U.S. GOVERNMENT ACCOUNTABILITY OFFICE
441 G St. N.W.
Washington, DC 20548

June 30, 2015

The Honorable Harry Reid
Senate Minority Leader
United States Senate

Medical Device Companies: Trends in Reported Net Sales and Profits Before and After Implementation of the Patient Protection and Affordable Care Act

Dear Senator Reid:

The Patient Protection and Affordable Care Act (PPACA), as amended by the Health Care and Education Reconciliation Act of 2010 (HCERA), contained a number of provisions intended to increase the availability and affordability of health insurance coverage while also controlling costs—particularly beginning in 2014. Various PPACA provisions that were designed to control costs, including provisions that reduced Medicare reimbursement rates for certain types of services that rely on imaging devices, were implemented starting in 2010 through 2015.[1] PPACA also expanded coverage by requiring the creation of health insurance exchanges in each state, through which eligible individuals and small businesses could qualify for federal subsidies to purchase private health insurance coverage, by 2014. PPACA included a number of provisions to raise revenues in order to help finance these coverage expansions, such as the medical device tax.[2] Specifically, PPACA established a 2.3 percent excise tax on the sale of certain medical devices in the United States after December 31, 2012, which the Joint Committee on Taxation estimates will raise cumulative revenues of $20 billion for fiscal years 2013 through 2019.[3] Congress exempted from the tax certain medical devices that are typically purchased by the general public at retail for individual use, such as eyeglasses, contact lenses, and hearing aids.[4]

The medical device industry has raised concerns that PPACA—and in particular the medical device excise tax—will adversely affect the medical device market. For example, opponents of the tax have said that the tax would result in a cancellation of capital investments, decreased

[1]The Medicare program provides health coverage for persons age 65 or over, certain individuals with disabilities, and individuals with end-stage renal disease.

[2]See Pub. L. No. 111-148, §§ 9009, 10904, 124 Stat. 119, 862, 1016 (2010) (hereafter PPACA), as amended by the Health Care and Education Reconciliation Act of 2010, Pub. L. No. 111-152, § 1405, 124 Stat. 1029, 1064 (2010) (hereafter HCERA) (codified at 26 U.S.C. § 4191). For purposes of this report, references to PPACA encompass the provisions of HCERA. Thus, while HCERA enacted the medical device tax described in this report, we refer to the tax in relation to PPACA as the better known law.

Medical devices include instruments that are intended to be used for the diagnosis, cure, mitigation, treatment, or prevention of a disease. Medical device companies produce a wide variety of products that range from tongue depressors and surgical clamps to more complicated devices, such as hip replacements and heart pacemakers.

[3]26 U.S.C. § 4191. See Joint Committee on Taxation, JCX-17-10, Mar. 20, 2010.

[4]Under PPACA, any other medical devices determined by the Secretary of the Treasury to be generally purchased by the general public at retail for individual use are to be exempt. The Department of the Treasury issued regulations on December 7, 2012, establishing a two-prong test for determining whether a medical device falls within this retail exemption. *Taxable Medical Devices*, 77 Fed. Reg. 72924 (Dec. 7, 2012) (codified at 26 C.F.R. § 48.4191-2(b)).

hiring, and a reduction in research and development. Furthermore, opponents have said that small companies will be disproportionately impacted by the tax because these companies tend to have lower profit margins than larger companies and may not be able to afford the tax. However, proponents of the tax have argued that PPACA coverage expansions have the potential to increase patient demand for medical devices, thereby offsetting any negative impact of the medical device excise tax on companies. For example, proponents have cited a study conducted by the Congressional Research Service (CRS) that suggests the tax is unlikely to significantly impact medical device company profits, in part because the added costs would be largely passed on to consumers through higher prices.[5] CRS's report pointed out that demand for medical devices would likely increase as a result of PPACA's coverage expansions, although it did not analyze the extent to which demand may increase.[6]

You asked us to examine trends in medical device sales and profits over the last decade, including before and after the implementation of PPACA. Specifically, we examined reported net sales and net profits from 2005 through 2014 for certain publicly traded companies whose primary revenue source is from medical devices, and how these companies reported being affected by PPACA in public financial disclosure statements.[7]

To describe reported net sales and net profits from 2005 through 2014 for certain publicly traded companies whose primary revenue source is from medical devices and how these companies reported being affected by PPACA in public financial disclosure statements, we obtained selected financial data from the Securities and Exchange Commission (SEC) for medical device companies based on publicly available financial disclosure statements that are filed annually with the agency.[8] SEC provided us with 2005 through 2014 financial data from Standard and Poor's Compustat database, a commercially available database containing data that are

[5]The CRS report suggests that demand for medical devices, like for other health care products, is minimally price-sensitive. This would allow medical device companies to increase prices without experiencing a significant decrease in demand. Jane G. Gravelle and Sean Lowry, *The Medical Device Excise Tax: Economic Analysis,* Congressional Research Service R43342 (Washington, D.C.: Jan. 9, 2015). For additional studies that examined the impact of the medical device excise tax on companies, see Lisa Swirksi, *Medical Device Manufacturer Profits*, *(*Yonkers, N.Y.: Consumers Union, September 2013); and Josh Archambault, and Xiaofei (Jackie) Zhou, *First, Do No Harm: The Impact of the Affordable Care Act on Massachusetts' Medical Device Industry,* (Boston, Mass: Pioneer Institute for Public Policy Research, April 2013).

