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The Medical Device Excise Tax: An Unfair Burden

ELIZABETH M. BOLKA*

INTRODUCTION

The Patient Protection and Affordable Care Act (PPACA), also known as “Obamacare,” signed into law by President Obama on March 23, 2010,¹ is a complex healthcare reform act that, together with the Health Care and Education Reconciliation Act,² substantially overhauls the U.S. healthcare system. The more than 900-page Act aims to reduce the cost of healthcare and improve healthcare coverage for all Americans.³

In June 2012, the Supreme Court upheld the constitutionality of the most controversial provision of the PPACA, the individual mandate,⁴ under Congress’s taxing power, but declared that the requirement that states either accept the expansion of Medicaid or lose their existing Medicaid funding was not a valid exercise of Congress’s spending power.⁵ With the upholding of the individual mandate, the likelihood that the PPACA’s provisions would all come into play became nearly certain, to the dismay of the law’s opponents. After President Obama’s reelection in November 2012, the PPACA’s implementation over the next few years became a reality.⁶

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1. Patient Protection and Affordable Care Act (PPACA), Pub. L. No. 111-148, 124 Stat. 119 (2010) (codified as amended in scattered sections of U.S.C.), *available at* <http://www.gpo.gov/fdsys/pkg/BILLS-111hr3590enr/pdf/BILLS-111hr3590enr.pdf>.

2. Health Care Education and Reconciliation Act of 2010 (HCERA), Pub. L. No. 111-152, 124 Stat. 1029.

3. “The law allows Americans to make health insurance choices that work for them while guaranteeing access to care for our most vulnerable citizens, and provides new ways to bring down costs and improve quality of care.” Letter from Jim R. Esquea, Assistant Sec’y for Legislation, Dep’t of Health & Human Servs., to Lamar Alexander, Ranking Member, Comm. on Health, Educ., Labor & Pensions, U.S. Senate (June 3, 2013), *available at* <http://online.wsj.com/public/resources/documents/LettertoAlexander.pdf>.

4. PPACA § 1501(b), 42 U.S.C. § 5000A (2012). The individual mandate requires that, beginning in 2014, all individuals maintain “minimum essential coverage, which includes eligible employer coverage, individual coverage, grandfathered plans, and federal programs such as Medicare and Medicaid, among others . . . [or] pay a penalty for noncompliance.” DAVID NEWMAN, CONG. RESEARCH SERV., R41331, INDIVIDUAL MANDATE AND RELATED INFORMATION REQUIREMENTS UNDER PPACA 1–3 (2011), *available at* <http://healthreformgps.org/wp-content/uploads/CRSreportonPPACAUG2011.pdf>. This mandate has been the most controversial aspect of the healthcare reform to date. *E.g.*, Wilton B. Hyman, *An Explanation of the Patient Protection and Affordable Care Act*, 38 OHIO N.U. L. REV. 579, 580 (2012); Perry W. Payne, Jr., *The Patient Protection and Affordable Care Act of 2010 and the Requirement to Maintain Minimum Essential Coverage (Individual Mandate): Constitutional Challenges and Potential Impact on Health Policy*, 55 HOW. L.J. 937, 940 (2012); Christopher B. Serak, *State Challenges to the Patient Protection and Affordable Care Act: The Case for a New Federalist Jurisprudence*, 9 IND. HEALTH L. REV. 311, 314–15 (2012).

5. Nat’l Fed. of Indep. Bus. v. Sebelius, 132 S. Ct. 2566 (2012).

6. *See, e.g.*, Kate Pickert, *What Obama’s Re-election Means for Health Care*,

In addition to the mandates, subsidies, and tax credits designed to increase coverage, the PPACA necessarily includes a slew of revenue-generating provisions, including several new taxes and fees imposed on various sectors,⁷ to cover the new costs.⁸ One of the revenue-generating provisions that has garnered significant opposition from corporations and legislators is the new 2.3% manufacturer's and importer's medical device excise tax (MDET).⁹ This provision poses serious concerns in the eyes of medical device manufacturers who claim the amount of the tax is disproportionate to any expected increase in sales from the increased number of Americans receiving medical care.¹⁰ The manufacturers also vow that the tax, imposed on gross revenue rather than profits, will force them to cut substantial costs by decreasing expenditures on research and development (R&D), laying off workers, and shifting domestic production overseas.¹¹

Discussion of repeal of the MDET began almost as soon as the PPACA became law, and the medical device industry began throwing millions of dollars into lobbying for its repeal.¹² Over the past two years a number of bills have been proposed in both the House and Senate to repeal the tax, and a repeal provision became a sticking point during the budget negotiations that led to a sixteen-day government shutdown in October 2013.¹³ Despite the significant news coverage surrounding the MDET, few Americans seem to understand what all the hype is about.

This Note attempts to shed light on the MDET by examining its history, its technicalities, and the political arguments on both sides in depth. It then takes the position that even if manufacturers and lobbyists have exaggerated the negative effects of the tax, the MDET is still unwise tax and economic policy that never should have been implemented without more comprehensive research into the effects of the healthcare law on the medical device industry. The MDET imposes an unfair burden on manufacturers, hurts the economy by killing jobs in a high-paying industry, and stifles innovation by discouraging start-ups and driving up companies' tax expenses. This Note urges Congress to repeal the MDET, or, in lieu of complete repeal, revise the tax to decrease the negative economic impact by making some modifications and future revisions such as exempting start-up

TIME.COM (Nov. 8, 2012), <http://swampland.time.com/2012/11/08/what-obamas-re-election-means-for-health-care/#ixzz2BeJkAu5s> (describing the Affordable Care Act as having a "more certain future under an Obama second term").

7. Other beneficiaries of the PPACA who are required to pay additional fees include hospitals and health insurance providers. *See infra* notes 18–23 and accompanying text.

8. PPACA §§ 9001–9023 (codified in scattered sections of I.R.C.).

9. The MDET is codified at I.R.C. § 4191 (2012) and is occasionally referred to as section 4191. It was enacted by section 1405 of the HCERA, Pub. L. No. 111-152, 124 Stat. 1029, 1064–65.

10. *See infra* notes 137–46 and accompanying text.

11. *See infra* Part III.B.

12. *See infra* notes 31–33, 167–68.

13. *See, e.g.,* Greg Avery, *Government Shutdown Deal Doesn't Repeal Medical Device Tax*, DENV. BUS. J. (Oct. 18, 2013, 2:14 PM), http://www.bizjournals.com/denver/blog/boosters_bits/2013/10/government-shutdown-deal-doesnt.html; DSWright, *Durbin Offers Medical Device Tax Repeal To End Shutdown*, FDL (Oct. 1, 2013, 8:26 AM), <http://news.firedoglake.com/2013/10/01/durbin-offers-medical-device-tax-repeal-to-end-shutdown/>.

manufacturers, exempting certain uses that confer no direct benefit to the manufacturer, and revising the rate of tax as more information about the actual benefits received by manufacturers as a result of an increase in the number of insured Americans becomes available. These changes would represent a compromise between proponents of the tax and medical device manufacturers, who fear that the MDET, in the wake of an already difficult and uncertain regulatory environment, could force them to make major operating changes. This Note does not seek to opine on Obamacare as a whole or take a political stance on any issue—it merely examines, somewhat in a vacuum, this one component of the PPACA, the actual consequences of which are still unclear.

Part I examines the legislative history and the goals of the MDET, including a discussion of the various forms the tax has taken. Part II delves into more detail about the mechanics of the MDET, focusing on which devices, which manufacturers, and which prices will be taxed. Part III examines the actual impact to date and the potential future impact of the tax on the medical device industry and the economy. It first provides background on the industry and then reviews studies on the MDET and actual steps companies have taken in preparation for or in response to the MDET. Part III then considers some of the counterarguments made by proponents of the PPACA who claim manufacturers are exaggerating the impact of the MDET. Part IV looks at the congressional response to the MDET, including a brief summary of the slew of bills that have been proposed to repeal the tax and the current political debate surrounding the tax. Finally, Part V argues that proponents of the MDET have incorrectly inflated the positive impact of the PPACA on the medical device industry and that the tax will force companies to either pass the tax on to the end consumer (typically the medical service provider) or cut spending by decreasing R&D, laying off workers, shifting production overseas, or decreasing planned hiring. This Note urges Congress to repeal the MDET because it is unwise tax policy that did not undergo the necessary review to make sure it was logical and fair and because it does not further the broad economic mission of getting Americans back to work.¹⁴ It then proposes that in lieu of complete repeal, members of Congress could work together to compromise in order to revise some of the most onerous provisions of the MDET to avoid losing more U.S. jobs, to avoid deterring start-ups' innovations, and to make the tax burden match the benefits manufacturers might receive.

I. THE BILL

The MDET is one of many revenue-generating provisions included in the PPACA to help cover the costs of expanded health care coverage.¹⁵ The tax took effect on January 1, 2013,¹⁶ amid much debate about Obamacare and the “fiscal

14. See, e.g., Press Release, Office of the Press Sec'y, The White House, Weekly Address: Creating Jobs and Getting All Americans Back to Work (Aug. 6, 2011), available at <http://www.whitehouse.gov/the-press-office/2011/08/06/weekly-address-creating-jobs-and-getting-all-americans-back-work>.

15. PPACA §§ 9001–23 (codified in scattered sections of I.R.C.).

16. I.R.C. § 4191 (2012).

cliff.”¹⁷ In order to provide a background setting for the debate surrounding the MDET, this Part examines the goals and legislative history behind inclusion of the MDET in the PPACA.

A. *The Path to the MDET*

The goal behind the MDET, like many of the other revenue-generating provisions in the PPACA, is to spread the cost of expanding health coverage among the government, individuals, and the corporate sectors that will benefit from it.¹⁸ It is one of many new taxes and fees imposed on various sectors of the healthcare industry. Other such taxes include a 40% excise tax on high-cost, employer-sponsored healthcare plans,¹⁹ a 10% excise tax on indoor tanning services,²⁰ an annual fee on branded prescription pharmaceutical manufacturers and importers,²¹ and an additional unearned income Medicare contribution tax on high-income taxpayers,²² to name just a few.²³

The MDET has evolved significantly since it was first introduced. Originally, the tax was proposed as a \$4 billion annual fee to be imposed on the medical device manufacturing sector and allocated according to market share.²⁴ However, the medical device industry managed to halve the amount of revenue generation that

17. “The ‘fiscal cliff’ is a term used to describe a bundle of momentous U.S. federal tax increases and spending cuts that are due to take effect at the end of 2012 and early 2013. In total the measures are set to automatically slash the federal budget deficit by \$503 billion between FY 2012 and FY 2013, according to the most recent Congressional Budget Office (CBO) projections. . . . The abrupt onset of such significant budget austerity in the midst of a still-fragile economic recovery has led most economists to warn of a double-dip recession and rising unemployment in 2013 if Washington fails to intervene in a timely fashion.” Jonathan Masters, *What Is the Fiscal Cliff?*, COUNCIL ON FOREIGN REL. (Dec. 12, 2012), <http://www.cfr.org/economics/fiscal-cliff/p28757>.

18. See Letter from Charles N. Kahn III, President & CEO, Fed’n of Am. Hosps., Rick Pollack, Exec. Vice President, Advocacy & Pub. Policy, Am. Hosp. Ass’n, Michael Rodgers, Senior Vice President, Pub. Policy and Advocacy, The Catholic Health Ass’n of the U.S., Curtis Rooney, President, Healthcare Supply Chain Org., & Deborah Sprindzunas, Exec. Dir., Ass’n for Healthcare Res. & Materials Mgmt., to I.R.S., at 2 (May 7, 2012), available at <http://www.aha.org/advocacy-issues/letter/2012/120508-cl-tax-med-dev.pdf> [hereinafter Hosp. Ass’n Letter] (“The concept of ‘shared responsibility’ for funding and implementing healthcare reform, among all population segments and affected economic interests, was a core element of the legislative bargain from the very beginning.”).

19. PPACA § 9001, I.R.C. § 4980I (2012).

20. PPACA § 9017, I.R.C. § 5000B (2012).

21. PPACA § 9008, 42 U.S.C. § 1395t (2012).

22. HCERA § 1402, I.R.C. § 1411 (2012).

23. For further discussion of the PPACA’s revenue-generating provisions, see Hyman, *supra* note 4, at 629–37. For an overview of all of the new tax provisions of the PPACA with links to more detailed discussion of each, see *Affordable Care Act Tax Provisions*, IRS.GOV, <http://www.irs.gov/uac/Affordable-Care-Act-Tax-Provisions> (last updated Feb. 28, 2014).

