

Estimates of Medical Device Spending in the United States

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Abstract

Advances in medical technology have long been believed to be a major driver of health care costs, but surprisingly little is known about the aggregate value and prices of one of the major types of medical technology, medical devices and diagnostics. This data note analyzes spending on medical devices for 1989-2004. Prices for medical devices consistently grew more slowly than either the Medical Consumer Price Index or the Consumer Price Index as a whole.

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 is a major driver of health cost increases.¹ Other findings have suggested that returns on spending on medical technologies can far exceed their costs, particularly when longer term benefits are measured in terms of productivity and reduced disability.²

Literature on the systemic effects of advances in medical technology generally uses the term in a broad sense to include such factors as: (1) the development and use of new and improved medical devices and diagnostics; (2) development of new medical procedures; (3) improvements in existing procedures; (4) increases in the number of procedures performed because of increased safety, effectiveness, or convenience, (5) development of new pharmaceutical products. Surprisingly little research has been done on the separate impact of medical devices, and there is virtually no published analysis on basic questions about medical spending on the devices themselves and on the role of price versus volume change.³ In part, this is because devices are rarely purchased separately from hospital, other institutional, or physician services and therefore do not appear as a separate line item in the national health spending accounts.

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This data note attempts to fill this gap by analyzing expenditures on medical devices as a share of overall national health expenditures and of growth in medical costs. In addition, our study analyzes the growth in the prices of medical devices and separates out price effects from other factors contributing to the growth in spending on medical devices and diagnostics.

Findings

In this study, we estimated the cost of medical devices and diagnostics and the contribution of these products to increases in national health expenditures. We attempted to use the same methodological rigor in estimating medical device spending as is used by CMS (The Centers for Medicare and Medicaid Services) in compiling estimates of the major categories of national health care spending. The findings were interesting and, to some degree unexpected:

- Medical devices are a relatively small share of total national health expenditures
- Over the fifteen year period studied, medical devices remained fairly constant as a share of national health expenditures
- Prices for medical devices grew more slowly than either the CPI for medical services or the CPI overall.

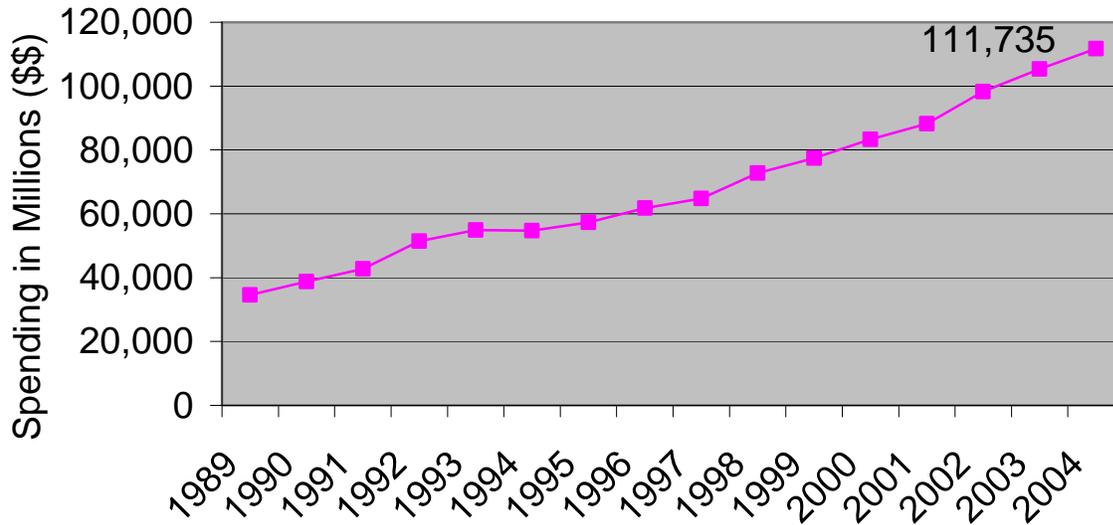
Discussion

As described in the methodological appendix, we began our analysis by selecting categories from the North American Industry Coding 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 2004, the latest year studied, spending on medical devices and in vitro diagnostics totaled \$111.7 billion, or 6.0% of total national health expenditures (Figure 1).²