[6]A study by Wells Fargo Securities attempted to analyze the increase in demand for medical devices, finding that the PPACA coverage expansions will likely increase sales for 10 key categories of devices enough to offset the effects of the medical device tax. Wells Fargo Securities, *Healthcare Coverage Expansion: A Shot in the Arm for MedTech* (Apr. 1, 2013).

[7]Net sales represent a company's gross sales less the cost of discounts, returns and allowances. Net profit represents a company's net income (or loss) after expenses are subtracted from total earnings. Companies report net sales and net profit data on their income statement, which, depending on the company, can include results from their business in the United States as well as other countries.

[8]Federal securities laws require certain companies, including those that have a certain number of shareholders or that have a class of securities registered on a U.S. stock exchange, to file annual disclosure statements with SEC describing their financial conditions and business practices, called either a 10-K or 20-F depending on whether the company is based in the United States or overseas. Domestic and foreign companies that have a limited number of shareholders in the United States and whose stock is not listed on a U.S. stock exchange are generally not required to submit data to SEC. For example, Siemens Healthcare is a major foreign-based manufacturer of medical devices; but, its parent company no longer submits an annual report to SEC as the number of its U.S.-based shareholders does not meet SEC's required threshold for reporting financial data and it is not listed on a U.S. stock exchange. Not all companies have fiscal years that align with the calendar year. However, for the purposes of our study, if the company's fiscal year ended after March 30th, we considered the fiscal year to be the same as the calendar year. If the fiscal year ended anywhere from January 1st through March 30th, we considered the fiscal year to be the same as the prior calendar year.

electronically extracted from company financial disclosure statements filed with SEC. Specifically, SEC provided us with net sales and net profit data during the time period for the 193 companies in the Compustat database whose primary source of revenue was from medical devices based on each company's Standard Industrial Classification (SIC) code in 2014.[9] For 31 of these companies, we obtained the 2014 net sales and net profit data from the financial disclosure statements available on the SEC website rather than from the Compustat database because 2014 data were not yet available for these companies in Compustat at the time of our review. SEC also provided us with data on market capitalization—that is, the total combined value of the company's stock—for these 193 companies based on its analysis of Compustat data. For these 193 companies, we analyzed data for the 102 that reported net sales and net profits each year from 2005 through 2014.[10] We adjusted net sales and net profits to constant 2014 U.S. dollars using the gross domestic product deflator to account for inflation. We also categorized companies by size based on their market capitalization in 2013.[11] (See encl. I for a list of these companies by size.) In addition, we reviewed the 2014 financial disclosure statements from the SEC website for each of the 102 companies to determine if and how they described being affected by PPACA. Specifically, we reviewed a standard section called "Risk Factors" in the financial disclosure statements, in which companies identify and describe the factors that they anticipate may affect their businesses. Federal securities laws generally require this section be included for all companies to inform investors about risks that may affect a company, but companies have the discretion to report the types of factors that may impact their businesses.[12] We reviewed the risk factors companies discussed in their 2014 financial disclosure statements because, in addition to being the most recent year available, this was the

[9]Companies with a primary source of revenue from medical devices may also manufacture other types of products that are not considered to be medical devices. Consequently, financial data reported on these companies' annual reports may include revenue from products other than medical devices subject to the tax. In addition, companies with multiple lines of business for which medical device sales may not constitute their primary revenue source, such as Johnson & Johnson and General Electric, were not included in our study. Based on data we obtained from SEC on active SEC registrants, 218 companies indicated their primary source of revenue was from medical devices in 2014 based on the following SIC codes: 3841-surgical and medical instruments and apparatus; 3842-orthopedic, prosthetic, and surgical appliances and supplies; 3843-dental equipment and supplies; 3844-x-ray apparatus and tubes and related irradiation apparatus; and 3845-electromedical and electrotherapeutic apparatus. Of these 218 companies, 193 had net sales, net profit, or market capitalization data available in Compustat between 2005 and 2014. The remaining 25 companies did not have data in the Compustat database.

[10]We excluded 91 companies from our analysis. Of these 91 companies, 85 did not have 10 years of net sales and net profit data from 2005 through 2014, or they did not have a 2013 market capitalization value. This could mean these companies entered the market or were not publicly traded throughout the time period. We chose to examine market capitalization as of 2013 because it was the most recent year available, as complete data for 2014 were not available for all 102 companies from the Compustat database at the time of our review. While market capitalization could have changed over the period, we examined 2013 data because we assumed they most closely reflected the current size of these companies. Two companies were excluded because they did not have data available in U.S. dollars. Four other companies were excluded because, upon review of their 2014 financial disclosure statements, we learned that they no longer participated in the medical device business.

[11]We defined categories for company size based on a review of 2013 market capitalization and the filing status companies self-reported on their 2014 10-Ks. We defined large-sized companies as those that had a market capitalization—that is, the total combined value of the company's stock—in 2013 of over $1 billion, medium-sized companies as those that had a market capitalization of $1 billion to greater than $100 million, and small-sized companies as those that had a market capitalization of $100 million or less. We identified 30 large-, 35 medium-, and 37 small-sized companies.