24. S. FIN. COMM., FRAMEWORK FOR COMPREHENSIVE HEALTH REFORM 18 (2009), available at <http://www.kaiserhealthnews.org/Stories/2009/September/08/~~/media/Images/KHN%20Features/2009/Sep/08/090509baucus.ashx>.

the tax would raise to \$2 billion a year.²⁵ The \$2 billion fee included in the initial bill²⁶ was to be allocated using a ratio of a covered entity's gross receipts from medical device sales taken into account during the preceding calendar year to the aggregate gross receipts of all covered entities' medical device sales during that year.²⁷ If a covered entity's aggregate gross receipts from medical devices were less than \$5 million, the entity would not pay any portion of the fee.²⁸ If the gross receipts were between \$5 and \$25 million, the entity would pay 50% of its allocated amount, and if the gross receipts exceeded \$25 million, the covered entity would pay 100% of its allocated portion of the fee.²⁹ This fee was to be treated as an excise tax for refund purposes.³⁰ This original fee therefore hit large manufacturers heavily and did not reach the smaller industry participants.

The fee evolved into an excise tax after much lobbying by the largest medical device manufacturers who claimed it was unfair.³¹ Upon rejection of the annual fee, Congress originally set the excise tax rate at 2.9%,³² but again under lobbyist pressure, Congress reduced it to the 2.3% now included in section 4191.³³ The MDET is estimated to bring in about \$29 billion over the ten-year span covering 2013 to 2022, according to the Joint Committee on Taxation.³⁴

25. PAUL N. VAN DE WATER, CTR. ON BUDGET AND POLICY PRIORITIES, EXCISE TAX ON MEDICAL DEVICES SHOULD NOT BE REPEALED: INDUSTRY LOBBYISTS DISTORT TAX'S IMPACT 2 (2013).

26. PPACA § 9009, *repealed by* HCERA § 1405.

27. *Id.* § 9009 (a)–(b).

28. *Id.* § 9009(b)(2).

29. *Id.*

30. *Id.* § 9009(e).

31. *See Medical Device Tax Hits Most of Health Care Industry*, HEALIO ORTHOTICS & PROSTHETICS BUS. NEWS (June 2010), <http://www.healio.com/orthotics-prosthetics/internal-control/news/print/o-and-p-business-news/%7B6b3a12d2-dddb-45b5-bfff-a61664a0a1d1%7D/medical-device-tax-hits-most-of-health-care-industry>.

32. *Id.* Originally, only Class II and Class III devices were considered taxable medical devices. But when Congress lowered the rate during HCERA negotiations, it expanded the tax to apply to Class I devices as well in order to generate the required \$20 billion in revenue. *Id.*; *New Health Reform Law Expands Medical Device Excise Tax to Class I Devices*, NAT'L ASS'N FOR THE ADVANCEMENT OF ORTHOTICS & PROSTHETICS (Apr. 2, 2010), http://www.naaop.org/alerts.asp?alert_id=10000714.

33. I.R.C. § 4191 (2012).

34. JOINT COMM. ON TAXATION, DESCRIPTION OF H.R. 436, THE "PROTECT MEDICAL INNOVATION ACT OF 2011," JCX-45-12 (2012). In March 2010 the committee estimated that the excise tax would raise \$20 billion over the 2013–19 period. The new \$29 billion estimate is higher only because it covers three more years. *Compare id.*, with JOINT COMM. ON TAXATION, ESTIMATED REVENUE EFFECTS OF THE AMENDMENT IN THE NATURE OF A SUBSTITUTE TO H.R. 4872, THE "RECONCILIATION ACT OF 2010," AS AMENDED, IN COMBINATION WITH THE REVENUE EFFECTS OF H.R. 3590, THE "PATIENT PROTECTION AND AFFORDABLE CARE ACT ('PPACA')," AS PASSED BY THE SENATE, AND SCHEDULED FOR CONSIDERATION BY THE HOUSE COMMITTEE ON RULES ON MARCH 20, 2010, JCX-17-10 (2010).

B. Proposed and Final Regulations

On December 27, 2010, the IRS published a notice requesting comments on the implementation and administration of the new tax.³⁵ The IRS considered the many responses it received to this notice as well as its consultation with the Food and Drug Administration (FDA) and the Centers for Medicare and Medicaid Services (CMS) in drafting proposed regulations, which were issued on February 3, 2012.³⁶ The proposed regulations were the only guidance medical device manufacturers had upon which to rely in preparing for the rapidly approaching start date of the tax until the IRS released final regulations on December 5, 2012.³⁷ At that time, the IRS also released interim guidance related to determination of the sales price, treatment of convenience kits, and other topics reserved in the final regulations,³⁸ as well as a set of frequently asked questions.³⁹ To date, a number of unresolved questions exist about administration of the MDET. However, the IRS did provide some relief for medical device manufacturers by waiving the penalty for failure to make timely semimonthly deposits for the first three quarters of 2013 as long as the manufacturer or importer showed a good faith attempt to comply with the reporting requirements and the failure was not due to willful neglect.⁴⁰

II. THE MDET

Section 4191 imposes a 2.3% tax on the sale price of “any taxable medical device by the manufacturer, producer, or importer.”⁴¹ But like most tax provisions, the meaning of this language is much more complicated than it appears. In order to understand the possible effects of the MDET, we must first take a detailed look at precisely what is included in the term “medical device,” who qualifies as a “manufacturer, producer, or importer,” and how the sales price is measured in sales between related parties.

A. What Will Be Taxed?

A “taxable medical device” is defined as “any device (as defined in section 201(h) of the Federal Food, Drug, and Cosmetic Act) intended for humans.”⁴² The

35. I.R.S. Notice 2010-89, 2010-52 I.R.B. 908.

36. Prop. Treas. Reg. § 48.4191-1 to -2, 77 Fed. Reg. 6028, 6035–37 (Feb. 7, 2012).

37. Taxable Medical Devices, 77 Fed. Reg. 72924, 72924–39 (Dec. 7, 2012) (to be codified at 26 C.F.R. pt. 48), available at <http://www.gpo.gov/fdsys/pkg/FR-2012-12-07/pdf/2012-29628.pdf>.

38. I.R.S. Notice 2012-77, 2012-52 I.R.B. 781.

39. *Medical Device Excise Tax: Frequently Asked Questions*, IRS.GOV, <http://www.irs.gov/uac/Medical-Device-Excise-Tax:-Frequently-Asked-Questions> (last updated Feb. 3, 2014).

40. I.R.S. Notice 2012-77, *supra* note 38, § 6(b), at 785.

41. I.R.C. § 4191(a) (2012).

42. *Id.* § 4191(b)(1). Under the FFDCFA, “device” is defined as an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is (1) recognized in the official National Formulary, or the

IRS's proposed and final regulations help clarify the statute, especially the definition of taxable medical device.⁴³ The final regulations state that for purposes of the MDET, a "taxable medical device" is one that is listed by the FDA under section 510(j) of the Federal Food, Drug, and Cosmetic Act (FFDCA) and 21 C.F.R. part 807.⁴⁴ The types of devices that fall under this description are varied and include items ranging from surgical gloves and dental instruments to coronary stents, pacemakers, defibrillators, and irradiation equipment.⁴⁵ Device manufacturers are already familiar with these longstanding classifications and should know for the most part what devices fall within the definition. The regulations also state that if a device is not listed with the FDA currently, but is later determined to be a "device," it will be considered a listed device with the FDA as of the date the FDA notifies the manufacturer or importer in writing of the change.⁴⁶

It is important to emphasize that this tax is a manufacturers' excise tax imposed on the gross sales of manufacturers, producers, and importers, rather than their net profits.⁴⁷ Therefore, even if a manufacturer makes no profit on the sale, it still has to pay the tax. But not every medical device sale is subject to the tax. First, like other excise taxes in the United States, taxable medical devices sold for use by the purchaser in further manufacture or for resale by the purchaser to a second purchaser for use in further manufacture are exempt.⁴⁸ Second, devices exported outside of the United States or sold for resale by the purchaser to a second purchaser for export are exempt.⁴⁹ Finally, section 4191 sets out a retail exemption

United States Pharmacopeia, or any supplement to them, (2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, . . . or (3) intended to affect the structure or any function of the body . . . , and which does not achieve its primary intended purposes through chemical action within or on the body . . . and which is not dependent upon being metabolized for the achievement of its primary intended purposes.

21 U.S.C. § 321(h) (2012).

43. Prop. Treas. Reg. § 48.4191-2(a), 77 Fed. Reg. 6028, 6035 (Feb. 7, 2012).

44. *Id.*

45. VAN DE WATER, *supra* note 25, at 2.

46. Treas. Reg. § 48.4191-2(a)(2) (2012). This provision is of specific concern to some critics who claim that mere notice from the FDA does not mean there has been a final determination that an item is required to be listed with the FDA, especially if appeals of the decision are ongoing. *E.g.*, Letter from Alan Mertz, President, Am. Clinical Lab. Ass'n, to Steven T. Miller, Deputy Comm'r for Servs. & Enforcement, I.R.S., at 2, 5–6 (May 7, 2012), available at http://www.acla.com/sites/default/files/Comments%20re%20taxable%20medical%20devices_1.pdf. Despite this criticism, the IRS declined to alter this provision in drafting the final regulations. T.D. 9604, 2012-52 I.R.B. 730, 732.

47. I.R.C. § 4191(a) (2012).

48. I.R.C. § 4221(a) (2012); *see also* Pia Flanagan, *Health Care Reform Tax Provisions Affecting Large Employers*, CORP. TAX'N, Nov.–Dec. 2010, at 5. Unlike other excise taxes though, the list of exemptions for the MDET has been shortened significantly to exclude the exemptions for supplies purchased for use on vessels or aircraft, items state and local governments purchase for their exclusive use, items nonprofit educational institutions purchase for their own use, and items purchased by qualified blood organizations for use in collecting, storing, or transporting blood. I.R.C. § 4221(a)(3)–(6).

49. I.R.C. § 4221(a); *see also* Flanagan, *supra* note 48.

for certain items that would otherwise fall under the FDA listing, including eyeglasses, contact lenses, hearing aids, and “any other medical device determined by the Secretary to be of a type which is generally purchased by the general public at retail for individual use.”⁵⁰

This final part of the retail exemption, stated in very broad terms, led to some confusion over exactly what type of items would be exempt. The IRS adopted a “facts and circumstances” approach that classifies a device as “generally purchased by the general public at retail for individual use” (i) if “it is regularly available for purchase and use by individual consumers who are not medical professionals,” and (ii) “if the design of the device demonstrates that it is not primarily intended for use in a medical institution or office or by a medical professional.”⁵¹ Because the medical device industry is ever evolving with new products constantly entering the market, most manufacturers, hospitals, and other industry participants favor the “facts and circumstances” approach taken by the IRS over other options, such as trying to create a list of devices that fall within the exemption.⁵²

The regulations give a nonexclusive list of factors to consider in determining whether a device is “available for purchase and use by individual consumers” that includes: (i) whether people can buy the items through retail businesses that sell items other than medical devices, such as drug stores and supermarkets; (ii) whether non-medical-professional consumers can safely and effectively use the device with little training; and (iii) whether the device is classified by the FDA as a “Physical Medicine Device.”⁵³ The regulations also contain a nonexclusive list of factors to consider in determining whether the device’s design demonstrates that the device is not primarily intended for use in a medical office or institution or by medical professionals. These factors include: (i) whether the device generally must be implanted, inserted, operated, or otherwise administered by a medical professional; (ii) whether the initial investment or ongoing cost is too high for the average consumer; (iii) whether the device is classified as an FDA Class III device;⁵⁴ (iv) whether the device is

50. I.R.C. § 4191(b)(2).

51. Treas. Reg. § 48.4191-2(b)(2) (2012).

52. See, e.g., Christopher J. Ohmes & Michael Udell, *Making Sense of the New Excise Tax on Medical Devices*, 133 TAX NOTES 1015, 1016–17 (2011) (discussing the difficulties the IRS would have in administering a product exemption list that would need to include over 5600 different products, with data about many of these products not publicly available); Richard T. Ainsworth, Andrew Schact, & Gail Wasylshyn, *Medical Devices Excise Tax (MDET)—A Market-Specific VAT?* 5–6 (Bos. Univ. Sch. of Law, Working Paper No. 12-30, 2012), available at <http://www.bu.edu/law/faculty/scholarship/workingpapers/documents/AinsworthRSchactAWasylshynG061812rev.pdf>; Hosp. Ass’ns Letter, *supra* note 18; Letter from Stephen J. Ubl, President & CEO, AdvaMed, to Steven T. Miller, Deputy Comm’r for Servs. & Enforcement, I.R.S., at 1, 12 (May 3, 2012) [hereinafter AdvaMed Letter (May 3, 2012)] (thanking the IRS for rejecting a product exemption approach in the Proposed Regulations), available at <http://www.advamed.org/NR/rdonlyres/37D7B123-68C3-4FBA-BA67-1918015B4DD1/0/20120503AdvaMedFinalTaxComments.pdf>.