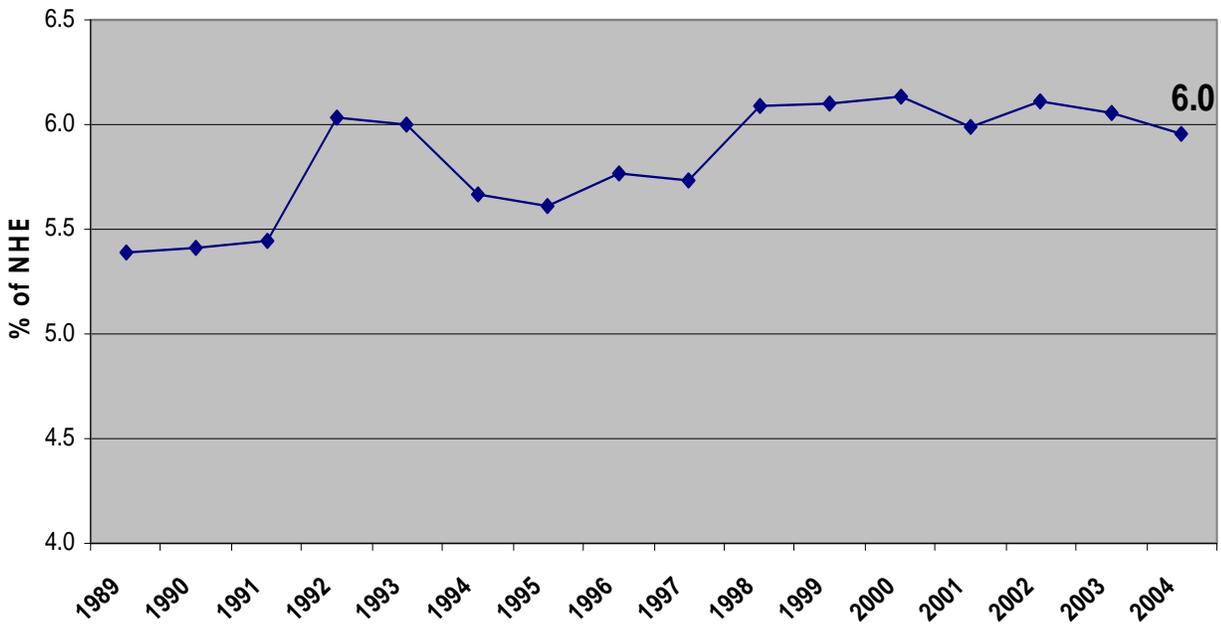
² See Table 1 in the Appendix on page 21 for the data underlying each of the following figures (1-4).

Figure 1. US Medical Device and In Vitro Diagnostic Spending, 1989 to 2004



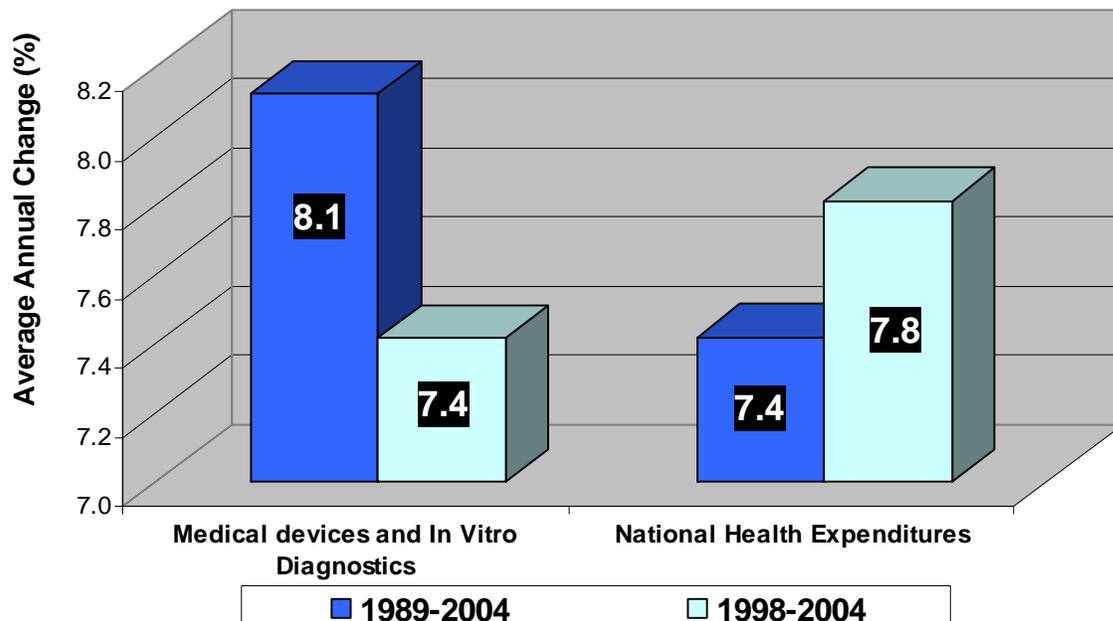
Throughout the fifteen-year study period (1989-2004), spending on devices remained relatively constant as a share of total national health expenditures. While spending as a share of expenditures did vary by year, it never fell below 5.4% and never rose above 6.1% (Figure 2).