[12]For example, companies may list factors that are applicable to the entire economy, such as the effects of changes in economic conditions; a specific industry sector, such as the effects resulting from compliance with regulations governing the development, testing, and manufacturing of devices in the medical device sector; or to the company itself, such as a company's lack of profitable operations in recent periods. Since we wanted to examine how PPACA affected a company's business, we limited our review to the Risk Factors section, although companies could have potentially reported on PPACA in other sections of their financial disclosure reports.

year after which many PPACA provisions went into effect.[13] In addition, we spoke to representatives of three medical device industry trade groups—the Advanced Medical Technology Association, the Medical Device Manufacturers Association, and the Medical Imaging and Technology Alliance—to obtain their perspectives on the effects of PPACA.

While this report provides information on medical device sales and profits before and after implementation of PPACA provisions of particular relevance to medical device companies—such as the excise tax, reimbursement changes, and coverage expansions—our analyses do not establish a causal relationship between these provisions and changes in companies' sales and profits. This is because any changes in net sales and net profits could be due to factors aside from PPACA implementation, such as mergers and acquisitions, the introduction of new products, and product recalls. Additionally, the data that we used in our analyses do not isolate companies' sales in the United States from their sales in other countries, where tax-free sales may be made.[14] The inclusion or absence of a discussion of the impact of PPACA on medical device companies in the Risk Factors section of the 2014 financial disclosure statements does not provide a comprehensive assessment of the impact of PPACA because companies have some discretion about whether to report factors that may or may not be material to their businesses. Moreover, the results of our analyses are not generalizable to all medical device companies that are subject to the tax because we obtained data that excluded companies that are not required to submit financial disclosure reports to SEC, such as private companies that have a limited number of shareholders or do not have stock listed on a U.S. stock exchange. Industry trade groups we interviewed noted that, in general, companies that have been publicly traded for at least a decade may often be larger and more financially stable than many companies that are not publicly traded or that are newly established.

We assessed the reliability of the data provided to us by SEC from Standard and Poor's Compustat database and the data available on the SEC website by reviewing applicable securities laws, regulations, and accounting standards outlining the required form and content of company filings with SEC and discussing the data with SEC officials. We also performed data reliability checks for a sample of companies, such as comparing the Compustat data to the financial disclosure statements available on the SEC website and checking for outliers. We analyzed the data as they were reported by companies to SEC in their financial disclosure statements or extracted into the Compustat database. We did not otherwise independently verify the accuracy or completeness of the information. After taking these steps, we determined the data were sufficiently reliable for our purposes.

We conducted this performance audit from February 2015 to June 2015 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

[13]Specifically, the excise tax applied to certain medical devices sold starting in 2013. Also, expanded health insurance coverage—through states electing to expand Medicaid and the establishment of health insurance exchanges offering health plans eligible for premium tax credits—began as of January 1, 2014.

[14]See 26 C.F.R. § 48.4191-1(e). Companies may elect to report data on sales in the United States as part of the financial disclosures they file with SEC. However, unlike net sales and net profit data, companies are not generally required to report this information; therefore, the data were not complete enough for us to separately report U.S. sales.

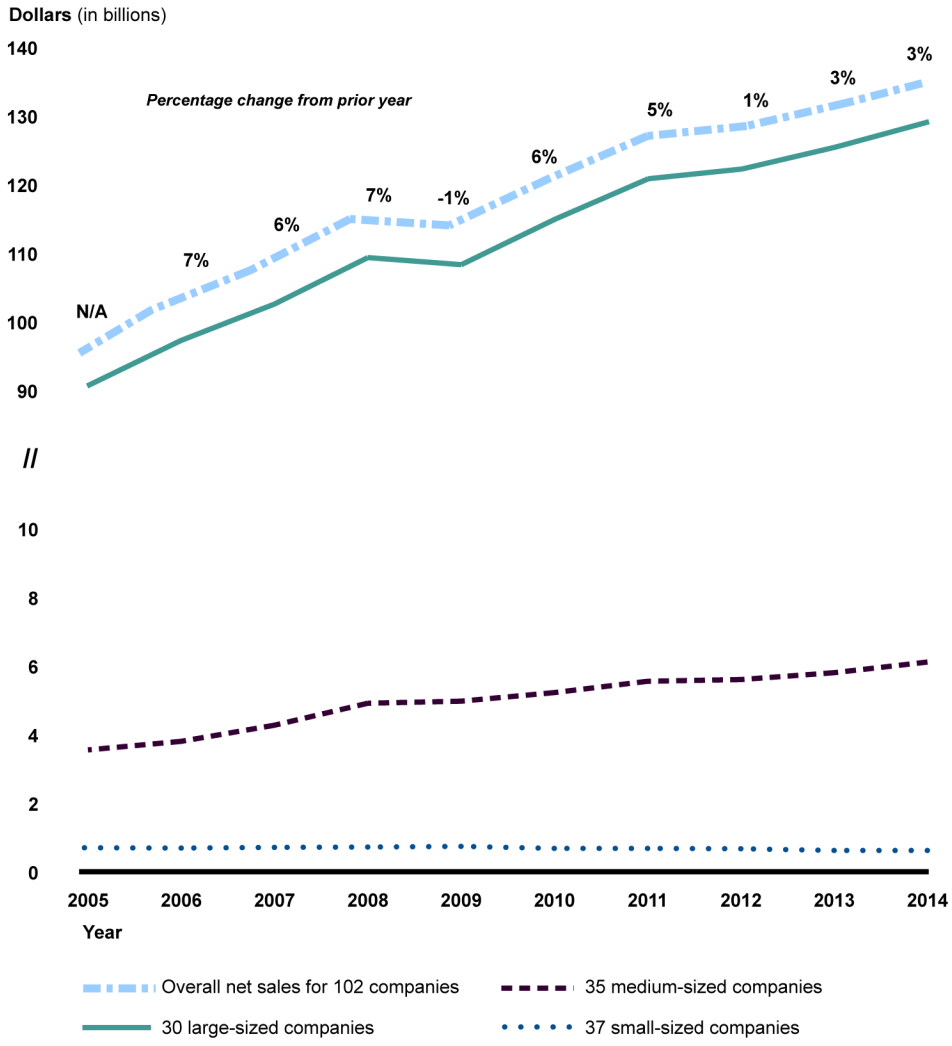
Medical Device Companies Reported Net Sales and Profits That Increased Overall from 2005 through 2014 and Were Uncertain about the Full Impact of PPACA