53. Treas. Reg. § 48.4191-2(b)(2)(i) (2012).

54. Medical devices are classified as either Class I, II, or III, and the level of regulation increases from Class I to Class III. Class III devices require the highest level of regulatory

classified under certain parts or subparts of 21 CFR;⁵⁵ and (v) whether the device qualifies as durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS), for which payment under Medicare Part B is available exclusively on a rental basis.⁵⁶ Because the list is nonexclusive, there may be facts and circumstances related to either part of the test that could be relevant in determining whether a device qualifies for the retail exemption.⁵⁷

Finally, the regulations satisfied some complaints about uncertainty surrounding the tax by providing a “safe harbor” that assumes certain devices to be “generally purchased by the general public at retail for individual use.”⁵⁸ The “safe harbor” list includes items such as over-the-counter devices in the relevant FDA classification regulation⁵⁹ and devices that qualify as DMEPOS under the relevant sections for Parenteral and Enteral Nutrition and Durable Medical Equipment and Orthotic Devices, subject to certain requirements.⁶⁰

In addition to questions about what products fall under the retail exemption, manufacturers and industry groups are still left with questions about the taxability of specific items such as medical software licenses, donated medical devices, and medical convenience kits. The IRS addressed each of these topics in the interim guidance it issued along with the final regulations.⁶¹ Until the IRS issues further guidance, it will treat medical software licenses as leases of

controls and typically must go through a premarket approval process. For more information on FDA classifications, see *Overview of Device Regulation*, FDA, <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/default.htm>.

55. Devices falling in these categories are primarily intended for use by medical professionals and include the following:

21 CFR part 862 (Clinical Chemistry and Clinical Toxicology Devices), 21 CFR part 864 (Hematology and Pathology Devices), 21 CFR part 866 (Immunology and Microbiology Devices), 21 CFR part 868 (Anesthesiology Devices), 21 CFR part 870 (Cardiovascular Devices), 21 CFR part 874 (Ear, Nose, and Throat Devices), 21 CFR part 876 (Gastroenterology—Urology Devices), 21 CFR part 878 (General and Plastic Surgery Devices), 21 CFR part 882 (Neurological Devices), 21 CFR part 886 (Ophthalmic Devices), 21 CFR part 888 (Orthopedic Devices), or 21 CFR part 892 (Radiology Devices).

Treas. Reg. § 48.4191-2(b)(2)(ii)(D)(1) (2012).

56. *Id.* § 48.4191-2(b)(2)(ii).

57. In the tax directive included with the final regulations, the IRS reemphasized that other circumstances could be relevant and that the list is not a checklist of factors but a list of relevant factors that may or not apply in a given situation. T.D. 9604, 2012-52 I.R.B. 733–34.

58. Treas. Reg. § 48.4191(b)(2)(iii) (2012).

59. These include devices that are part of the FDA’s online IVD Home Use Lab Tests database, available at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfiVD/Search.cfm>, and devices described as “OTC” or “over the counter” in the FDA’s classification regulation heading, product code name, device classification name, or the “classification name” field in the FDA’s devices registration and listing database, available at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfi/rl.cfm>. Treas. Reg. § 48.4191(b)(2)(iii)(A)–(C).

60. *See id.* § 48.4191(b)(2)(iii)(D). For example, payment must be available on a purchase basis under Medicare Part B payment rules. Prosthetics and orthotics must fit the definition in 42 C.F.R. § 414.202 and cannot require implantation or insertion by a medical professional, and parental and enteral nutrients, equipment, and supplies must fit the definition in 42 C.F.R. § 414.102(b). *Id.*

61. I.R.S. Notice 2012-77, *supra* note 38.

taxable medical devices as of the date the parties entered the lease agreement⁶² and donations of taxable medical devices by the manufacturer to an eligible donee⁶³ as nontaxable sales.⁶⁴

The taxability of “convenience kits,” or sets of two or more devices enclosed in a single package for the convenience of the healthcare professional, and whether the acts of “kitting” or sterilizing kits constitute “further manufacturing,” were topics of heated debate.⁶⁵ Under section 201(h) of the FFDCFA, many medical kits are listed as new or different medical devices, separate from the devices included in the kits.⁶⁶ In other words, the kit assembler would be the “last manufacturer” rather than the manufacturer who produced the component medical device included in the kit.⁶⁷

Whether “kitting” is considered manufacturing can have a huge impact on the amount of tax revenue collected as well as from whom it is collected. After the IRS and Treasury Department promulgated the proposed regulations, many distributors worried that they would be taxed on “kitting” activities that consist merely of packing various taxable and nontaxable medical devices into kits, sometimes sterilizing them, and distributing them to hospitals and other users.⁶⁸ They submitted letters to the IRS explaining that taxing such activity as further manufacturing goes against the legislature’s intent and would likely result in double taxation of some items, taxation of some items that should be exempt, and the unintended taxation of a service where no new goods are manufactured.⁶⁹

Although the proposed regulations expressly stated that kit assembly qualified as further manufacturing,⁷⁰ the IRS took into account the numerous letters and comments it received on the topic and reversed its position in the interim guidance it issued along with the final regulations.⁷¹ The interim rule satisfies many manufacturers and kit assemblers’ complaints by exempting domestically produced convenience kits from the tax and, instead, imposing the tax on the manufacturers who sell the component parts of the kits.⁷² Under the interim rule, sales of imported convenience kits will be taxed only on the price

62. *Id.* at 6.

63. An eligible donee is one described in section 170(c) of the Code. *Id.*

64. *Id.*

65. *See, e.g.*, Letter from Linda Rouse O’Neill, Vice President Gov’t Affairs, Health Indus. Distribs. Ass’n, to Douglas H. Shulman, Comm’r, I.R.S. (May 7, 2012) [hereinafter HIDA letter], available at http://www.hida.org/App_Themes/Member/docs/GA/Medical%20Device%20Tax/HIDA_Medical-Device-Tax-IRS-Comments-FINAL_5-7-12.pdf; Hosp. Ass’ns Letter, *supra* note 18, at 8–9.

66. *See id.*

67. *See* Ainsworth et al., *supra* note 52, at 10.

68. *See, e.g.*, HIDA letter, *supra* note 65; Hosp. Ass’ns Letter, *supra* note 18.

69. *See, e.g.*, HIDA letter, *supra* note 65; *Leading Executives from Across the Country Urge the Senate to Repeal the Device Tax*, MED. DEVICE MFRS. ASS’N (Nov. 14, 2012), <http://www.medicaldevices.org/news/news.asp?id=139148&hhSearchTerms=%22leahey+and+letter%22>.

70. Treas. Reg. § 4221-2(b) (2012).

71. I.R.S. Notice 2012-77, *supra* note 38.

72. *Id.*

allocable to the taxable devices in the kit.⁷³ The IRS and Treasury Department plan to study further the taxability of convenience kits before releasing additional guidance,⁷⁴ so although the present interim guidance is a small win for “kitters,” the long-term application of section 4191 to convenience kits remains uncertain.

B. Who Will Be Taxed?

Only the final manufacturer or importer will be taxed because there are exemptions for sales of devices sold for further manufacture or export.⁷⁵ The definition of “manufacturer” is common for all excise taxes and includes “any person who produces a taxable article from scrap, salvage, or junk material, or from new or raw material, by processing, manipulating, or changing the form of an article or by combining or assembling two or more articles.”⁷⁶ Manufacturers include producers and importers.⁷⁷ For the MDET, manufacturers that fall under this definition are generally those that must register as medical device manufacturers with the FDA.⁷⁸

Who will be liable for the MDET is a question of major concern because not only do manufacturers and importers have the burden of paying the tax, they also take on an enormous administrative burden in implementing the appropriate systems to track and pay the tax. Various hospital associations expressed concern in a letter regarding the proposed regulations about the problems associated with hospitals being taxed as importers.⁷⁹ Under the current law, hospitals indeed qualify as importers if they purchase medical devices from abroad. The various hospital associations stated that hospitals are unfamiliar with excise taxes and do not have the administrative capability at this time to implement such a tracking and payment process.⁸⁰

The administrative burden is not unique to hospitals though. All manufacturers will bear significant and unpredictable costs in addition to the 2.3% tax on sales due to the cost of implementing the MDET, including the costs of developing or purchasing new information technology software to deal with tracking the taxable devices and reporting the tax to the IRS. A December 2012 survey of eighty-one medical device companies of varying sizes conducted

73. *Id.*; see also Grant Thornton, *IRS Finalizes Rules for Medical Device Excise Tax*, MONDAQ (Dec. 19, 2012), <http://www.mondaq.com/unitedstates/x/212332/sales+taxes+VAT+GST/IRS+Finalizes+Rules+For+Medical+Device+Excise+Tax>.

74. I.R.S. Notice 2012-77, *supra* note 38.

75. See *supra* note 48 and accompanying text.

76. Treas. Reg. § 48.0-2(a)(4)(i) (2012).

77. *Id.*

78. FFDC § 510, 21 U.S.C. § 360(a)–(d), (i), (j) (2012); 21 C.F.R. §§ 807.20, 21 (2013) (requiring establishments that manufacture, prepare, propagate, compound, assemble, process, repack, or relabel medical devices to register their establishments and list the devices intended for sale upon first beginning operation, and requiring them to update this list annually).

79. *E.g.*, Hosp. Ass’n Letter, *supra* note 18, at 9.

80. *Id.*

by the Advanced Medical Technology Association (AdvaMed)⁸¹ revealed that implementation of MDET solutions will cost the medical device industry an estimated \$400 to \$667 million.⁸² Such expected costs make it even more important for industry participants to know whether their activities subject them to the MDET so they can put in place the necessary systems to properly comply.

Although the MDET applies to manufacturers and importers, nothing in the statute prohibits these manufacturers from passing some, or all, of the burden of the tax on to healthcare providers. This was a major concern for hospital associations, which recommended in their comment letter regarding the proposed regulations that the IRS should expressly prohibit medical device manufacturers from passing the tax on to healthcare providers, thereby escaping the manufacturers' portion of the "shared responsibility" of healthcare reform and receiving a windfall.⁸³ Congress did not adopt this recommendation in the final regulations, however, and since the implementation of the tax, it is clear that at least some manufacturers are passing the tax directly on to healthcare providers.⁸⁴ The ability to pass the tax on as a line-item charge further complicates the question of which institutions are really going to bear the burden of the MDET.⁸⁵

81. AdvaMed is an industry group that "advocates on a global basis for the highest ethical standards, timely patient access to safe and effective products, and economic policies that reward value creation." *About AdvaMed*, ADVAMED, <http://advamed.org/page/56/about-advamed>. The group has been very outspoken against the MDET and has conducted several studies on its impact. *See Medical Device Tax*, ADVAMED, <http://advamed.org/issues/19/medical-device-tax>.

82. ADVANCED MED. TECH. ASS'N, MDET SURVEY RESULTS: UNDERSTANDING THE TRUE IMPACT OF THE MEDICAL DEVICE EXCISE TAX (MDET) (2012) [hereinafter ADVAMED SURVEY, Dec. 2012]; *Device Makers Need Many Months, Millions of Dollars To Figure Out Medtech Tax Compliance*, MASSDEVICE (Dec. 18, 2012), <http://www.massdevice.com/news/device-makers-needs-many-months-millions-dollars-figure-out-medtech-tax-compliance>.

