PIONEER INSTITUTE
PUBLIC POLICY RESEARCH

POLICY BRIEF

First, Do No Harm

The Impact of the Affordable Care Act on Massachusetts' Medical Device Industry

by Josh Archambault and Xiaofei (Jackie) Zhou

Introduction

As part of the financing for the Patient Protection and Affordable Care Act (PPACA), a new excise tax was imposed on medical devices, effective January 1, 2013. This tax is of particular interest to Massachusetts policymakers and citizens because of the number of medical device companies that do business in the state and the number of jobs that are supported by the industry.

According to a 2011 study by Deloitte, over 400 companies in Massachusetts focus on medical devices, making the Commonwealth the state with the second-most employees in the industry – 24,268 as of 2008.[2] A 2010 report by The Lewin Group estimated the spin-off effects of the industry to be 82,500 additional jobs in related industries.[2]

While support for or opposition to the controversial federal healthcare law is often construed along partisan lines, the medical device tax stands in stark contrast. There is strong bipartisan support for its repeal. Former Senator Scott Brown (R) supported the repeal of the provision, and recently sworn-in Senator Elizabeth Warren (D) campaigned on its repeal.[3] Senator Warren, along with former Senator John Kerry (D) and fourteen other Democratic Senators who voted for the PPACA, signed a December 11, 2012, letter requesting at minimum its delay.[4] Senator Al Franken (D-MN) has gone so far as to call the provision a "job-killing tax" that will hurt the United State's leadership position in the global medical technology industry. Representatives Erik Paulsen (R-MN) and Ron Kind (D-WI) recently introduced a bipartisan repeal bill that was supported by 175 House members, including three of the Commonwealth's congressional delegation.[5]

Josh Archambault is Pioneer's Director of Health Care Policy & Program Manager for the Middle Cities Initiative. Prior to joining Pioneer, Josh was selected as a Health Policy Fellow at the Heritage Foundation in Washington, D.C. In the past, Josh served as a Legislative Director in the Massachusetts State Senate and as Senior Legislative Aide in the Governor's Office of Legislative Affairs. His work has appeared or been cited in outlets such as the *Wall Street Journal, The New York Times, Fox News*, and *The Boston Globe*. Josh holds a Masters in Public Policy from Harvard University's Kennedy School and a BA in Political Studies and Economics from Gordon College.

Xiaofei (Jackie) Zhou is currently a Masters candidate in economics at Boston University. She received her undergraduate degree at Guangdong University of Foreign Studies in economics with a specialization in finance.

Center for Health Care Solutions

April 2013

This brief is one of many in a series from Pioneer Institute examining the direct effects of the PPACA on Massachusetts. The purpose of this report is to estimate the annual impact of the law's tax on the 19 biggest medical device companies conducting business in Massachusetts.

Due to data availability, the final cost estimate does not include the hundreds of smaller and less mature companies that are located in the Commonwealth. While these companies will pay a smaller annual tax amount compared to the 19 in this brief due to their size, they are likely to be more heavily burdened since manufacturers and importers have to pay the tax regardless of their profitability.

The medical device tax is sure to have an immediate influence on the marketplace by: increasing the cost of devices to the end user, sending more money out of Massachusetts to Washington D.C. and exacting a lasting deleterious impact on future research and development in the medical device industry in Massachusetts.

Key Facts on the Medical Device Tax

(1) The new 2.3 percent medical device excise tax will apply to manufacturers and importers.

(2) The tax will be paid on United States sales of certain medical devices starting January 1, 2013.

(3) The Internal Revenue Service (IRS) issued final regulation on the new medical device tax on December 5, 2012.[6]

Under the final regulation, a "taxable medical device" is a device that is listed with the Food and Drug Administration (FDA) under section 510(j)[7] of the Federal Food, Drug and Cosmetic Act, and CFR Title 21, part 807,[8] pursuant to FDA requirements. As a result, there are some exemptions to the medical device excise tax. First, eyeglasses, contact lenses, and hearing aids are excluded from the medical device tax. Second, devices that are purchased by the general public at retail pharmacies for individual use will also fit the retail exemption. Full guidance on determining whether a given type of device qualifies for the retail exemption is provided in the final regulation as well.

A medical device can be sold tax-free for use by the purchaser for further manufacture (or for resale by the purchaser to a second purchaser for further manufacture) or for export (or for resale for export). The manufacturer, the first purchaser, and sometimes the second purchaser will need to be registered with the IRS to make the tax-free sale.

In general, the manufacturer or importer of a taxable medical device is responsible for filing Form 720, Quarterly Federal Excise Tax Return, and paying the tax to the IRS. However, if tax liability exceeds $2,500 for the quarter, semi-monthly deposits will be required. The first deposit was due on January 29, 2013.

The due dates for Form 720 are as follows[9]:

For the months:	Due by:
January, February, March	April 30
April, May, June	July 31
July, August, September	October 31
October, November, December	January 31

Calculating the Medical Device Tax Base

The medical device excise tax base is based on the price for which a taxable medical device is sold. The sale price includes the total cost paid for the device as well as charges for containers, coverings and for preparing the article for shipment. The following costs will be excluded from the sale price:

(i) The manufacturer excise tax;

(ii) the actual cost of transportation, delivery, and insurance;

(iii) discounts, rebates and similar allowances granted to the purchaser;

(iv) local advertising fee; and

(v) optional warranty.