Medical Device Companies Reported Net Sales and Profits That Increased Overall from 2005 through 2014, but Results Varied by Company Size

The 102 medical device companies we reviewed reported net sales that increased overall from about $95 billion in 2005 to about $136 billion in 2014—about a 43 percent increase over the period and an average annual rate of increase of about 4 percent.[15] (See fig. 1.) Of these 102 medical device companies, 30 large-sized companies constituted nearly all of the total net sales—at least 95 percent of the total in each year from 2005 through 2014—while 35 medium-sized companies constituted about 4 percent of the total net sales in each year, and 37 small-sized companies constituted less than or equal to 1 percent of the total net sales in each year.

[15]All financial data are adjusted to 2014 U.S. dollars using the gross domestic product deflator. To determine the average annual rate of change, we calculated a compounded annual growth rate.

Figure 1: Overall Net Sales Reported by the Medical Devices Companies GAO Reviewed, 2005 through 2014



Source: GAO analysis of company financial disclosure data from the Securities and Exchange Commission. | GAO-15-635R

Notes:

The figure contains a scale break in the vertical axis (dollars) to better show the change in net sales for medium-sized and small-sized companies, which combined represented about 5 percent of total net sales for all companies reviewed in each year.

Data are adjusted to 2014 U.S. dollars using the gross domestic product deflator.

We defined large-sized companies as those that had a market capitalization—that is, the total combined value of the company's stock—in 2013 of over $1 billion, medium-sized companies as those that had a market capitalization of $1 billion to greater than $100 million, and small-sized companies as those that had a market capitalization of $100 million or less.

Much of the growth in reported net sales from 2005 through 2014 was driven by large- and medium-sized medical device companies, which experienced average annual rates of increase in net sales of about 4 percent and 6 percent, respectively. Specifically, net sales increased for large-sized companies from $90.8 billion to $129.3 billion (about 42 percent over the period) and increased for medium-sized companies from $3.5 billion in 2005 to $6.1 billion in 2014 (about 72 percent over the period). In contrast, small-sized companies experienced a decrease in net sales, with an average annual rate of decrease of about 1 percent and a decrease in sales from $700 million in 2005 to $616 million in 2014 (about a 12 percent decrease over the period). (See table 1.) (Encl. II provides reported net sales for each year of the period by company size.)

Table 1: Overall Net Sales by Company Size Reported by the Medical Device Companies GAO Reviewed, 2005 through 2014

Number and company size	Overall net sales (in billions) 2005	2014	Percentage change	Average annual rate of change
30 large-sized companies	$90.8	$129.3	42%	4%
35 medium-sized companies	3.5	6.1	72	6
37 small-sized companies	0.7[a]	0.6[a]	(12)	(1)
Overall net sales for 102 companies	**$95.0**	**$136.0**	**43%**	**4%**

