical devices. See "Assessing the Impact of Medical Technology Innovations on Human Capital; Phase I Final Report (Part A): State- of-the-Science Literature 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.

1. Medical devices are a relatively small and constant share of national health expenditures.

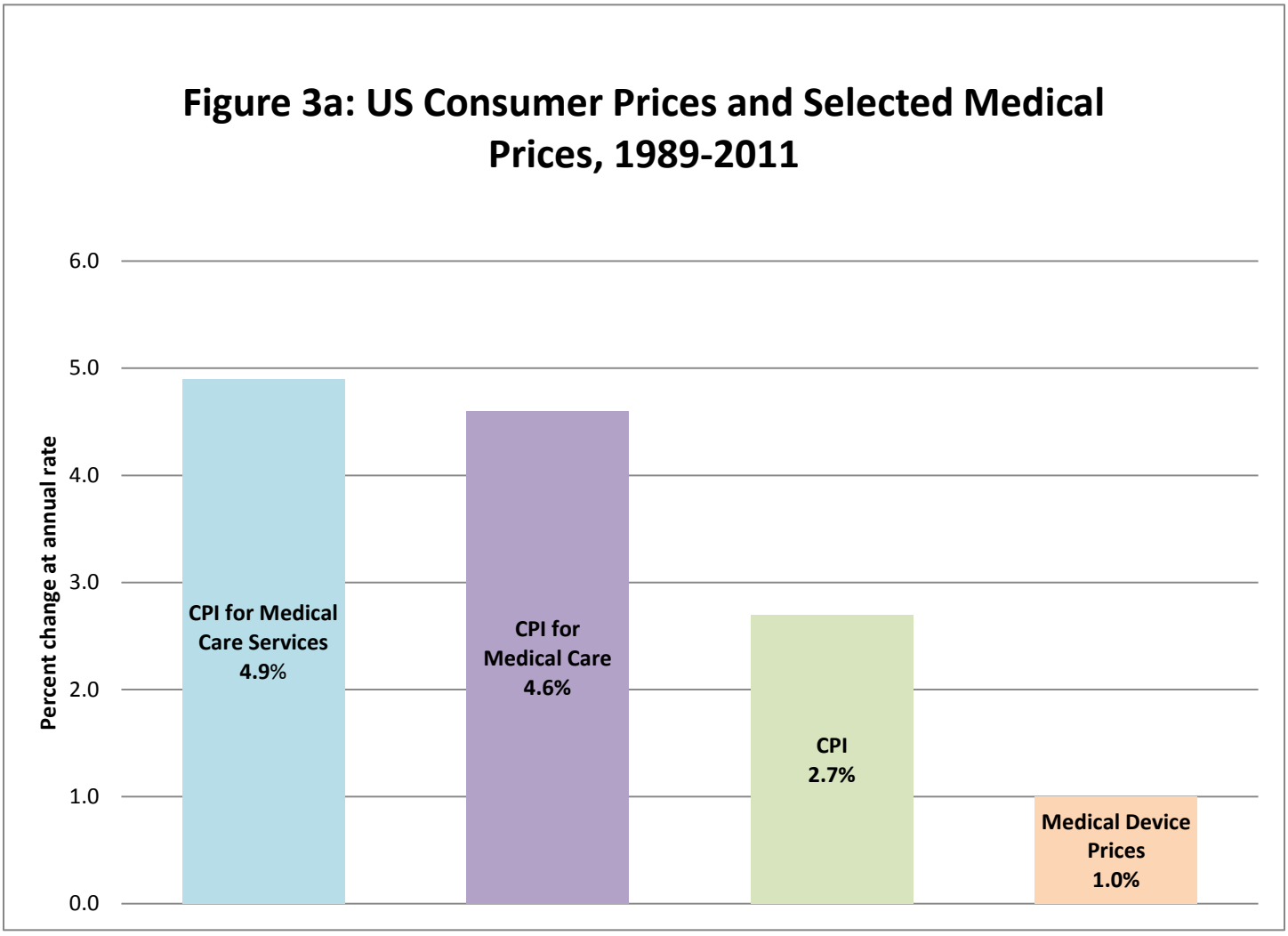
    - In 2011 medical device spending totaled $159.4 billion or 5.9 percent of total national health expenditures ($2.7 trillion) [Figure 1]