Calculating How Much It Will Cost Massachusetts Companies

We calculated an estimated impact of the medical device tax for the 19 largest local medical device companies based on the following data and methodology:

Massachusetts' largest medical device firms were selected from the 2007 and 2008 *Boston Business Journal's* Book of Lists. The final list was updated for total Massachusetts employment levels from the 2012 Book of Lists, utilizing the list of life- science firms. For public companies, data from the latest annual report located on their respective websites was referenced. For private companies, the estimated revenue from the content aggregator website findthecompany.com was utilized.

As a reminder, due to the availability of data, hundreds of smaller companies are left out of our estimate. It has been argued that these smaller companies will be most heavily burdened by the tax as they are often immature and without a reliable source of revenue. Many are selling one device and/or still in the research and development phase on a second device.

To calculate the medical device excise tax estimate, the 19 companies were separated into two groups: public companies and private companies. For public companies, total U.S. medical device sales are the tax base, as listed in their annual report.

Where geographic sales or product line information for the private companies was lacking, the assumption was made that the total revenue was equal to the total medical device sales in the United States (U.S.). Therefore, the estimated medical device tax base may be a slight overestimation of the true tax burden if they have significant international operations or other products that are not classified as medical devices.

Table 1. Estimated Medical Device Tax on 19 Massachusetts Companies

Company	MA Employees	Total Revenue	Estimated Tax Base	Estimated Tax (t=2.3%)
Philips Healthcare	3,200	$29,380,000,000	$5,337,000,000[10]	$122,751,000
Covidien	1,800	$11,574,000,000	$4,282,477,881	$98,496,991
Boston Scientific Corp.	2,825	$7,622,000,000	$4,010,000,000	$92,230,000
Smith & Nephew Endoscopy	795	$4,270,000,000	$1,756,000,000	$40,388,000
Hologic Inc.	1,200	$2,002,652,000	$1,210,141,440	$27,833,253
Accellent Inc.	215	$531,782,000	$405,578,750	$9,819,275
Haemonetics Corp.	656	$727,844,000	$352,160,000	$8,099,680
Zoll Medical Corp.[11]	572	$523,700,000	$274,000,000	$6,302,000
NxStage Medical Inc.	200	$217,256,000	$217,256,000	$4,996,888
Analogic Corp.	885	$516,571,000	$176,657,130	$4,063,114
Abiomed Inc.	190	$126,375,000	$115,263,120	$2,651,052
Anika Therapeutics Inc.	114	$55,557,000	$61,956,386	$1,424,997
LeMaitre Vascular Inc.	120	$57,685,000	$36,918,400	$849,123
Cynosure Inc.	101	$110,602,000	$35,074,528	$806,714
Palomar Medical Technologies Inc.	170	$63,720,885	$22,578,522	$519,306
BioSphere Medical Inc.[12]	NA	$22,200,000	$22,200,000	$510,600
Ranfac Corp.	75	$11,300,000	$11,300,000	$259,900
NeuroMetrix Inc.	69	$10,396,775	$9,772,950	$224,778
AdvanSource Biomaterials	22	$1,666,000	$1,179,000	$27,117

Result

Based on 2011 revenue levels, we estimate the impact of the medical device tax to be more than $422 million a year. Of course, this is an overly conservative number since the hundreds of smaller companies working on medical devices in the Bay State are left out of this estimate. As the PPACA expands coverage to millions of Americans, supporters of the law believe that more and more people will seek medical care from hospitals, clinics and doctors, which could increase demand and sales of medical devices, but would also, result in a larger medical device tax base.

Effect

A survey on the possible outcomes of the medical device tax among forty-two senior executives of device manufacturers was conducted by KPMG for the Massachusetts Medical Device Industry Council in February of 2012.[13] From the findings of the survey it becomes apparent that companies are taking varying paths to deal with this excise tax.

First, 50 percent of companies will reduce the budget for research and development departments.

Second, 44 percent of the respondents will pass the new tax straight to end users. If the end users are healthcare service providers, they will raise their fee for service on patients to recover the higher price they paid. For individuals, either their out-of-pocket expense will be increased or future insurance premiums will be raised to pay for the tax.

Thirdly, 39 percent of the respondents will attempt to cut internal costs, while 25 percent will shrink the size of their workforce.

Most medical device company executives surveyed thought the tax will have an adverse impact on their medical device sales. While supporters of the PPACA have argued that the medical device industry will receive a dramatic increase in their revenue from newly insured citizens, the experience during the Massachusetts reform experiment does not support this position. Since Massachusetts is often cited as the inspiration for the PPACA, many expect similar outcomes to follow at the national level. However, none of the respondents to the KPMG survey reported an increase in sales following the passage of the 2006 reform law in the Commonwealth.