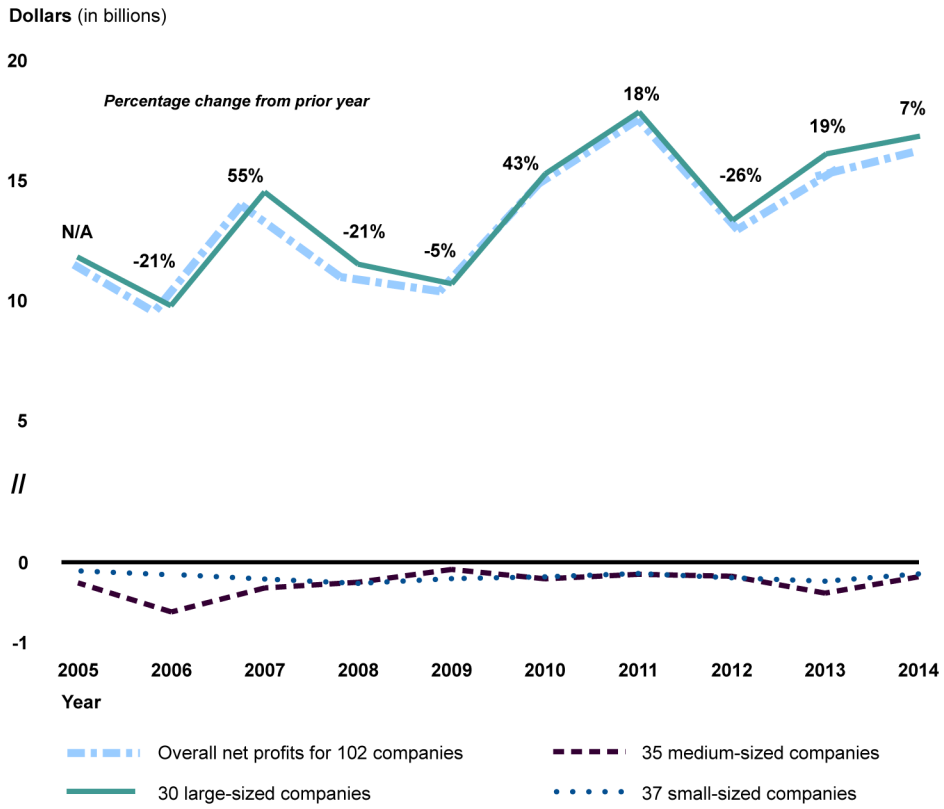
Source: GAO analysis of company financial disclosure data from the Securities and Exchange Commission. | GAO-15-635R

Notes: Data are adjusted to 2014 U.S. dollars using the gross domestic product deflator. Totals may not add due to rounding. For the average annual rate of change, we calculated a compounded annual growth rate. We defined large-sized companies as those that had a market capitalization—that is, the total combined value of the company's stock—in 2013 of over $1 billion, medium-sized companies as those that had a market capitalization of $1 billion to greater than $100 million, and small-sized companies as those that had a market capitalization of $100 million or less.

[a]Net sales for the small-sized companies were $700 million in 2005 and $616 million in 2014.

Net profits reported by the 102 medical device companies we reviewed also increased overall from about $11.4 billion in 2005 to about $16.5 billion in 2014—about a 44 percent increase over the period and an average annual rate of increase of about 4 percent. However, there were three time periods during which the overall net profit decreased. Specifically, overall net profit decreased from $11.4 billion to $9 billion from 2005 through 2006, from $14.0 billion to $10.4 billion from 2007 through 2009, and from $17.5 billion to $13 billion from 2011 through 2012. (See fig. 2.)

Figure 2: Overall Net Profit or Loss Reported by the Medical Device Companies GAO Reviewed, 2005 through 2014



Source: GAO analysis of company financial disclosure data from the Securities and Exchange Commission. | GAO-15-635R

Notes:

The figure contains a scale break in the vertical axis (dollars) to better show the change in net profits for medium-sized and small-sized companies, which had net losses in each year.

Data are adjusted to 2014 U.S. dollars using the gross domestic product deflator.

We defined large-sized companies as those that had a market capitalization—that is, the total combined value of the company's stock—in 2013 of over $1 billion, medium-sized companies as those that had a market capitalization of $1 billion to greater than $100 million, and small-sized companies as those that had a market capitalization of $100 million or less.

Nearly all of the reported increase in overall net profit was attributable to the 30 large-sized companies, as the 35 medium- and 37 small-sized companies experienced net losses in each year. Specifically, over the time period, the large-sized medical device companies experienced a reported increase in net profits from $11.8 billion to $16.9 billion (about 43 percent over the period), an average annual rate of increase of about 4 percent. In contrast, the medium- and small-sized medical device companies reported experiencing net losses in each year. The extent of the reported net loss decreased for medium-sized companies over the time period from a net loss of $267 million in 2005 to a net loss of $191 million in 2014 (about 28 percent over the period), an average annual rate of decrease in net losses of about 4 percent. The extent of the net loss reported for small-sized companies increased from a net loss of $112 million to a net loss of $155 million (about 38 percent over the period), an average annual rate of increase of about 4 percent in net losses. (See table 2.) The net losses reported for both medium- and small-sized companies fluctuated between 2010—when PPACA was passed—and 2014, but they decreased overall from 2010 through 2014. (See encl. III for the reported net profit or loss for each year of the period by company size.)

Table 2: Overall Net Profit or Loss by Company Size Reported by the Medical Device Companies GAO Reviewed, 2005 through 2014

Number and company size	Overall net profit or loss (in billions) 2005	2014	Percentage change	Average annual rate of change	Increase or decrease in net profit or loss
30 large-sized companies	$11.8	$16.9	43%	4%	Increase in net profit
35 medium-sized companies	(0.3)[a]	(0.2)[a]	(28)	(4)	Decrease in net loss
37 small-sized companies	(0.1)[b]	(0.2)[b]	38	4	Increase in net loss
Overall net profit for 102 companies	**$11.4**	**$16.5**	**44%**	**4%**	**Increase in net profit**

Source: GAO analysis of company financial disclosure data from the Securities and Exchange Commission. | GAO-15-635R

Notes: Data are adjusted to 2014 U.S. dollars using the gross domestic product deflator. Totals may not add due to rounding. For the average annual rate of change, we calculated a compounded annual growth rate. We defined large-sized companies as those that had a market capitalization—that is, the total combined value of the company's stock—in 2013 of over $1 billion, medium-sized companies as those that had a market capitalization of $1 billion to greater than $100 million, and small-sized companies as those that had a market capitalization of $100 million or less.