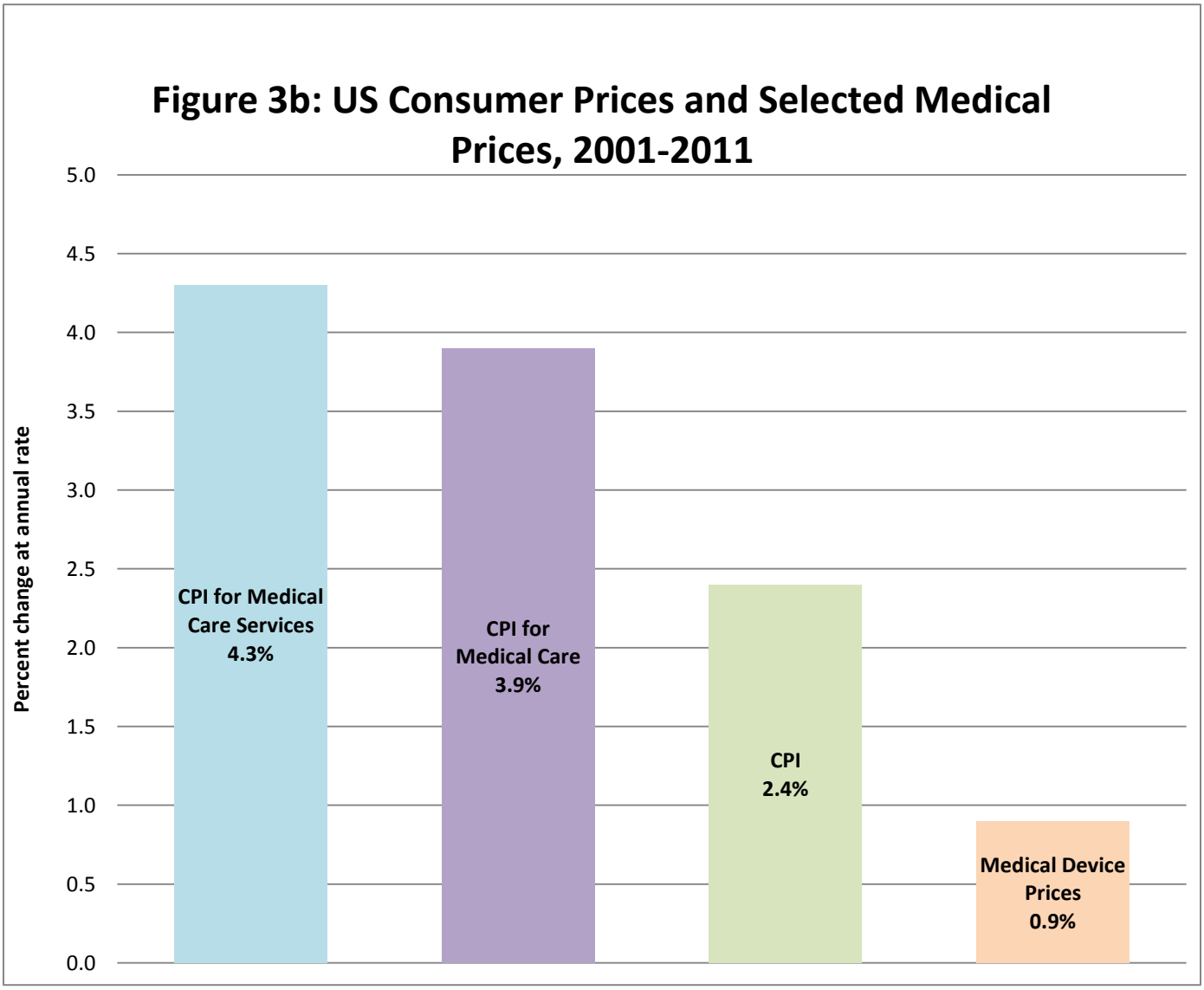
- During the 23-year period encompassed by our study (1989-2011), medical device spending has risen slightly as a percent of NHE—growing from 5.3 percent in 1989 to 5.9 percent in 2011—a 0.6 percentage point increase over the 23-year period [Figure 2]. Since 1992, although medical device spending as a share of NHE has varied somewhat, it has remained essentially constant at about six percent of NHE.