Figure 2. Medical Devices as a Percentage of National Health Expenditures



Over the full period, medical device spending increased at an average annual rate of 8.1% compared to 7.4% for overall national health expenditures. However, over the most recent six years (1998-2004), medical device spending has increased less rapidly than NHE—at a rate of 7.4% annually compared to 7.8% for NHE (Figure 3).

Figure 3. Average Annual Percentage Changes, Medical Devices, National Health Expenditure (NHE)

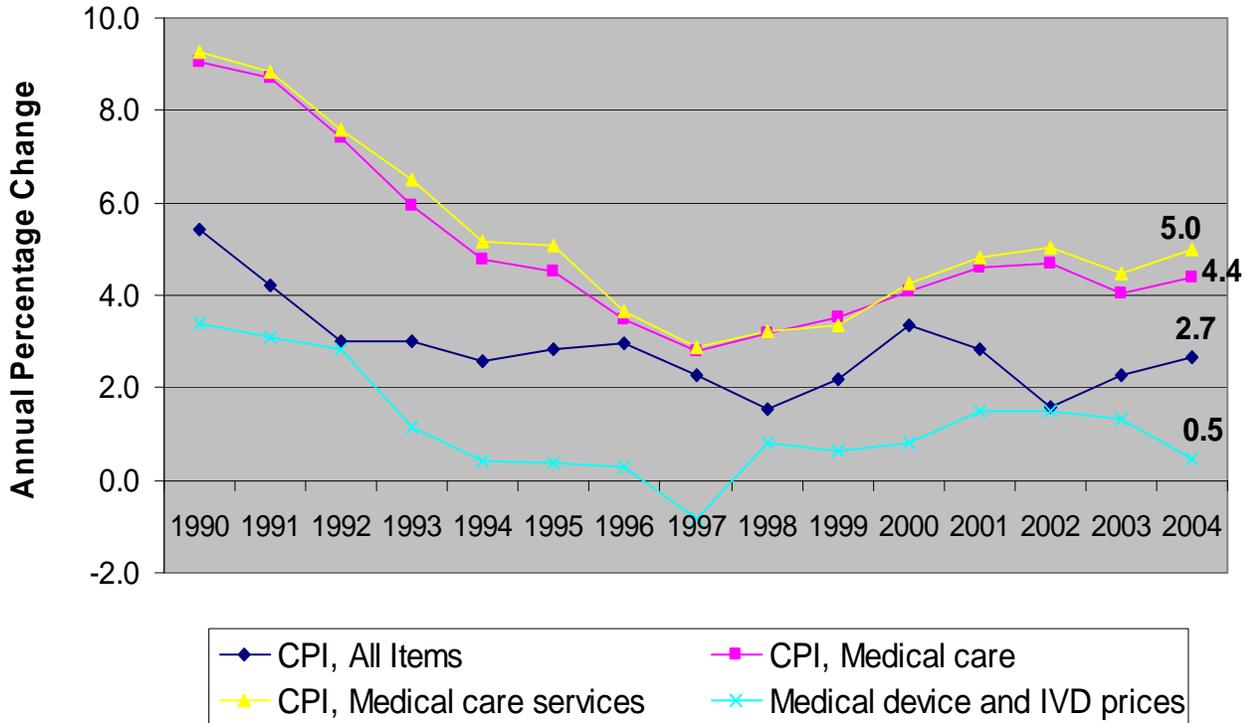


While medical device spending has grown at about the same rate as national health expenditures overall, prices for medical devices have actually grown far more slowly than the Medical Consumer Price Index or even the overall Consumer Price Index (Figure 4). During the fifteen-year study period, medical device prices have increased at an average annual rate of only 1.2%, compared to 5.0% for the MCPI and 2.8% for the CPI. This relatively slow rate of price increase suggests that the industry is highly competitive.