[a]The 35 medium-sized companies had a net loss of $267 million in 2005 and a net loss of $191 million in 2014.

[b]The 37 small-sized companies had a net loss of $112 million in 2005 and a net loss of $155 million in 2014.

Overall net profit margins—that is, the ratio of reported net profits to reported net sales—for the 102 companies we reviewed varied from 2005 through 2014, ranging from a low in 2006 of 9 percent to a high of 14 percent in 2011.[16] (See encl. IV for the net profit margin for each of year of the period by company size.) There are many company-specific factors that can contribute to changes in net sales and profits, such as product recalls and mergers and acquisitions, in addition to broader economic factors, such as the recent economic recession. For example, one of the companies in our review recalled its hip implant system in 2012 and reported lower net profits as a result of this recall and the related litigation.

Medical Device Companies Expressed Uncertainty about the Full Impact of PPACA, and Some Reported Likely Impacts from the Excise Tax, Reimbursement Changes, and Coverage Expansions

Of the 102 medical device companies whose 2014 financial disclosure statements we reviewed, 75 reported that they were uncertain about PPACA's full impact on their businesses.[17] For example, one company noted that it was unable to predict the full impact of PPACA because of the law's complexity and the lack of regulations and guidance currently in place. Another company noted that the impact of PPACA on its business was unclear because certain provisions in the law will not be in effect for a number of years, and there are many programs for which the details have not been fully established.

While the full impact of PPACA was uncertain for many of these companies, more than half of the 102 companies noted that the medical device excise tax has had or may have an impact on their businesses. For example, one company stated that the tax had adversely affected the results of its operations and cash flows, although the company has been implementing cost

[16]We calculated the net profit margin by dividing overall reported net profits by overall reported net sales.

[17]Two of these companies elected not to include a Risk Factors section in their financial disclosure reports, and, for the purposes of our analysis, we considered these companies to not have any risks. The remaining 25 companies did not report on the potential impact of PPACA on their businesses in the Risk Factors section.

reductions to mitigate the impact of the excise tax. Another company noted that it had not been able to pass along the cost of the tax to hospitals, which are its main customers, because they face cuts to their Medicare reimbursement rates due to PPACA. In another example, one small-sized medical device company noted that it is still evaluating the potential impact of the excise tax on its business.

Moreover, more than half of the 102 companies reported that changes in reimbursements for medical devices or other cost controls resulting from PPACA have had or may have an impact on their businesses. For example, one company noted that PPACA had created uncertainty regarding reimbursement and delivery of services, resulting in reluctance on the part of health care providers to improve their practices with new products and equipment and, therefore, adversely impacting the company's revenues. Another company noted that pilot programs to evaluate alternative payment methodologies and other changes to the payment systems resulting from PPACA may adversely affect its business. In another example, a company noted that demand for the medical devices it produces could decrease if fewer hospital procedures are performed due to reductions in Medicare reimbursement rates.

Lastly, 15 of the 102 companies reported that they were uncertain about how coverage expansions resulting from PPACA might impact their businesses. Two of these companies reported that the coverage expansions may positively impact their businesses—for example, by increasing demand—while the remaining companies stated that they were currently unable to determine how coverage expansions might affect them.

Industry trade group representatives we interviewed told us the medical device excise tax and changes in reimbursements—particularly to Medicare hospital reimbursements—have had the greatest impact on their member companies.[18] They also stated that coverage expansions would likely not have a large impact on medical device companies because—according to these representatives—the population benefitting from coverage expansions mainly consists of infrequent users of medical devices.[19]

Agency Comments

We provided SEC with a draft of this report for review. SEC provided technical comments, which we incorporated into the report as appropriate.

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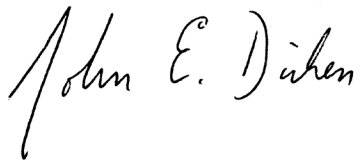
As agreed with your office, unless you publicly announce the contents of this report earlier, we plan no further distribution until 30 days from the report date. At that time, we will send copies to the Chairman of the Securities and Exchange Commission and other interested parties. In addition, the report will be available at no charge on the GAO website at http://www.gao.gov. If you or your staff have any questions about this report, please contact me at (202) 512-7114 or

[18]For example, in a 2014 Advanced Medical Technology Association member-company survey, 75 percent of the 55 respondents noted one or more of the following impacts due to the excise tax: deferred or cancelled capital investments or plans to open new facilities; reduced investment in start-up companies; reduced or deferred increases in employee compensation; or, among start-up companies, difficulty raising capital. In addition, 66 percent of the 55 respondents said they had decided to slow or halt U.S. job creation as a result of the excise tax, and more than half of respondents said they had reduced research and development expenses. See Advanced Medical Technology Association, *Impact of the Medical Device Excise Tax*, (Washington, D.C.: January 2015).