83. Hosp. Ass'ns Letter, *supra* note 18, at 2–7.

84. The Healthcare Supply Chain Association (HSCA) launched a website called Medical Device Tax Watch "to serve as a clearinghouse of information for its hospital and healthcare provider partners on the medical device excise tax (MDET), and to gather information and create awareness of medical device industry efforts to pass the costs of the device tax on to American hospitals and other health care providers." *About*, MED. DEVICE TAX WATCH, <http://www.devicetaxwatch.com/p/about.html>. HSCA has posted a list of thirty-nine suppliers who are shifting the burden directly to providers. *Cost-Shifting Suppliers*, MED. DEVICE TAX WATCH, <http://www.devicetaxwatch.com/p/cost-shifting-suppliers.html>.

85. Economist Kyle Pomerleau of the Tax Foundation, a nonpartisan research organization that has monitored fiscal policy since 1937, noted that "the market power of hospitals could undercut the ability of device manufacturers to pass on much of the cost of this tax in the long run," especially in an industry such as the medical device industry that is composed of small firms lacking in bargaining power. KYLE POMERLEAU, TAX FOUND., FISCAL FACT NO. 364: THE ACA MEDICAL DEVICE TAX: BAD POLICY IN NEED OF REPEAL 3 (2013), available at <http://taxfoundation.org/sites/taxfoundation.org/files/docs/ff364.pdf>. Proponents of the MDET also recognize the likely inability of manufacturers to pass off the whole cost of the MDET to purchasers, but they indicate this is a good thing. *See VAN DE WATER*, *supra* note 25, at 6.

C. What Sales Price Will Be Taxed?

Under the MDET, what the sales price of a medical device includes can make a huge difference in the tax's implications. Recognizing "that the medical device industry encompasses a diverse group of manufacturers that produce a broad range of articles" and that the medical device industry uses a wide array of distribution chains, the IRS and the Treasury Department have requested additional comments on how best to determine the constructive sales price of items sold to related parties.⁸⁶ Under the interim rules issued along with the final regulations, the IRS provided five distribution scenarios with guidance about how to calculate the sale price. The table below summarizes these interim rules⁸⁷:

Table 1. Interim Sales Price Rules

Distribution Chain	Constructive Price Interim Rule
Sales at retail (to unrelated end users); no regular sales to independent wholesale distributors	75% of the actual selling price after taking into account adjustments provided by section 4216(a)
Sales to unrelated retailers; no regular sales to independent wholesale distributors	90% of the lowest price for which articles are sold to unrelated retailers, without adjustment for any exclusion
Sales to related retailers; no regular sales to independent wholesale distributors	75% of the product of 95% and the actual selling price ⁸⁸
Sales to related resellers that lease and sell at retail to unrelated end users	75% of the product of 95% and the actual selling price ⁸⁹
Sales to related resellers that only lease at retail; no regular sales to independent wholesale distributors	Actual selling price to related reseller, provided it reasonably approximates actual fair market price of the article

86. I.R.S. Notice 2012-77, *supra* note 38, § 3, at 782.

87. The table above is a concise summary of the IRS's interim guidance regarding constructive sale price. *Id.* at 782–83.

88. "The 5% discount is an allowance for the exclusions from the selling price otherwise allowed under § 4216(a). *See* Rev. Rul. 82-211. The additional 25% discount adjusts the selling price to approximate the selling price to an independent wholesale distributor. *See* Rev. Rul. 80-273." *Id.* at 783.

89. *Id.*

In order to maximize revenues and maintain consistency with other manufacturers' excise taxes, the sales price cannot be reduced for discounts or rebates,⁹⁰ and the price will include costs of packaging, shipping, and warranties.⁹¹

III. POTENTIAL ECONOMIC IMPACT OF THE MDET

Along with leaving some outstanding administrative questions unresolved, as noted in the previous Part, the MDET also carries with it the potential of hurting the medical device industry. This in turn may harm the U.S. economy, as medical device manufacturers are forced to cut costs by slashing jobs, moving jobs overseas, and decreasing spending on R&D. Manufacturers may also simply pass the tax on to customers (typically hospitals), further burdening that sector and forcing it to foot an even greater portion of the PPACA's revenue requirements.⁹² This Part describes the potential impact of the MDET on medical device manufacturers and on the U.S. economy as a whole. First, it looks at the U.S. medical device industry and the problems it faces today. Then, it examines the arguments both for and against the tax by looking at studies and actual responses by various corporations.

A. The Medical Device Industry

The medical device sector is one of the United States' strongest industries and is one of very few sectors that exports more than it imports.⁹³ It employs over four

90. The IRS decided not to adopt the recommendations of AdvaMed and others to allow rebates to be taken into account in calculating the sales price. *See* AdvaMed Letter (May 3, 2012), *supra* note 52, at 8–10 (explaining how common volume and other discounts and rebates are in the medical device industry and how they are often provided pursuant to contract and thus treated as excludible purchase price adjustments for federal income tax and accounting purposes); T.D. 9604, 2012-52 I.R.B. 730, 738 (declining to adopt the recommendation and providing that “a manufacturer may take a rebate into account in determining sale price only to the extent the rebate is made prior to the close of the quarter during which the sale associated with the rebate is made”).

91. Mitchell Kopelman & Ori Epstein, *Medical Device Tax 101*, MED. DEVICE & DIAGNOSTIC INDUSTRY (Aug. 20, 2012), <http://www.mddionline.com/article/medical-device-tax-101>.

92. Apart from the medical device tax, hospitals have already begun reacting to Obamacare by laying off large numbers of their workforce. For example, in the fall of 2013, Indiana University Health (IUH) laid off more than 800 employees. IUH and other hospitals across the country cite the new health care law as a key reason, but also point to decreased Medicaid funding, decreased inpatient stays, an aging population, and lower reimbursement rates as causes for the layoffs. *See, e.g.*, Paul Davidson & Barbara Hansen, *Hospitals Reducing Payrolls*, USA TODAY, Oct. 14, 2013, at 1B; Kimberly Leonard, *Is Obamacare to Blame for Hospital Layoffs?*, U.S. NEWS & WORLD REP. (Sept. 20, 2013), <http://health.usnews.com/health-news/hospital-of-tomorrow/articles/2013/09/20/is-obamacare-to-blame-for-hospital-layoffs-is-obamacare-to-blame-for-hospital-layoffs>.

93. Letter from eighteen U.S. Democratic senators to Harry Reid, Majority Leader, U.S. Senate (Dec. 4, 2012), *available at* <http://online.wsj.com/public/resources/documents/MedDeviceLetter12102012.pdf>.

hundred thousand Americans directly and an estimated two million indirectly.⁹⁴ These jobs typically pay about 40% above average wages.⁹⁵ Furthermore, the medical device sector invests significant resources in innovation, increasing R&D investment by 9% from 2007 to 2009.⁹⁶

Small, innovative companies fuel the industry, with 80% of medical technology companies having fewer than fifty employees and 98% having fewer than five hundred employees.⁹⁷ Medical device development is extremely capital intensive and risky due to the long product development cycles—typically seven to ten years—required for research and clinical studies, manufacturing, and product launch.⁹⁸ Companies must also deal with a very complex regulatory environment both in the United States and worldwide.

The medical device regulatory environment in the United States is extremely complicated, and companies must obtain approval for new devices from the FDA through a series of difficult filings, clinical trials, and plant audits.⁹⁹ Often, companies with novel developments do not have clear regulatory guidance on the process,¹⁰⁰ thus delaying and further complicating introduction of the device to the market. Companies must also convince the CMS to cover or reimburse consumers for the cost of the devices, often without clear guidance or protocol for keeping the FDA and CMS on similar tracks.¹⁰¹

The industry has experienced significant growth in recent years despite a difficult economic environment; however, the U.S. regulatory scheme, worldwide competition, and now the MDET create considerable barriers to continued growth in the United States, and some analysts question whether the United States can maintain its dominance in the industry with the upcoming changes.¹⁰²

94. Yair Holtzman, *The U.S. Medical Device Industry in 2012: Challenges at Home and Abroad*, MED. DEVICE & DIAGNOSTIC INDUSTRY (July 17, 2012), <http://www.mddionline.com/article/medtech-2012-SWOT>.

95. LEWIN GRP., STATE ECONOMIC IMPACT OF THE MEDICAL TECHNOLOGY INDUSTRY 8 (2010), available at http://www.lewin.com/~media/lewin/site_sections/publications/stateeconomicimpactofthemedicaltechnologyindustry61510.pdf.

96. Holtzman, *supra* note 94.

97. Letter from more than 800 companies and groups to Senators Harry Reid, Richard Durbin, Mitch McConnell & Jon Kyl (Nov. 13, 2012) [hereinafter Letter from 800 groups], available at <http://www.azbio.org/pinniped/wp-content/uploads/2012/11/2012-11-13-device-tax-letter-to-senate-leadership.pdf>; see also MED. DEVICE MFRS. ASS'N & NAT'L VENTURE CAPITAL ASS'N, MEDICAL TECHNOLOGY AND VENTURE CAPITAL: A FRUITFUL YET FRAGILE ECOSYSTEM 2 (2009).

98. MED. DEVICE MFRS. ASS'N & NAT'L VENTURE CAPITAL ASS'N, *supra* note 97, at 13.

99. *Id.* at 14. The basic requirements include establishment registration, medical device listing, premarket notification (510(k)) or premarket approval (PMA), investigational device exemption (IDE) for clinical studies, quality system (QS) regulation, labeling requirements, and medical device reporting (MDR). *Medical Devices: Overview of Device Regulation*, FDA, <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/default.htm> (last updated Mar. 5, 2013).

100. MED. DEVICE MFRS. ASS'N & NAT'L VENTURE CAPITAL ASS'N, *supra* note 97, at 14.

101. *Id.* at 14–15.

102. See, e.g., Holtzman, *supra* note 94.

B. Negative Economic Effects

The MDET adds one more problem to those faced by the medical device manufacturing sector today. Manufacturers and other opponents of the MDET claim that it is an “egregious job-killing tax[]”¹⁰³ that will “destroy jobs and stifle innovation”¹⁰⁴ because in order to pay for this new tax, medical device manufacturers will have to cut costs and, therefore, jobs and R&D expenditures. In one of the strongest job-producing industries in the nation, the anticipated job loss could be devastating for the economy.¹⁰⁵ Furthermore, some argue that the effects will be felt the most by smaller manufacturers and start-ups because these manufacturers typically offer products at very low profit margins or are already operating at a loss.¹⁰⁶ Unfortunately, it is these small manufacturers who develop most of the new innovations and life-saving products that keep the medical device industry flourishing.¹⁰⁷

Opponents argue that medical device manufacturers will move jobs offshore in order to cut costs.¹⁰⁸ The trade association for medical device manufacturers, AdvaMed, commissioned a study in 2011 to examine the likely impacts of the MDET, which found that “[u]nder reasonable assumptions, the tax could result in job losses in excess of 43,000 and employment compensation losses in excess of \$3.5 billion.”¹⁰⁹ Cook Medical Chairman Steve Ferguson indicated that the effects will likely be even more drastic.¹¹⁰

103. 158 CONG. REC. H3584 (daily ed. June 7, 2012) (statement of Rep. Black).

104. Devon Herrick, *The Job-Killing Medical Device Tax*, ISSUE BRIEFS (Nat’l Ctr. for Policy Analysis, Dall., Tex.), Feb. 2012, at 1, available at <http://www.ncpa.org/pdfs/ib106.pdf>; see also Ramesh Ponnuru, *Put Simply, the New Medical-Device Tax Will Steal Jobs*, STAR TRIB., Jan. 4, 2012, <http://www.startribune.com/opinion/commentaries/136625483.html>.

105. See Herrick, *supra* note 104, at 2–3.

106. See, e.g., MassDevice Staff, *Medical Device Tax Would Mostly Hit the Biggest Firms*, MEDCITY NEWS (Mar. 24, 2010, 12:22 PM), <http://medcitynews.com/2010/03/medical-device-tax-would-mostly-target-the-biggest-companies/> (“The tax’s impact on smaller firms might be more pronounced.”).