During much of this fifteen year period, 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 to 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 remained constant 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 not only than the MCPI but than the CPI as a whole.

Figure 4. Annual Percentage Change, Consumer Price Index (CPI), CPI for Medical Care, CPI for Medical Services, Medical Device Prices, 1989 to 2004



Methodological Appendix

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.⁴ 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 Coding 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 eight 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 (NAICS339116) 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 2002 there were over 700 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 11 thousand of the 700 thousand establishments were medical and diagnostic labs, but there were 23 thousand food-processing establishments, many with quality assurance labs, and about four 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. 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 appliances 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. Unfortunately, sufficient data were not available to implement this plan. For example, Census data indicate that for 2004, X-ray tubes valued at \$199 million were 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) for 1997 indicate that \$119 million of the shipments of electromedical and electrotherapeutic apparatus was purchased and used by that same industry. This made up only about 1 percent of the industry's output.

Appendix 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 Economic Census data were not used directly in deriving the estimates but were consulted as a control on the ASM data; much more detail is available for Census years.

The Census Bureau website provides bridge tables linking the NAICS codes with the Standard Industrial Classification (SIC) codes. The 1997 and 2002 Economic Censuses were tabulated using NAICS, and the earlier Censuses were tabulated using the SIC. NAICS changed between 1997 and 2002, but no manufacturing classifications changed. (The Economic Census for manufacturing did have some changes made by Census, however. They classified hospital beds in a different NAICS category.)

Data on non-medical irradiation equipment are from the Census Bureau's *Current Industrial Reports*, Series MA334S, "Electromedical and Irradiation Equipment." This publication ended in 2004, but the products covered will appear in another of the CIR series reports in the future. Personal industrial safety devices and protective clothing are available in the ASM. Anti-glare glasses and related goods were interpolated between Census years (and extrapolated to 2004) using a residual nsk (not separately known) category 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 leave 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 were

significant. For 2004, total exports for NAICS category 339112 were \$7.8 billion, compared with domestic exports of 4.8 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 from data published in the Economic Census.⁵

Census data classifies 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, 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 were 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, no data on commissions by agents and brokers were available; so they were extrapolated forward using 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 1993-2004, 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 2002 values were repeated for 2003 and 2004.

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

Real Output and Fisher Indexes

Real output is the term generally applied to output that is adjusted to eliminate price change. Expenditures in current dollars or current prices are measures of the output in the prices that existed when the items were actually purchased. There are several methods available to adjust current-dollar measures to eliminate price change. The simplest is to measure everything in the prices of a single base year. Thus, if there were only one commodity in the economy, say apples, expenditures in current dollars would be the number of apples sold times the price of apples in each year; the real or constant-dollar value would be the number of apples sold in each year times the price of apples in the base year (for example, 2000).

With multiple commodities sold in the economy, the calculation becomes a little more complicated. Expenditures in current dollars can be thought of as a series *quantities* multiplied by their corresponding *prices*. If a single fixed base year is used for measuring real expenditures, constant dollar expenditures may be thought of as the quantity of commodity one times the base-year price of commodity one, plus the quantity of commodity two times the base year price of commodity two, etc. The problem with this simple approach is that it is biased. If the base year is earlier than the period one is examining, the change in real expenditures will contain an upward bias. This results from the fact that the fastest growing commodities in the economy tend to be those with the smallest price increases (or those with falling prices); these commodities will be over weighted by the higher price in the earlier base year.

In recent years, economists have begun using a weighting system based on the Fisher formula. In this formula the geometric mean of the weights of two adjoining years is used. The Fisher index is calculated by first calculating a Paasche (P in the formula below) and a Laspeyres (L) for each year-to-year change. The Fisher index (F) is the square root of the product of the P and L indexes. In the formulas below, the q's are the quantities and the p's are the prices of individual commodities in the current year (t) and the preceding year (t-1).

$$P = \frac{\sum p(t) \cdot q(t)}{\sum p(t) \cdot q(t-1)}$$

$$L = \frac{\sum p(t-1) \cdot q(t)}{\sum p(t-1) \cdot q(t-1)}$$

$$F = \text{Square root of } (P \cdot L) = (P \cdot L)^{1/2}$$

The resulting indexes are actually indexes of change. For example, P might result in an increase of 12 percent from year t-1 to year t, for an index value of 1.12, and L might result in an increase of 7 percent for a value of 1.07. Then F would be the square root of the product of 1.12 and 1.07 or 1.095.