2. Medical device price changes have been consistently low over the period from 1989 to 2011. Medical device prices have increased at an average annual rate of 1.0 percent, compared to the Consumer Price Index (CPI) increase of 2.7 percent, the Medical Care Consumer Price Index (MC-CPI) increase of 4.6 percent, and the Medical Care Services Consumer Price Index (MCS-CPI) increase of 4.9 percent. [Figure 3a]



The most recent 10-year period reveals a similar pattern. For the 10-year period ending in 2011, medical device prices have increased at an average annual rate of 0.9 percent, compared to the CPI increase of 2.4 percent, the MC-CPI increase of 3.9 percent, and the MCS-CPI increase of 4.3 percent. [Figure 3b]



Discussion

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.

Our first finding was that medical devices make up a relatively small and constant share of national health expenditures. In 2011, the latest year that can be studied using Census Bureau data, spending on medical devices and in-vitro diagnostics totaled $159.4 billion, or 5.9 percent of total national health expenditures (Figure 1).[6]

Throughout the 23-year study period (1989-2011), spending on devices grew slowly as a share of total national health expenditures. While device spending as a share of total national health expenditures did vary by year, over the entire period it increased from 5.3 percent to 5.9 percent (Figure 2). However, virtually all of this growth in medical device spending as a share of NHE took place between 1989 and 1992. The share of medical device spending as a percent of NHE, while varying from year to year, has been essentially flat at about 6.0 percent since 1992. Over the full period, medical device spending increased at an average annual rate of 7.2 percent compared to 6.7 percent for overall national health expenditures. Since 1992, however, medical device spending has increased at a rate of 6.1 percent annually compared to 6.2 percent for NHE.

While medical device spending has grown at about the same rate as national health expenditures overall, prices for medical devices have actually grown far more slowly than the Medical Consumer Price Index or even the overall Consumer Price Index (Figure 3b). Over the period from 1989 to 2011, medical device prices have increased at an average annual rate of only 1.0 percent, compared to 4.6 percent for the MC-CPI and 2.7 percent for the CPI. This relatively slow rate of price increase suggests the industry is highly price competitive.

Conclusion

During much of the 23-year period 1989 to 2011, 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 been growing more slowly than both the MC-CPI and the CPI as a whole.

[6] The release of data from the Census Bureau's 2012 Economic Census has been delayed until late 2014 or early 2015.

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.[7] To develop a clear "device boundary," we 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."

The device boundary would have eliminated in-vitro diagnostic substances (NAICS 325413). These commodities are "substances" rather than devices.

We 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 "medical boundary" we used manufacturing categories in NAICS (the North American Industry Classification System) 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 data. The medical boundary narrows the 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.

Devices such as computers and autos that are used by the health services industry as well as by many other industries were not included.

Dental equipment and supplies (NAICS 339114) and dental laboratories (NAICS 339116) were excluded, 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 drop Laboratory apparatus and furniture (NAICS 339111) because the apparatus portion was largely non-medical and no data were available to allocate the total. In 2007 there were 630

[7] 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.

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 13,000 of the 630,000 establishments were medical and diagnostic labs, but there were 25,000 food-processing establishments, many with quality assurance labs, and about 4,000 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. 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.

We further narrowed the scope by dissecting some of the remaining categories into medical and non-medical components, and where possible (with sufficient statistical accuracy), removed the non-medical portion to improve the estimates. The categories removed were: 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.

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.

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.

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 and 2007 Economic Censuses were tabulated using NAICS, and the earlier Censuses were tabulated using the SIC. The Census Bureau website provides bridge tables linking the NAICS codes with the Standard Industrial Classification (SIC) codes. Product shipments data from the 2012 Economic Census are scheduled for release in late 2014 or early 2015.