107. See Alan Kahn, *The Dynamics of Medical Device Innovation: An Innovator’s Perspective*, in THE CHANGING ECONOMICS OF MEDICAL TECHNOLOGY 89, 90–91 (Annetine C. Gelijns & Ethan A. Halm eds., 1991); *Mind Control or Design Control*, HEALING INNOVATION (Oct. 2, 2012), <http://healinginnovation.com/2012/10/02/mind-control-or-design-control/>.

108. E.g., DIANA FURCHTGOTT-ROTH & HAROLD FURCHTGOTT-ROTH, EMPLOYMENT EFFECTS OF THE NEW EXCISE TAX ON THE MEDICAL DEVICE INDUSTRY 2 (2011) [hereinafter ADVAMED STUDY, Sept. 2011], available at http://heartland.org/sites/default/files/090711_employmenteffectoftaxonmedicaldeviceindustryfinal.pdf.

109. *Id.* at 2. Some argue that this study and the study commissioned by AdvaMed in 2012 are not credible. E.g. Christopher Flavelle, *Expert Briefing: Medical Device Tax*, BLOOMBERG BUSINESSWEEK, Mar. 26, 2012, at B15.

110. See SCOTT NELSON, MEDSIDER, WILL THE MEDICAL DEVICE TAX FORCE YOU TO THE UNEMPLOYMENT LINE? (2012), available at http://medsider.com/wp-content/uploads/transcriptions/SteveFerguson_MedsiderInterviews_2012.pdf.

Recent business decisions by medical device manufacturers provide significant support for the arguments that the MDET will result in job loss or stunted hiring. In the two years leading up to the tax's implementation, a number of manufacturers began to find ways to cut costs in preparation. In the latter part of 2012, the medical device industry eliminated thousands of jobs, with many employers pointing to the medical device tax as a significant factor behind their layoffs.¹¹¹ In November 2011, device maker Stryker Corporation announced that it would cut five percent of its global workforce, citing preparation for the MDET as a main reason.¹¹² Similarly, in September 2012, Welch Allyn announced a number of changes it planned to put in place to "proactively prepare the company to address the onerous U.S. medical-device tax."¹¹³ These changes include reducing its 2750-person workforce by ten percent over the next three years, closing its manufacturing plant in Beaverton, Oregon, and consolidating its North American operations in Tijuana, Mexico.¹¹⁴

Cook Medical, the largest privately owned medical device manufacturer in the United States, has taken a more vocal stance against the tax than some of the larger public companies.¹¹⁵ Cook cited the MDET as the reason why it decided to shelve its plans to roll out five new plants across the Midwest over the next five years, having estimated that the new tax will cost the company between \$20 and \$30 million annually.¹¹⁶ Cook stated that it had hoped to be able to expand manufacturing facilities to small U.S. towns that were hit hard by job loss, but with the new MDET, Cook is forced to shift its focus on future growth overseas.¹¹⁷

In addition to Stryker, Welch Allyn, and Cook, other manufacturers such as NuVasive¹¹⁸ and St. Jude Medical¹¹⁹ have cited the MDET as a reason behind

111. *Layoffs: Medical Device Companies Cut 2,000 Jobs in 2 Months*, MASSDEVICE (Sept. 14, 2012), <http://www.massdevice.com/news/layoffs-medical-device-companies-cut-2000-jobs-2-months>.

112. Press Release, Stryker Corp., Stryker Announces Actions to Drive Over \$100 Million in Annual Productivity Gains (Nov. 10, 2011) [hereinafter Stryker Press Release], available at <http://phx.corporate-ir.net/phoenix.zhtml?c=118965&p=irol-newsArticle&ID=1629222>.

113. Mike Verespej, *Welch Allyn Shifting Work Abroad, Blames Pending Medical-Device Tax*, PLASTICSNEWS.COM (Sept. 17, 2012, 6:00 AM), <http://www.plasticsnews.com/article/20120917/NEWS/309179973>.

114. *Id.*

115. Press Release, Cook Med., Cook Medical Urges House of Representatives and Senate to Support Repeal of Medical Device Tax (June 4, 2012), available at <https://www.cookmedical.com/web/newsroom/article/-/blogs/cook-medical-urges-house-of-representatives-and-senate-to-support-repeal-of-medical-device-tax>. For an interesting interview with the Cook Group's chairman, see NELSON, *supra* note 110.

116. J.K. Wall, *Cook Medical Shelves Midwest Expansion Plans*, IBJ.COM (July 27, 2012), <http://www.ijb.com/cook-medical-shelves-midwest-expansion-plans/PARAMS/article/35735>.

117. *Id.*

118. NuVasive, a company that produces implants and invasive disks that surgeons can fit into a person's spine to deal with severe back pain, states that the MDET will cost it about \$12 million, reducing its operating profit by fourteen percent and potentially resulting in elimination of over one hundred highly skilled jobs. *Federal Policies Affecting Innovation and Job Growth in the Biotech and Pharmaceutical Industries: Hearing Before the H. Comm. on Oversight & Gov't Reform*, 112th Cong. (2011) [hereinafter Lukianov statement], available at http://oversight.house.gov/wp-content/uploads/2012/01/4-21-11_Lukianov_SD

cutting jobs or shifting production overseas. A December 2012 AdvaMed survey of eighty-one medical device manufacturers indicates that approximately “62 percent of the companies expect to include layoffs or reduced hiring as part of their response to the tax.”¹²⁰

One of the most concerning effects of the MDET is the potential for it to further decrease innovation in an industry already experiencing a decline in venture capital funding and other difficulties due to regulatory uncertainty.¹²¹ Medical device innovation is part of a long-term solution to reducing healthcare costs. A large study conducted by researchers and a coalition of seven leading healthcare organizations found that advances and innovation in healthcare from 1980 to 2000 produced health gains (based on a number of factors such as death and disability rates, hospital stay days, and life expectancies) of \$2.40 to \$3.00 for each dollar spent on healthcare.¹²² The majority of medical device innovations come from small companies, often start-ups with a new idea. A survey of ninety-eight medical device start-up executives found that thirty-eight percent plan to foot at least some of the cost of the tax by decreasing investment in R&D.¹²³ By creating another obstacle to entry into the market, the MDET has the potential to deter companies from investing in medical device innovation. This effect ultimately hurts patients and inhibits the United States from maintaining its leading position in the medical device industry. Decreased investment in R&D, layoffs, hiring freezes, and movement overseas indicate that the MDET could have grave consequences for one of America’s leading industries.

_Testimony.pdf (statement of Alex Lukianov, Chairman & CEO, NuVasive, Inc.); *see also About Us*, NUVASIVE, <http://www.nuvasive.com/about-us/>.

119. St. Jude Medical laid off about eight hundred workers from August to November of 2012 as part of a companywide reorganization designed to cut \$50 to \$60 million in costs in 2013. Although the company stated that the MDET is just one of many factors that contributed to the layoffs, the amount of cost savings for 2013 is very close to what company executives anticipate paying for the MDET. James Walsh, *St. Jude Cutting Another 500 Jobs; Med-Tech Company Laid Off 300 People in August*, STAR TRIB., Nov. 2, 2012, at 1A.

120. ADVAMED SURVEY, Dec. 2012, *supra* note 82.

121. *See* Joseph Walker, *Funding Dries Up for Medical Startups*, WALL ST. J. (Nov. 4, 2013, 7:58 PM), <http://online.wsj.com/news/articles/SB10001424052702304470504579164122110690860>.

122. VALUE GRP., THE VALUE OF INVESTMENT IN HEALTH CARE 2 (2004), *available at* http://www.aha.org/content/2004/pdf/Value_Report.pdf (“The study suggests that the value of improved health in the U.S. population over the past 20 years significantly outweighs the additional health care expenditures that accompanied the improvements.”). The study specifically looked at four conditions that are among the most common causes of death and disability—heart attack, type 2 diabetes, stroke, and breast cancer—and sought to quantify in dollar terms the total value of investment (VOI) in health care expenditures. *Id.*

123. Arezu Sarvestani, *Survey: Medtech Startups Respond to the Medical Device Tax*, MASSDEVICE (Apr. 4, 2013), <http://www.massdevice.com/news/survey-medtech-startups-respond-medical-device-tax>. Additionally, the survey revealed that 28% of these executives plan to expand overseas rather than domestically, 23% plan to shift resources away from growth, 34% plan to pass costs on to consumers, 23% plan to try to raise additional capital, and 23% plan to reduce staff or hire less in order to offset the MDET. *Id.*

C. Counterarguments in Favor of the MDET

Despite the evidence of corporate actions in preparation for the MDET, those in favor of the tax respond that the industry's grave predictions of vast layoffs and decreased investment in innovation are greatly exaggerated. First, advocates of the MDET claim the industry studies are not based on "reasonable assumptions" because they overstate companies' incentives to move offshore and ignore the positive effects on demand created by the PPACA.¹²⁴ Because the tax applies equally to imported and domestically produced devices, proponents urge that the tax will not force manufacturers overseas.¹²⁵ They also argue that the medical device industry is not being singled out since the tax is just one of many new levies imposed on sectors that will gain business due to health reform.¹²⁶ Finally, advocates contend that the tax will not decrease innovation in the industry because "[g]overnment pressure to lower healthcare costs could . . . forc[e] developed nations to turn to innovative technology to achieve better results at lower costs."¹²⁷

Supporters of the tax claim it is not the MDET causing employers to lay off employees and move jobs overseas but rather other factors related to medical regulations and the economy in general that have caused these shifts.¹²⁸ These proponents point out that many companies, while blaming the MDET in part for their economic difficulties, acknowledge that other factors contribute and may play an even greater role. When Stryker Corporation revealed plans to cut 1000 workers, or five percent of its workforce, it cited the tax as only one cause behind its decision, and also pointed to other restructuring aims "to allow for continued investment in strategic areas and drive growth despite the ongoing challenging

124. Flavelle, *supra* note 109.

125. VAN DE WATER, *supra* note 25, at 3.

126. *Id.* at 1. In an interview that aired on December 13, 2012, President Obama explained:

The health care bill is going to provide those health care companies, 30 million new customers. It's going to be great for business and they're doing really well right now and they're going to get 30 million more customers as a consequence, so this additional tax essentially comes back to them as new customers. . . . The idea is that when you have 30 million more people coming in, you're going to make money, you can do a little more to help facilitate and make sure people are getting the health care they need.

Full Transcript of Frank Vascellaro's Interview with Obama, CBS MINN. (Dec. 13, 2012, 5:37 PM), <http://minnesota.cbslocal.com/2012/12/13/full-transcript-of-frank-vascellaros-interview-with-obama/> [hereinafter *Vascellaro Interview*].

127. PRICEWATERHOUSECOOPERS LLP, MEDICAL TECHNOLOGY INNOVATION SCORECARD: THE RACE FOR GLOBAL LEADERSHIP 12 (2011), available at http://download.pwc.com/ie/pubs/2011_medical_technology_innovation_scorecard_the_race_for_global_leadership_jan.pdf.

128. VAN DE WATER, *supra* note 25, at 4 ("[T]he effect of the excise tax on the medical device industry will be 'trivial compared with other shifts,' such as 'scandals, recalls, stingy customers, [and] anxious regulators,' all of which have left the industry in a 'rut.'" (quoting *Left to Their Own Devices: Medtronic and the Woes of America's Medical-Technology Industry*, ECONOMIST (Sept. 10, 2011), <http://www.economist.com/node/21528644>)).

economic environment and market slowdown for elective procedures.”¹²⁹ Welch Allyn also stated that its layoffs were spurred not only from preparation for the MDET but also in preparation for “significant changes driven by health-care reform and market dynamics.”¹³⁰ Some analysts state that regardless of the MDET, the industry would have had to cut jobs due to “weak sales for the last several years as people lost their jobs and health insurance, and as cash-strapped governments around the world slashed spending.”¹³¹ To be fair, some medical device companies may have used the MDET as a scapegoat for cutting employees or shifting production overseas when those decisions may have been made regardless of the MDET; however, it is also possible that the MDET was the final nail in the coffin in favor of such operating decisions.