Conclusion

One of the stated goals of the PPACA is to expand insurance coverage. In order to do so, the law includes over 20 taxes or revenue-raising mechanisms. Inherent to this policy exercise will be tradeoffs. While some will gain insurance coverage, the individuals and industries taxed will make adjustments to their behavior or mode of conducting business. The KPMG survey makes it clear that the medical device industry is not immune from this reality.

What has been lacking from the debate is an informed review of the financial consequences of each provision of the PPACA in the Commonwealth. Undeniably, the medical device tax will impact the industry locally for the foreseeable future. Policymakers have to ask themselves if the potential benefits are worth the downside risks of employment loss, declines to future funding for research and development, higher prices for end users, and more private dollars being sent out-of-state in the form of new taxes.

Congress has shown a bipartisan willingness to change the PPACA, illustrated by the repeal of the small business reporting requirement of a 1099 form for sales over $600, the Community Living Assistance Services and Supports Act (CLASS Act), Free Choice Vouchers, and the fiscal cliff deal that cut future funding for health insurance co-operatives.[14] Only time will tell if the medical device tax will follow the same fate.

Endnotes

1. Deloitte (2011). The Medical Device Industry in Massachusetts. Prepared for MassMedic. Retrieved May 3, 2011, from http://www.massmedic.com/wp-content/uploads/2012/05/Deloitte-Study.pdf

2. The Lewin Group (2010). State Economic Impact of the Medical Technology Industry. Prepared for AdvaMed. Retrieved January 15, 2012, from http://www.lewin.com/~/media/lewin/site_sections/publications/stateeconomicimpactofthemedicaltechnologyindustry61510.pdf

3. Elizabeth Warren (2012). A Climate for Innovation. Op-ed. MassMedic.com. Available at: http://www.massdevice.com/blogs/massdevice/mass-sen-hopeful-elizabeth-warren-device-tax-fda-and-climate-innovation

4. Byron York (Dec. 11, 2012). "Democrats urge delay for 'job-killing' Obamacare tax," *Washington Examiner*. Retrieved from http://washingtonexaminer.com/democrats-urge-delay-for-job-killing-obamacare-tax/article/2515711#.UPY0m6G1Ygc

5. MassDevice. "Medical device tax: Paulsen re-boots repeal bid with new bill, Senate measure to follow."Available at: http://www.massdevice.com/news/medical-device-tax-paulsen-re-boots-repeal-bid-with-new-bill-senate-measure-follow. Original co-sponsors from Massachusetts included Representatives Niki Tsongas, Bill Keating, and Michael Capuano. Since the bill was filed Representatives Lynch and Senator "Mo" Cowan have joined the call for repeal. Representative Markey has expressed some tepid support for its repeal. Tracy Jan, "Senate Moves to End Medical Device Tax," *Boston Globe*, March 22, 2013. Available at: http://bostonglobe.com/news/politics/2013/03/22/senate-passes-bill-repeal-medical-device-tax-industry-urges-house-same/XIMZ9O9mImp7nB3hBF7iHN/story.html

6. Internal Revenue Service. Final Regulation on Medical Device Tax. Retrieved from https://s3.amazonaws.com/public-inspection.federalregister.gov/2012-29628.pdf

7. Source: http://medical.cms.itri.org.tw/pdf/u01.pdf

8. Source: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRsearch.cfm?CFRPart=807

9. Internal Revenue Service. Medical Device Excise Tax: Frequently Asked Question. Retrieved from http://www.irs.gov/uac/Medical-Device-Excise-Tax:-Frequently-Asked-Questions

10. The exchange rate of the last day in the fiscal year in the estimated tax-base calculation was used.

11. As there is no medical device sales data for the U.S. sales in the latest fiscal year, the medical device sales data for North America was used to approximate total U.S. medical device sales.

12. BioSphere Medical Inc. had been acquired by Merit Medical Systems Inc. in September 2010. The total sales revenue of BioSphere Medical Inc. came from the annual report of Merit Medical Systems Inc.

13. MassMEDIC (2012). Job, R&D Cuts are Likely Steps to Deal with Device Tax. Retrieved March 14, 2012, from http://www.massmedic.com/2012/03/14/jobs-rd-cuts-are-likely-steps-to-deal-with-device-tax-survey-of-medtech-execs-shows-anticipated-impact-of-impending-medical-excise-tax/

14. Sarah Kilff, "The Fiscal Cliff Cuts $1.9 Billion From Obamacare. Here's How." *Washington Post*, Wonk Blog, Available at: http://www.washingtonpost.com/blogs/wonkblog/wp/2013/01/02/the-fiscal-cliff-cuts-1-9-billion-from-obamacare-heres-how/

About Pioneer

Pioneer Institute is an independent, non-partisan, privately funded research organization that seeks to improve the quality of life in Massachusetts through civic discourse and intellectually rigorous, data-driven public policy solutions based on free market principles, individual liberty and responsibility, and the ideal of effective, limited and accountable government.

PIONEER INSTITUTE
PUBLIC POLICY RESEARCH

85 Devonshire Street, 8th Floor, Boston, MA 02109 |
T: 617.723.2277 F: 617.723.1880 |
www.pioneerinstitute.org