[19]According to industry trade group representatives, the most frequent users of medical devices are persons age 65 years and older and the disabled, who were already covered by Medicare prior to PPACA coverage expansions.

dickenj@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. GAO staff who made key contributions to this report were Rashmi Agarwal, Assistant Director; Daniel Lee; Sarah-Lynn McGrath; Laurie Pachter; Merrile Sing; Jennifer Whitworth; and Michael Zose.

Sincerely yours,



John E. Dicken
Director, Health Care

Enclosures – 4

The 102 Medical Device Companies That GAO Reviewed, by Company Size

Large-sized companies	Medium-sized companies	Small-sized companies
1. 3M CO	1. ACCURAY INC	1. ALLIED HEALTHCARE PRODS INC
2. ALIGN TECHNOLOGY INC	2. ALPHATEC HOLDINGS INC	2. ALPHA PRO TECH LTD
3. BARD (C.R.) INC	3. ANGIODYNAMICS INC	3. ARRHYTHMIA RESEARCH TECH
4. BAXTER INTERNATIONAL INC	4. ANIKA THERAPEUTICS INC	4. BOVIE MEDICAL CORP
5. BECTON DICKINSON & CO	5. ANTARES PHARMA INC	5. CARDICA INC
6. BOSTON SCIENTIFIC CORP	6. ARADIGM CORP	6. CAS MEDICAL SYSTEMS INC
7. CANTEL MEDICAL CORP	7. ATRICURE INC	7. DELCATH SYSTEMS INC
8. CONMED CORP	8. ATRION CORP	8. DIGIRAD CORP
9. CYBERONICS INC	9. BIOLASE INC	9. DYNATRONICS CORP
10. DENTSPLY INTERNATL INC	10. CERUS CORP	10. ECHO THERAPEUTICS INC
11. DEXCOM INC	11. CRYOLIFE INC	11. ESCALON MEDICAL CORP
12. EDWARDS LIFESCIENCES CORP	12. CUTERA INC	12. FONAR CORP
13. ENDOLOGIX INC	13. CYNOSURE INC	13. GUIDED THERAPEUTICS INC
14. HILL-ROM HOLDINGS INC	14. CYTORI THERAPEUTICS INC	14. ISORAY INC
15. HOLOGIC INC	15. DERMA SCIENCES INC	15. MELA SCIENCES INC
16. INSULET CORP	16. ENTEROMEDICS INC	16. MGC DIAGNOSTICS CORP
17. INTUITIVE SURGICAL INC	17. EXACTECH INC	17. MILESTONE SCIENTIFIC INC
18. MASIMO CORP	18. HANSEN MEDICAL INC	18. NEPHROS INC
19. MEDTRONIC INC	19. ICAD INC	19. NEUROMETRIX INC
20. MINDRAY MEDICAL INTL	20. ICU MEDICAL INC	20. NON INVASIVE MONITOR
21. NUVASIVE INC	21. INOVIO PHARMACEUTICALS INC	21. NUO THERAPEUTICS INC
22. RESMED INC	22. INVACARE CORP	22. ONCOLOGIX TECH INC
23. SPECTRANETICS CORP	23. IRIDEX CORP	23. PERSEON CORP
24. ST JUDE MEDICAL INC	24. LEMAITRE VASCULAR INC	24. PRECISION OPTICS CORP INC
25. STRYKER CORP	25. LUMINEX CORP	25. PRO-DEX INC/CO
26. TELEFLEX INC	26. MERIT MEDICAL SYSTEMS INC	26. QUANTRX BIOMEDICAL CP
27. THORATEC CORP	27. NATUS MEDICAL INC	27. RETRACTABLE TECHNOLOGIES INC
28. VARIAN MEDICAL SYSTEMS INC	28. NXSTAGE MEDICAL INC	28. SPAN-AMERICA MEDICAL SYS INC
29. WRIGHT MEDICAL GROUP INC	29. ORASURE TECHNOLOGIES INC	29. SPECTRASCIENCE INC
30. ZIMMER HOLDINGS INC	30. ROCKWELL MEDICAL INC	30. STEREOTAXIS INC
	31. RTI SURGICAL INC	31. TIGER X MEDICAL INC
	32. SURMODICS INC	32. TRIMEDYNE INC
	33. TEARLAB CORP	33. UROLOGIX INC

Large-sized companies	Medium-sized companies	Small-sized companies
	34. UTAH MEDICAL PRODUCTS INC	34. VASOMEDICAL INC
	35. VASCULAR SOLUTIONS INC	35. VIRTUALSCOPICS INC
		36. WOUND MANAGEMENT TECH INC
		37. ZYNEX INC

Source: GAO analysis of company financial disclosure data from the Securities and Exchange Commission. | GAO-15-635R

Notes: We reprinted company names as they were reported in the Compustat data that we obtained from SEC. We defined large-sized companies as those that had a market capitalization—that is, the total combined value of the company's stock—in 2013 of over $1 billion, medium-sized companies as those that had a market capitalization of $1 billion to greater than $100 million, and small-sized companies as those that had a market capitalization of $100 million or less.