MDET proponents also argue that the excise tax will not disproportionately affect small businesses because the bulk of the burden will fall on the large firms that account for the lion’s share of revenue in the industry. The industry has estimated revenue of \$106–\$116 billion per year,¹³² with approximately ten manufacturers accounting for eighty-six percent of the sales of covered medical devices.¹³³ Large manufacturers such as Medtronic, Baxter International, and Boston Scientific will therefore pay the bulk of the tax.¹³⁴ This analysis fails to take into account that although these large firms may pay the bulk of the tax, the smaller firms with low profit margins would feel the impact of even a small portion of the tax more acutely than large firms.¹³⁵ Concededly, large manufacturers likely can absorb the tax with little difficulty: their stock prices continued to rise in 2013 despite the excise tax.¹³⁶ However, small, private manufacturers’ earnings are not reflected in these statistics, and it is likely these manufacturers cannot handle such a tax without changing business practices significantly or taking massive blows to their bottom lines.

Finally, most of the supporters of the MDET view it as a necessary component of the PPACA—a small component that needs to remain intact in order to achieve the much larger goal of providing healthcare to all Americans. They acknowledge that the MDET imposes a burden on the medical device industry but reason that such a burden is outweighed by the benefits of Obamacare. Under Obamacare,

129. Stryker Press Release, *supra* note 112; Yvonne Zipp, *Stryker Corp. to Complete Planned Layoffs of 1,000 Workers by End of 2012*, MLIVE (Nov. 19, 2012, 2:34 PM) http://www.mlive.com/business/west-michigan/index.ssf/2012/11/stryker_corp_to_complete_layof.html.

130. Verespej, *supra* note 113.

131. Debra Sherman, *Analysis: Medtech Companies Face Job Cuts, Excise Tax or Not*, REUTERS, Dec. 20, 2012, available at <http://www.reuters.com/article/2012/12/20/us-medtech-idUSBRE8BJ15U20121220>. Frost & Sullivan analyst Venkat Rajan stated, “It’s easy to blame the tax, but it’s something that would have happened eventually at these companies.” *Id.*

132. VAN DE WATER, *supra* note 25, at 2–3; Flavelle, *supra* note 109.

133. MassDevice Staff, *supra* note 106.

134. *Id.*

135. *Id.*

136. The S&P Health Care Equipment Index rose over thirty percent in 2013. See *S&P Health Care Equipment Select Industry Index*, S&P DOW JONES INDICES, <http://us.spindices.com/indices/equity/sp-healthcare-equipment-select-industry-index>.

millions of otherwise uninsured Americans will have access to affordable health insurance.¹³⁷ Proponents of Obamacare and the MDET emphasize all of the positive impacts of the new health care law, such as prohibiting health insurers from denying coverage to individuals with preexisting conditions,¹³⁸ ensuring the quality of care through new care reports and compliance,¹³⁹ creating affordable insurance choices through state health insurance exchanges,¹⁴⁰ prohibiting insurers from rescinding coverage,¹⁴¹ eliminating lifetime limits on insurance coverage,¹⁴² and providing free preventive care benefits,¹⁴³ to name just a few.¹⁴⁴ However, these benefits do not justify charging a disproportionate amount of the costs of Obamacare to medical device manufacturers who will not receive a comparable increase in revenue due to new patients.¹⁴⁵ Many proponents of the PPACA recognize this problem and oppose the MDET, acknowledging that the negative economic results of the MDET likely outweigh the portion of funding of the PPACA that the tax provides.¹⁴⁶

IV. POLITICAL UPROAR

The outcry over the MDET caused the legislature to take action. On January 25, 2011, bills were introduced in both the House of Representatives and the Senate to repeal the MDET.¹⁴⁷ The Senate bill, the Medical Device Access and Innovation

137. *Facts on the Affordable Care Act*, OBAMACARE FACTS, <http://obamacarefacts.com/obamacare-facts.php>.

138. PPACA §§ 1201(2)(A), (4), 1501(a)(2)(I), 42 U.S.C. §§ 300gg-3(a), -4(a), 18091(2)(I) (2012).

139. 42 U.S.C. § 300gg-17(a)(1).

140. *Id.* § 18031(b)-(d).

141. *Id.* §§ 300gg-11 to -12.

142. *Id.* § 300gg-11(a)(1)(A), -11 note.

143. *Id.* § 300gg-13(a)(1)-(5).

144. For a helpful summary of key provisions of the PPACA, see Hyman, *supra* note 4.

145. *See infra* notes 170-80. Furthermore, although some manufacturers may be able to pass the tax on to healthcare providers, it is unlikely that most manufacturers will be willing or able to pass on the bulk of the tax. *See, e.g.*, Evan Bayh, *ObamaCare's Tax Raid on Medical Devices*, WALL ST. J., Sept. 28, 2012, at A17 (explaining that "[b]ecause many devices are sold to hospitals, physicians and other providers through multiyear contracts, the prices are already locked in, so the tax cannot be passed on to the buyer"); Debra Sherman, *Trade Group Identifies Medical Device Makers Passing on Federal Tax*, REUTERS, Feb. 28, 2013, available at <http://www.reuters.com/article/2013/02/28/us-devices-tax-idUSBRE91R1NK20130228> (stating that the practice of charging the MDET as a line item on invoices is happening, but does not seem to be a broad or widespread practice, and "since so few companies are listed thus far, it's not out of the question that their cost-shifting effort will backfire in terms of their relationships with GPOs and hospitals" (quoting Amit Hazan, an analyst at SunTrust Robinson Humphrey)).

146. For example, some of the biggest Obamacare advocates in Congress staunchly oppose the MDET despite their support of healthcare reform as a whole. Typically these congressmen and women are from states where medical device manufacturing is a big driver of the state's economy.

147. Medical Device Access and Innovation Protection Act, S. 17, 112th Cong. (as introduced in the Senate, Jan. 25, 2011), available at <http://www.gpo.gov/fdsys/pkg/BILLS-112s17is/pdf/BILLS-112s17is.pdf>; Protect Medical Innovation Act of 2011, H.R. 436, 112th

Protection Act, obtained thirty-three cosponsors but ultimately died.¹⁴⁸ The House bill, titled the Protect Medical Innovation Act (PMIA) of 2011, was referred to the Committee on Ways and Means, which, after a mark-up session, reported in favor of the bill by a vote of twenty-three to eleven,¹⁴⁹ stating, “The Committee believes that the tax will increase the cost of healthcare, slow medical innovation, and lead to loss of jobs in the industry.”¹⁵⁰ The PMIA of 2011 was consolidated with three other related bills¹⁵¹ into a bill called the Health Care Cost Reduction Act of 2012 (HCCRA).¹⁵² The House of Representatives voted to pass this bill on June 7, 2012,¹⁵³ but it could not get through the Democrat-controlled Senate, likely because of the controversial “pay-for” mechanism designed to recapture overpaid health insurance tax credits to families.¹⁵⁴ President Obama had also vowed to veto the bill even if it had passed the Senate.¹⁵⁵

Cong. (as introduced in the House, Jan. 25, 2011), available at <http://www.gpo.gov/fdsys/pkg/BILLS-112hr436ih/pdf/BILLS-112hr436ih.pdf>.

148. *S. 17 (112th): Medical Device Access and Innovation Protection Act*, GOVTRACK.US, <http://www.govtrack.us/congress/bills/112/s17>. The bill was reintroduced in February 2013; it gained thirty-nine cosponsors but once again stalled in committee. *S. 232: Medical Device Access and Innovation Protection Act*, GOVTRACK.US, <https://www.govtrack.us/congress/bills/113/s232>.

149. H.R. REP. NO. 112-514, pt. 3, at 5 (2012).

150. *Id.* pt. 2, at 5.

151. The other three bills included in the consolidated H.R. 436 were the Restoring Access to Medications Act of 2012, H.R. 5842; the Health Flexible Spending Arrangements Improvements Act of 2012, H.R. 1004; and the Reconciliation Recommendation Related to the Recapture of Overpayments Resulting from Certain Federally Subsidized Health Insurance. Letter from Douglas W. Elmendorf, Dir., Cong. Budget Office, to David Dreier, Chairman, Comm. on Rules, U.S. House of Representatives 2 (June 5, 2012), available at http://cbo.gov/sites/default/files/cbofiles/attachments/hr436_0.pdf.

152. Health Care Cost Reduction Act of 2012, H.R. 436, 112th Cong. (as passed by House, June 7, 2012), available at <http://www.gpo.gov/fdsys/pkg/BILLS-112hr436eh/pdf/BILLS-112hr436eh.pdf>.

153. *H.R. 436 (112th): Health Care Cost Reduction Act of 2012*, GOVTRACK.US, <https://www.govtrack.us/congress/bills/112/hr436> (detailing timeline of bill’s path through House).

154. *Id.* It is clear that members of the House knew when passing the bill that the Senate would not agree to the pay-for provision. See 158 CONG. REC. H3611 (daily ed. June 7, 2012) (statement of Rep. Watt) (“We need . . . to repeal the medical devices tax. But this is not the way to pay for it, and we must find an acceptable pay-for.”); 158 CONG. REC. H3610 (daily ed. June 7, 2012) (statement of Rep. King) (“I support the legislation before us today, but I do so under the proviso and with the understanding that the pay-for that is being used right now is controversial on our side. I don’t think it’s the ideal pay-for. I don’t believe that it’s going to be the pay-for that the Senate would consider if it takes this measure up. It certainly won’t be the pay-for that the President will feel comfortable signing into law.”). For further discussion of the bill’s pay-for provision, see *H.R. 436—Health Care Cost Reduction Act of 2012 (Paulsen, R-MN)*, LEGIS. BULL. (Republican Study Comm., Wash., D.C.), June 7, 2012, available at http://rsc.scalise.house.gov/uploadedfiles/lbhr436_medicaldevicetax_otcrepeal_fsa_reform_06072012.pdf.

155. See Joseph Walker, *Senate Democrats Seek Delay in Medical-Device Tax*, WALL ST. J. WASH. WIRE (Dec. 10, 2012, 2:00 PM), <http://blogs.wsj.com/washwire/2012/12/10/senate-democrats-seek-delay-in-medical-device-tax/>; see also *H.R. 436—Health Care Cost Reduction*

As the effective date of the tax drew near, opponents continued to write letters urging Congress to take action before the January 1, 2013, implementation date. On November 13, 2012, over eight hundred organizations and businesses signed a letter to the majority and minority leaders of the Senate encouraging Congress to add repeal of the MDET to its list of priorities.¹⁵⁶ On December 4, 2012, eighteen Democratic senators also sent a letter to Senate majority leader Harry Reid requesting delayed enactment of the MDET, stating, “[W]e must do all we can to ensure that our country maintains its global leadership position in the medical technology industry and keeps good jobs here at home.”¹⁵⁷ Despite such opposition even from supporters of Obamacare overall, Congress refused to delay enactment of the MDET, and the tax took effect as planned on January 1, 2013.

Opponents have not given up hope, however, and continue to lobby Congress for prompt repeal of the tax. On February 6, 2013, Erik Paulsen introduced to the House of Representatives the PMIA of 2013, another bill to repeal the MDET.¹⁵⁸ The bill was referred to a committee for consideration, but again no fast action occurred. The main problem with this revised version of the repeal bill is that it lacks any pay-for provision. This is Democrats’ main sticking point, and passage of any bill without an offsetting revenue-generating provision to pay for Obamacare is improbable. On March 20, 2013, Representative Dan Maffei (D-N.Y.) introduced another bill to the House titled the Medical Device Tax Elimination Act.¹⁵⁹ This bill would also repeal the MDET and contains a pay-for provision that may be more palatable to Democrats than the pay-for provision included in the HCCRA.¹⁶⁰ Maffei’s bill would fully offset the cost of repealing the MDET by wiping out three current tax incentives for large oil companies.¹⁶¹ As of the writing of this Note, Maffei’s bill has only six cosponsors¹⁶² while Paulsen’s PMIA of 2013 has rounded up 271, enough to pass the

Act of 2012 (Paulsen, R-MN), supra note 154, at 2; Vascellaro Interview, supra note 126.

156. Letter from 800 groups, *supra* note 97.

157. Letter from eighteen U.S. Democratic senators, *supra* note 93.

158. Protect Medical Innovation Act of 2013, H.R. 523, 113th Cong. (2013), *available at* <http://www.gpo.gov/fdsys/pkg/BILLS-113hr523ih/pdf/BILLS-113hr523ih.pdf>. The Medical Device Access and Innovation Protection Act was also reintroduced to the Senate on February 7, 2013, but passage seems unlikely. Medical Device Access and Innovation Protection Act, S. 232, 113th Cong. (2013), *available at* <http://www.gpo.gov/fdsys/pkg/BILLS-113s232is/pdf/BILLS-113s232is.pdf>; S. 232: *Medical Device Access and Innovation Protection Act, supra* note 148.