One disadvantage of the Fisher formula is that the indexes for aggregates are not additively related to the components from which they have been computed. A series of annual changes is often chained forward and backward from a base year to produce a time series. For example, GDP is presented in “chained 2000 dollars.” However, even for such “dollar-denominated series,” the aggregates are not the sum of the components.

Both the fixed-weighted and Fisher methodology were used to derive real estimates for purposes of this study. When compared with the results of the Fisher methodology, the fixed-weighted estimates did not show a significant bias over the entire period, but there were some differences in annual changes and sub-period.

Medical device spending was deflated 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 PPI's are applicable to both (because exports are a subtraction, their prices do not affect the calculations).⁶

(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.

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.”⁷

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.

There is one anomaly in the wholesale trade data worthy of mention. The share of wholesale sales of Surgical, medical and hospital supplies passing through retail channels jumped from 1.5 percent in 1997 to 13.1 percent in 2002. The statistics as presented in the Economic Census statistical tables seem to be internally consistent, so we used them as shown. This resulted in a strong upward trend in retail margins for this group (from about \$0.2 billion in 1997 to about \$3 billion in 2002). It is possible that a company or establishment changed its classification in Census data over that period. If that is the case, the increase may actually belong in a specific year rather coming about gradually over that time period.

¹ See V.R. Fuchs, “Economics, Values and Health Care Reform,” *The American Economic Review* 86, no. 1 (1996): 1–25, 19.

² D.M. Cutler and M. McClellan, “Is Technological Change Worth It?” *Health Affairs* 20, no. 5 (2001): 11-29.

³ A recent 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 Medical Technology Assessment Working Group, Center for Demographic Studies, Duke University, “Assessing the Impact of Medical Technology Innovations on Human Capital; Phase I Final Report (Part A): State-of-the-Science Literature Reviews,” 31 January 2001, Prepared for the Institute for Medical Technology Innovation, http://www.inhealth.org/MediaCenter/Duke_Final_Report_A_State_of_the_Science_Literature_Reviews.pdf

⁴ 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.

⁵ 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, and 1997. The 2002 tables will be published in 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.

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

⁷ United States Census Bureau, *Annual Capital Expenditures, 1999: C-4*.

Appendix

Table 1.--Measures of Expenditures and Prices Underlying Figures 1 through 4

Year	Expenditures for medical devices (including IVD's) in the United States [Millions of dollars]	Expenditures for medical devices (including IVD's) in the United States as a percent of CMS National Health Expenditures [Percent]	<u>Percent change from preceding year in selected price measures</u>			
			Medical devices [Percent]	All items [Percent]	CPI for all urban consumers Medical care [Percent]	Medical services [Percent]
1989	34619	5.4
1990	38818	5.4	3.4	5.4	9.0	9.3
1991	42751	5.4	3.1	4.2	8.7	8.9
1992	51401	6.0	2.8	3.0	7.4	7.6
1993	54955	6.0	1.2	3.0	5.9	6.5
1994	54711	5.7	0.4	2.6	4.8	5.2
1995	57275	5.6	0.4	2.8	4.5	5.1
1996	61815	5.8	0.3	3.0	3.5	3.7
1997	64811	5.7	-0.8	2.3	2.8	2.9
1998	72743	6.1	0.8	1.6	3.2	3.2
1999	77458	6.1	0.6	2.2	3.5	3.4
2000	83307	6.1	0.8	3.4	4.1	4.3
2001	88216	6.0	1.5	2.8	4.6	4.8
2002	98291	6.1	1.5	1.6	4.7	5.1
2003	105311	6.1	1.3	2.3	4.0	4.5
2004	111735	6.0	0.5	2.7	4.4	5.0

Abbreviations: IVDs - invitro diagnostic devices; CMS - Centers for Medicare and Medicaid Services; CPI - consumer price index