Overall Net Sales, by Year and Company Size, Reported by the Medical Device Companies GAO Reviewed, 2005 through 2014

Year	30 large-sized companies (in billions)	35 medium-sized companies (in billions)	37 small-sized companies (in billions)	Overall net sales for 102 companies (in billions)
2005	$90.8	$3.5	$0.7[a]	**$95.0**
2006	97.4	3.8	0.7[a]	**101.9**
2007	102.7	4.3	0.7[a]	**107.7**
2008	109.5	4.9	0.7[a]	**115.1**
2009	108.5	5.0	0.7[a]	**114.2**
2010	115.1	5.2	0.7[a]	**121.0**
2011	121.0	5.6	0.7[a]	**127.2**
2012	122.4	5.6	0.7[a]	**128.7**
2013	125.6	5.8	0.6[a]	**132.0**
2014	129.3	6.1	0.6[a]	**136.0**

Source: GAO analysis of company financial disclosure data from the Securities and Exchange Commission. | GAO-15-635R

Notes: Data are adjusted to 2014 U.S. dollars using the gross domestic product deflator. Totals may not add due to rounding. We defined large-sized companies as those that had a market capitalization—that is, the total combined value of the company's stock—in 2013 of over $1 billion, medium-sized companies as those that had a market capitalization of $1 billion to greater than $100 million, and small-sized companies as those that had a market capitalization of $100 million or less.

[a]The 37 small-sized companies had sales of $700 million in 2005, $693 million in 2006, $708 million in 2007, $718 million in 2008, $744 million in 2009, $678 million in 2010, $677 million in 2011, $674 million in 2012, $621 million in 2013, and $616 million in 2014.

Overall Net Profit or Loss, by Year and Company Size, Reported by the Medical Device Companies GAO Reviewed, 2005 through 2014

Year	30 large-sized companies (in billions)	35 medium-sized companies (in billions)	37 small-sized companies (in billions)	Overall net profit for 102 companies (in billions)
2005	$11.8	$(0.3)[a]	$(0.1)[b]	**$11.4**
2006	9.8	(0.6)[a]	(0.2)[b]	**9.0**
2007	14.5	(0.3)[a]	(0.2)[b]	**14.0**
2008	11.5	(0.3)[a]	(0.3)[b]	**11.0**
2009	10.7	(0.1)[a]	(0.2)[b]	**10.4**
2010	15.3	(0.2)[a]	(0.2)[b]	**14.9**
2011	17.9	(0.2)[a]	(0.2)[b]	**17.5**
2012	13.3	(0.2)[a]	(0.2)[b]	**13.0**
2013	16.1	(0.4)[a]	(0.2)[b]	**15.5**
2014	16.9	(0.2)[a]	(0.2)[b]	**16.5**

Source: GAO analysis of company financial disclosure data from the Securities and Exchange Commission. | GAO-15-635R

Notes: Data are adjusted to 2014 U.S. dollars using the gross domestic product deflator. Totals may not add due to rounding. We defined large-sized companies as those that had a market capitalization—that is, the total combined value of the company's stock—in 2013 of over $1 billion, medium-sized companies as those that had a market capitalization of $1 billion to greater than $100 million, and small-sized companies as those that had a market capitalization of $100 million or less.

[a]The 35 medium-sized companies had net losses in each year of $267 million in 2005, $630 million in 2006, $330 million in 2007, $259 million in 2008, $99 million in 2009, $216 million in 2010, $160 million in 2011, $184 million in 2012, $395 million in 2013, and $191 million in 2014.

[b]The 37 small-sized companies had net losses in each year of $112 million in 2005, $161 million in 2006, $219 million in 2007, $273 million in 2008, $214 million in 2009, $191 million in 2010, $150 million in 2011, $203 million in 2012, $246 million in 2013, and $155 million in 2014.

Net Profit Margin, by Year and Company Size, Based on Data Reported by the Medical Device Companies GAO Reviewed, 2005 through 2014

Year	30 large-sized companies	35 medium-sized companies	37 small-sized companies	Net profit margin for 102 companies
2005	13%	(8)%	(16)%	**12%**
2006	10	(17)	(23)	**9**
2007	14	(8)	(31)	**13**
2008	11	(5)	(38)	**10**
2009	10	(2)	(29)	**9**
2010	13	(4)	(28)	**12**
2011	15	(3)	(22)	**14**
2012	11	(3)	(30)	**10**
2013	13	(7)	(40)	**12**
2014	13	(3)	(25)	**12**

Source: GAO analysis of company financial disclosure data from the Securities and Exchange Commission. | GAO-15-635R

Notes: Data are adjusted to 2014 U.S. dollars using the gross domestic product deflator. We calculated net profit margin as the ratio of reported net profits to reported net sales. We defined large-sized companies as those that had a market capitalization—that is, the total combined value of the company's stock—in 2013 of over $1 billion, medium-sized companies as those that had a market capitalization of $1 billion to greater than $100 million, and small-sized companies as those that had a market capitalization of $100 million or less.

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