159. Medical Device Tax Elimination Act, H.R. 1295, 113th Cong. (2013), *available at* <http://www.gpo.gov/fdsys/pkg/BILLS-113hr1295ih/pdf/BILLS-113hr1295ih.pdf>.

160. *See supra* note 154.

161. The bill proposes to (1) eliminate the section 199 domestic production activities deduction for oil companies, which is expected to generate \$9 billion over 2014–23; (2) ban oil companies from using the Last-In, First-Out (LIFO) method of accounting for inventory that allows companies to deduct the cost of oil most recently added to their inventories, which is expected to generate \$14 billion; and (3) ban oil companies from claiming foreign tax credits, which is expected to generate \$6 billion. Press Release, Dan Maffei, U.S. Congressman, Maffei Introduces Legislation to Repeal Medical Device Tax (Mar. 20, 2013), *available at* <http://maffei.house.gov/media-center/press-releases/maffei-introduces-legislation-to-repeal-medical-device-tax>.

162. Medical Device Tax Elimination Act, H.R. 1296, 113th Cong. (2013), *available at* <https://www.govtrack.us/congress/bills/113/hr1295>.

House and approaching a two-thirds majority.¹⁶³ If the PMIA of 2013 were to pass the House, the Senate may be more receptive than it was the first time around. On March 21, 2013, the Senate voted in favor of repealing the MDET seventy-nine to twenty in a largely symbolic, nonbinding vote.¹⁶⁴ The overwhelming bipartisan support demonstrated by this nonbinding vote reveals the discontent of legislators and sets the stage for true repeal, according to Indiana Senator Dan Coats.¹⁶⁵

Opponents of the tax became hopeful in the fall of 2013 when repeal of the MDET became one of the main sticking points in the congressional negotiations to end the government shutdown.¹⁶⁶ The repeal of the tax seemed to be one of very few issues with bipartisan support¹⁶⁷ and a way for Republicans to whittle away at the President's healthcare law; however, Senate Democrats (despite prior efforts to repeal the tax) refused to include repeal as part of a larger budget agreement. The MDET thus remains intact for now, with members of Congress, medical device industry spokespeople and lobbyists still pushing for repeal as part of larger tax reform negotiations set to take place in 2014.¹⁶⁸ With the tax having been in effect

163. Protect Medical Innovation Act of 2013, H.R. 523, 113th Cong. (2013), available at <http://www.govtrack.us/congress/bills/113/hr523>.

164. The vote was nonbinding because it concerned an amendment to a Senate budget resolution, cosponsored by Senators Orrin Hatch (R-Utah) and Amy Klobuchar (D-Minn.), that is unlikely to be accepted by the Republican-controlled House. *E.g.*, Tom Curry, *Senate Votes to Kill Part of 2010 Health Care Overhaul*, NBCNEWS.COM (Mar. 22, 2013, 9:18 AM), http://nbcpolitics.nbcnews.com/_news/2013/03/22/17414901-senate-votes-to-kill-part-of-2010-health-care-overhaul?lite.

165. Arezu Sarvestani, *Medical Device Tax: Senate Repeal Vote Was More Than Symbolic, Says Indiana Sen. Coats*, MASSDEVICE (Apr. 4, 2013), <http://www.massdevice.com/news/medical-device-tax-senate-repeal-vote-was-more-symbolic-says-indiana-sen-coats>.

The nonbinding vote also demonstrates the significant lobbying power of the medical device manufacturing industry. Since the announcement of the MDET, medical device makers have been throwing money at legislators in an effort to win support for repeal of the tax. Based on data collected by the Center for Responsive Politics, medical device makers have spent about \$30 million annually on lobbying efforts for the last five years. *Medical Devices & Supplies: Lobbying, 2012*, CENTER FOR RESPONSIVE POL., <http://www.opensecrets.org/industries/lobbying.php?cycle=2012&ind=H4100>.

166. *See, e.g.*, Alex Nussbaum & Michelle Fay Cortez, *Medical Device-Tax Delay Turns Focus of U.S. Budget Fight*, BLOOMBERG (Oct. 15, 2013, 12:45 PM), <http://www.bloomberg.com/news/2013-10-15/medical-device-tax-delay-turns-focus-of-u-s-budget-fight.html>. The government shutdown lasted from October 1 through October 16, 2013.

167. Bipartisan support can be attributed to the broad distribution of medical device manufacturers across the nation, in both Republican and Democratic areas, who have been pressuring their representatives to repeal the tax. *See, e.g.*, Ezra Klein, *This Is Why the Medical Device Tax Is in So Much Trouble*, WASH. POST (Oct. 14, 2013, 4:35 PM), <http://www.washingtonpost.com/blogs/wonkblog/wp/2013/10/14/this-is-why-the-medical-device-tax-is-in-so-much-trouble/>. According to a 2010 study by the Lewin Group, the top five states with the highest percentages of employment in the medical technology industry are Minnesota (1.06%), Utah (0.93%), Delaware (0.79%), Massachusetts (0.78%), and Indiana (0.75%). *See* LEWIN GRP., *supra* note 95, at 6.

168. *See, e.g.*, Maureen Groppe, *Effort Continues to Repeal Medical Device Tax*, USA TODAY (Oct. 27, 2013, 12:22 PM), <http://www.usatoday.com/story/money/business/2013/10/27/medical-device-tax-repeal/3189315/>.

for only a year, the actual impact of the tax and the possibility of repeal still remain in question.¹⁶⁹

V. REPEAL OR REVISION OF THE MDET

Although it is unlikely that the MDET is the sole cause of medical companies' decisions to lay off employees or shift production overseas, or that the tax will kill the American medical device industry, medical device manufacturers and lobbyists have good reason to continue urging repeal. This Part first argues that the MDET is an unwise tax and economic policy that should never have been implemented and should now be repealed for three reasons. First, and most importantly, the reasoning behind inclusion of the MDET as a revenue generator for Obamacare is based on flawed assumptions that were not thoroughly investigated. Congress and the President failed to comprehensively analyze the expected increased revenue device manufacturers would receive from additional insured individuals. In fact, there is no evidence that manufacturers will receive much, if any, benefit. Second, the nature of excise taxes does not fit with the complexity of the medical device industry's supply chain and leads to unnecessary and extremely burdensome administrative costs that Congress has failed to consider sufficiently. Finally, the tax does not comport with sound economic policy and serves to discourage the type of job creation and innovation the Obama administration has been pushing for.

But because total repeal seems doubtful in the near future, this Part concludes by providing an alternative to complete repeal. Such an alternative would focus on removing some of the most burdensome portions of the MDET by (1) exempting start-ups from the tax for a certain period of time in order to encourage small start-ups to continue investing in research and development of innovative medical

169. Some medical device companies' stock prices have continued to rise in 2013 despite the start of the MDET, but it is unclear whether this trend will continue. *See, e.g.*, Russ Britt, *Despite Bipartisan Howls, Medical-Device Tax Persists*, MARKETWATCH (Jan. 22, 2014, 9:32 AM), <http://www.marketwatch.com/story/the-obamacare-tax-that-nobody-wants-2014-01-22?pagenumber=1>. A survey by Emergo Group, a leading medical device consulting company, revealed that the MDET did not have quite as negative an impact as expected. EMERGO GRP., GLOBAL MEDICAL DEVICE INDUSTRY OUTLOOK FOR 2014, at 18–19 (2014) (In 2013, 53% of firms surveyed predicted a “somewhat negative” or “very negative” impact and 27% expected “no impact”; in 2014, after one year of the tax, only 45% of the same managers reported that the MDET actually had a “somewhat negative” or “very negative” impact, and 34% said it had “no impact.” Fifty percent of respondents said they made no significant changes in response to the MDET.). A study by AdvaMed shows a bleaker picture, reporting that as a result of the MDET, 30.6% of respondents reduced R&D, almost 10% relocated or expanded manufacturing abroad rather than in the United States, and 75% reported other negative impacts such as deferring or cancelling capital investments, reducing investment in start-ups, or reducing or deferring increases in employee compensation. The study extrapolates that the total job impact was approximately 33,000; however, these results were based on a survey of just thirty-eight companies. ADVAMED, IMPACT OF THE MEDICAL DEVICE EXCISE TAX (2014), *available at* <http://advamed.org/res.download/417>; Press Release, AdvaMed, *New Survey Reveals Real World Impact of Medical Device Tax* (Feb. 18, 2014), *available at* <http://advamed.org/news/89/new-survey-reveals-real-world-impact-of-medical-device-tax>.

devices; (2) exempting otherwise taxable devices (such as product samples, demonstration products, and evaluation products) when they are not used in a taxable manner; (3) adopting the IRS's interim guidance regarding convenience kits and constructive sales pricing; and (4) revising the tax rate after the first couple years of the tax's existence to more accurately reflect the increase in revenue medical device manufacturers of various device categories receive as a result of the increased number of insured Americans.

A. An Unfair Burden Based on Flawed Assumptions

When deciding to impose a tax or fee on medical device manufacturers, Congress reasoned that these manufacturers would benefit from an increased customer base due to the sweeping coverage of Obamacare.¹⁷⁰ However, no studies were ever conducted to analyze whether this increased coverage would actually increase manufacturers' revenue, and if so, by how much.¹⁷¹ Congress appears to have just decided upon a revenue amount that it needed to reach, and the MDET was part of the "revenue grab."¹⁷²

According to most medical device manufacturers, the belief that the PPACA will increase medical device sales due to an increased customer base is misplaced because the newly insured individuals generally are not those who require most medical devices subject to the MDET.¹⁷³ As Cook Medical Chairman Steve Ferguson stated:

[W]hen you look at the basic population that [Congress] wanted [the PPACA] to cover, those are not people who use our products. They're not people who have GI problems, because almost all of the medical problems are age-related except those that occur in major traffic accidents or those other types of issues. . . . [E]ven if you look at that younger patient that may have picked up insurance under ObamaCare, if they're in a car accident and they're rushed via ambulance to the

170. See *supra* note 126 and accompanying text.

171. See Letter from 800 groups, *supra* note 97; NELSON, *supra* note 110. A review of the congressional record and committee reports indicates that no financial studies were done to assess the benefit medical device manufacturers might receive from the increased number of insured individuals. Although such an economic analysis could lead to highly diverging results depending on the methods used, some attempt to correlate revenue to medical device manufacturers with the projected number of newly insured individuals ought to have been made.

172. See Letter from 800 groups, *supra* note 97; NELSON, *supra* note 110

173. See Letter from 800 groups, *supra* note 97; see also MATT DOLAN, ROTH CAPITAL PARTNERS, FULL REPORT: INNOVATION 101—TECHNOLOGY & INNOVATION IN THE MEDICAL DEVICE INDUSTRY 4–5 (2012), available at http://www.roth.com/files/marketing/email_blasts/Roth%20Capital%20CONNECT.pdf (finding 88% of uninsured patients are under fifty-five years old, while only 2% are over sixty-five years old: in stark contrast, the average age of patients receiving five common medical devices, such as cardiac stents, knee replacements, and heart valves, ranges from sixty to over seventy-five).

local hospital, they're going to be covered regardless of whether they have insurance or not.¹⁷⁴

This belief has been echoed by much of the industry. The December 2012 AdvaMed study on the impact of the MDET revealed that, based on the eighty-one companies surveyed, 80% expect less than a 1% increase in revenue from new customers and 90% expect less than a 2% increase.¹⁷⁵ Although some proponents of the tax believe certain sectors of the medical device manufacturing industry may benefit from the number of newly insured individuals because many more people will opt to have elective surgeries, such as hip or knee replacements,¹⁷⁶ this argument is pure conjecture—the same type of conjecture relied upon by the drafters of the MDET.