Data on non-medical irradiation equipment are from the Census Bureau's Current Industrial Reports (Series MA334S, "Electromedical and Irradiation Equipment" through 2004 and Series MA334A, Electromedical Equipment and Analytical Instruments" for 2005 through 2010. Because these

publications were discontinued, the non-medical share for 2011 was assumed to be equal to the 2010 share. Personal industrial safety devices and protective clothing are available in the ASM.

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 "re-exports"; 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 on the basis of 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 in order to develop estimates needed to reconcile NAICS with the SIC and to remove non-medical portions of the broad categories discussed above.

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.[8]

[8] 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 and 2002. 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.

Census data through 1997 classified wholesalers into three groups: Merchant wholesalers (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 of 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 and 1997. 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 and 2007 The 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 5234501; 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 (excluding the non-medical portions discussed above). 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 and the share of wholesale trade going to retail trade and export were interpolated linearly between Census years and the 2007 values were repeated for subsequent years.

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 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
Exports at port value	4	
Exports margin	1	
Imports at port of entry price		4
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 six-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 PPI's are applicable to both (because exports are a subtraction, their prices do not affect the calculations).[9]
>
> (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.

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 nonsampling errors. Nonsampling 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." [10]

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

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

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.

Tables

National Health Expenditure vs. Medical Devices

Year	National Health Expenditures (billions $)	Medical Devices Expenditures (billions $)	Medical Devices as a Share of NHE
1989	647.5	34.6	5.3%
1990	724.3	38.8	5.4%
1991	791.5	42.8	5.4%
1992	857.9	51.4	6.0%
1993	921.5	55.0	6.0%
1994	972.7	54.7	5.6%
1995	1027.4	57.3	5.6%
1996	1081.8	61.8	5.7%
1997	1142.6	64.8	5.7%
1998	1208.9	72.5	6.0%
1999	1286.5	76.9	6.0%
2000	1377.2	82.4	6.0%
2001	1493.4	87.0	5.8%
2002	1638.0	96.3	5.9%
2003	1778.0	103.9	5.8%
2004	1905.7	111.9	5.9%
2005	2035.4	125.1	6.1%
2006	2166.7	132.2	6.1%
2007	2302.9	137.9	6.0%
2008	2411.7	147.9	6.1%
2009	2504.2	145.6	5.8%
2010	2599.0	155.6	6.0%
2011	2692.8	159.4	5.9%

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

Year	National Health Expenditures	Medical Devices Expenditures
1990	11.9%	12.1%
1991	9.3%	10.1%
1992	8.4%	20.2%
1993	7.4%	6.9%
1994	5.6%	-0.4%
1995	5.6%	4.7%
1996	5.3%	7.9%
1997	5.6%	4.9%
1998	5.8%	11.8%
1999	6.4%	6.1%
2000	7.1%	7.2%
2001	8.4%	5.5%
2002	9.7%	10.7%
2003	8.6%	8.0%
2004	7.2%	7.6%
2005	6.8%	11.8%
2006	6.5%	5.7%
2007	6.3%	4.3%
2008	4.7%	7.3%
2009	3.8%	-1.6%
2010	3.8%	6.9%
2011	3.6%	2.5%

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 Device Prices
1990	9.3%	9.0%	5.4%	3.4%
1991	8.9%	8.7%	4.2%	3.1%
1992	7.6%	7.4%	3.0%	2.8%
1993	6.5%	5.9%	3.0%	1.2%
1994	5.2%	4.8%	2.6%	0.4%
1995	5.1%	4.5%	2.8%	0.4%
1996	3.7%	3.5%	3.0%	0.3%
1997	2.9%	2.8%	2.3%	-0.8%
1998	3.2%	3.2%	1.6%	0.4%
1999	3.4%	3.5%	2.2%	0.3%
2000	4.3%	4.1%	3.4%	0.4%
2001	4.8%	4.6%	2.8%	1.1%
2002	5.1%	4.7%	1.6%	1.2%
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%	0.9%
2009	3.2%	3.2%	-0.4%	0.5%
2010	3.5%	3.4%	1.6%	0.5%
2011	3.1%	3.0%	3.2%	0.7%