Some of the only hard evidence available on the PPACA's potential impact on medical device sales comes from Massachusetts, a state that enacted a healthcare law similar to the PPACA in 2006.¹⁷⁷ In Massachusetts, there has been no evidence that medical device manufacturers have realized any increase in sales as a result of expanded healthcare coverage,¹⁷⁸ and some sources indicate that Massachusetts manufacturers actually saw a decrease in growth compared to the rest of the United States.¹⁷⁹ Such evidence indicates that the whole reasoning behind imposing the MDET to help cover the costs of the PPACA is likely misplaced. If the medical device industry will receive very minimal, if any, increases in revenue due to the increased number of insured Americans, then burdening the industry with over \$2 billion annually in MDET becomes a punitive measure that not only punishes industry participants, but also hurts the entire U.S. economy. As NuVasive CEO Alex Lukianov put it, "The goal of Health Care reform is to ensure that the best medical solutions are applied in the most efficient and cost-effective ways, not to penalize the companies that contribute to better healthcare & healthier more productive lives."¹⁸⁰ This is precisely what the MDET does—it places a tax on one of the industries that could help decrease healthcare costs through innovation.

B. An Inappropriate Tax for a Complicated Industry

The cost of paying the MDET is not the only burden placed on device manufacturers. The actual cost of the MDET is significantly greater than 2.3% of the gross sales of devices due to very high administrative and compliance costs. Even the IRS recognizes that the industry will face compliance costs¹⁸¹—as is the case with any new tax—but imposing an excise tax on such a complicated supply

174. NELSON, *supra* note 110.

175. ADVAMED SURVEY, Dec. 2012, *supra* note 82.

176. *See* Groppe, *supra* note 168.

177. Act of Apr. 12, 2006, ch. 58, 2006 Mass. Acts.

178. *See* Letter from 800 groups, *supra* note 97.

179. DOLAN, *supra* note 173, at 6–8 ("8 out of 9 companies experienced negative or neutral comparative growth rates in Massachusetts as compared to the rest of the US following the implementation of universal health care in that state.").

180. Lukianov statement, *supra* note 118.

181. T.D. 9604, 2012-52 I.R.B. 740.

chain poses more unique problems and additional burdens for manufacturers and importers than a characteristic excise tax. The calculation of the sales price is much more complicated for the MDET than for the typical excise tax because the industry is newer, less integrated, and comprised of very complex distribution channels.¹⁸² Even after several months of paying the tax, companies noted they were still struggling to understand exactly how to calculate the sales price and were likely overpaying.¹⁸³ The fact that only interim guidance, and not final regulations, has been released addressing how to calculate sales price further indicates that even experts find it difficult to create a workable taxing scheme that fairly and accurately taxes the correct items, at the correct price, in such a complex industry.

The complexity of complying with the tax places an even greater burden on smaller firms that do not have the money to hire experts to decipher the tax and therefore must divert personnel from productive jobs to compliance positions.¹⁸⁴ Not only will small companies and start-ups feel the financial burden of the tax more than the medical manufacturing giants, but they will also struggle more to implement and understand the tax. In sum, the administrative burdens of the tax, especially for smaller firms, can greatly increase the cost of the tax to the economy. When the costs of compliance make up a substantial portion of a tax's total cost, it is inherently inefficient.

C. Failure to Comport With Current Ideas of Sound Economic Policy

Furthermore, in a struggling U.S. economy where the focus has been on domestic job creation,¹⁸⁵ imposing a new tax burden on one of the leading job-creating industries goes against intelligent economic policy. A 2011 study by McKinsey Global Institute (MGI) found that in order to revive U.S. job creation, progress must be made in four dimensions: (1) development of the U.S. workforce's skills to match what employers are looking for; (2) expansion of U.S. workers' share of global economic growth by attracting foreign investment and spurring exports; (3) support of emerging industries and new business start-ups; and (4) speeding-up of regulatory decision making that hinders business expansion and new investment.¹⁸⁶ This same report notes that "[h]ealth care is pivotal, with the potential to create more than 5 million new jobs. . . . [Achieving the high-job-growth scenario] assumes that innovative approaches in primary care,

182. Kyle Pomerleau, *Obamacare Medical Device Tax Still Baffling Business*, TAX FOUND. TAX POL'Y BLOG (Mar. 20, 2013), <http://taxfoundation.org/blog/obamacare-medical-device-tax-still-baffling-business>.

183. *Id.*

184. *Id.*

185. Although the average unemployment rate has been steadily decreasing from a high of 10% in October 2009 to 7.8% in November 2012, getting Americans back to work remains a priority. *Labor Force Statistics from the Current Population Survey*, U.S. BUREAU OF LAB. STAT., <http://data.bls.gov/timeseries/LNS14000000>.

186. JAMES MANYIKA, SUSAN LUND, BYRON AUGUSTE, LENNY MENDONCA, TIM WELSH & SREENIVAS RAMASWAMY, MCKINSEY GLOBAL INST., AN ECONOMY THAT WORKS: JOB CREATION AND AMERICA'S FUTURE 7-8 (2011).

chronic disease management, and geriatric care would create new jobs.”¹⁸⁷ Unfortunately, the MDET does exactly the opposite of MGI’s recommendations for achieving a high-job-growth scenario. The MDET deters new medical device manufacturing start-ups by imposing on them a tax on gross revenues regardless of profits. In an industry that already struggles due to the FDA and CMS’s slow regulatory decision making,¹⁸⁸ the MDET adds yet another barrier to entry into the industry. Finally, it forces medical device manufacturers to look abroad to more business-friendly countries for expansion opportunities¹⁸⁹—exactly the opposite of what should be happening.

Put simply, imposition of the MDET requires one of America’s strongest job-creating industries to cut spending on jobs, new investment, and R&D in order to pay for a health care system from which it will receive few, if any, added benefits. For these reasons, Congress would be wise to repeal this tax before companies cut more jobs, decrease their investment in innovation, and spend more money and valuable time investing in compliance measures.

D. Ways to Decrease the Burden Without Complete Repeal

Since complete repeal of the MDET appears unlikely at this point, this subpart briefly examines a few small changes that could mitigate the harmful effects of the MDET. The following recommendations are not the only options for changing the tax, and such changes would not combat all of the negative effects of the MDET like a complete repeal, but they would be a good start. The changes would undoubtedly decrease the revenue generated by the tax, but they would not wipe out all revenue generated by this sector and would represent a compromise between the two sides of the debate over the MDET. The difference in revenue could be made up by tweaking some of the other provisions of the PPACA or by closing unrelated tax loopholes through comprehensive tax reform similar to Representative Maffei’s Medical Device Tax Elimination Act proposed in March.¹⁹⁰ This subpart does not seek to comprehensively lay out all of the intricacies of each proposal—it is merely included to highlight some possible areas for compromise to spur further discussion.

First, in order to encourage small start-up medical technology companies with innovative ideas to invest in R&D, the MDET could contain an exemption for start-up companies for a certain time period or until they become profitable. Since start-up companies account for much of the new innovation in the industry and typically produce very low profit margins or operate at a loss, imposing a new tax that eats up 2.3% of their profit margins makes no sense. Such a measure will deter start-ups from investing in new technology and will hurt innovation and job creation. The MDET could be amended to exempt start-up companies from the tax for a specified number of years—perhaps seven to ten, the average product

187. *Id.* at 4.

188. *See supra* notes 99–102 and accompanying text.

189. *See, e.g.*, Alex Lukianov, *Medical Devices Tax Hinders Innovation*, U-T SAN DIEGO (June 6, 2012, 6:00 PM), <http://www.utsandiego.com/news/2012/jun/06/medical-devices-tax-hinders-innovation/?page=1#article>.

190. *See supra* note 161.

development life cycle¹⁹¹—or until they reach a preset level of profitability, whichever happens first.

Such an exemption would also be in line with the legislature's intent. When originally imposed, the MDET was designed as an annual fee that would primarily hit the largest companies.¹⁹² By exempting start-ups from the MDET, Congress would be returning to the original rationale behind the MDET and would avoid discouraging further start-up companies with innovative ideas from entering the industry in the United States.

Second, certain uses of otherwise taxable medical devices should qualify them for an exemption from the MDET. Such exemptions should include products that are used for testing, development, and evaluation, as well as those that function as samples, demonstration devices, donations, or replacements provided to customers free of charge. These uses do not confer any direct benefit to the manufacturer.¹⁹³ Free samples, demonstration products, testing and development products, and donations further innovation and affordable access to health care by providing the means to instruct health care providers and patients in the correct use of the devices or by furthering important and necessary testing of devices. Although it is administratively simpler to apply the excise tax regardless of use, such application deters manufacturers from engaging in these very important and commonplace activities.

Several industry groups and manufacturers requested these exemptions in comment letters to the IRS after release of the proposed regulations and requested comments.¹⁹⁴ However, the IRS and Treasury Department expressly denied carving out most of these exceptions for uses¹⁹⁵ in the final regulations, stating, “[I]t is necessary to have consistent rules for all manufacturers excise taxes.”¹⁹⁶ The problem with this reasoning is that the MDET is not like other manufacturers' excise taxes. The majority of manufacturers' excise taxes are imposed on commodity items, such as cigarettes, alcohol, and gasoline, and serve to deter the purchase of such items.¹⁹⁷ Medical devices do not resemble these commodity items and thus warrant distinct treatment. Although there are some instances in which ease and consistency in administration override other considerations, this is not one of them. These uses are important for the development, testing, and training of patients and healthcare professionals in proper use of new medical devices; therefore, Congress should not discourage such uses by subjecting the devices to the MDET.

Third, the IRS should take the relatively uncontroversial move of adopting as final the interim guidance it issued regarding convenience kits and constructive

191. *See supra* note 98 and accompanying text.

192. *See supra* notes 24–30 and accompanying text.

193. AdvaMed letter (May 3, 2012), *supra* note 52.

194. T.D. 9604, 2012-52 I.R.B. 738; *see, e.g.*, AdvaMed letter (May 3, 2012), *supra* note 52.

195. The IRS did adopt, on an interim basis, a use exception for donations to eligible donees. I.R.S. Notice 2012-77, *supra* note 38, § 4(c), at 784.

196. T.D. 9604, 2012-52 I.R.B. 738.

197. *E.g.*, ERNST & YOUNG, EFFECT OF THE MEDICAL DEVICE EXCISE TAX ON THE FEDERAL TAX LIABILITY OF THE MEDICAL DEVICE INDUSTRY 1 (2012).

sales pricing. The interim guidance solves the problems of potential improper or double taxation of devices included in kits by excluding convenience kits from the definition of devices and instead imposing the tax at the component device level. This interim rule was a smart choice by the IRS and should be finalized in regulations. The interim guidance on calculating the constructive sales price based on varied distribution chains should also be adopted as final, adding any necessary revisions, based on industry participants' comments and recommendations. This rule provides medical device manufacturers flexibility in complying with the MDET and takes into account the varied distribution chains that exist in the medical device industry. Thus, it would be appropriate for the IRS to incorporate the interim guidance in final regulations.

Finally, section 4191 should contain a provision subjecting the MDET to adjustments as more information about its true impact becomes available. For example, if studies show that certain manufacturers (such as those who produce artificial hips and knees) receive a large ramp up in income as a result of the newly insured individuals covered under Obamacare who have chosen to undergo elective procedures, then perhaps the rate applied to certain devices should increase. Conversely, for those devices where it is clear that there has been little or no increase in sales as a result of additional insured people (such as defibrillators and stents), the rate should decrease to one that more accurately reflects the benefit such manufacturers receive. Although such an analysis will be difficult and undoubtedly subject to much scrutiny, it could help to achieve a fairer result.

CONCLUSION

As AdvaMed CEO Stephen Ubl stated, "The device tax no longer has anything to do with the debate over the Affordable Care Act; the issue now is whether our tax system is going to support or undermine America's ability to compete in the global economy."¹⁹⁸ The MDET is a tax provision that goes against the primary economic goal of keeping and creating more clean, high-paying jobs in manufacturing.¹⁹⁹ It punishes medical device manufacturers by forcing them to pay a tax at the top level, placing upon them one of the highest tax rates faced by any industry in the world.²⁰⁰ Since the tax applies at the top level to gross income, the true impact is actually an increase of 29% to the industry's effective tax rate.²⁰¹

Congress included the MDET in the PPACA to generate revenue, hypothesizing that medical device manufacturers would experience significant revenue gains from the greater number of insured Americans, but without ever studying just how much benefit manufacturers would actually receive. Based on company surveys, the experience of Massachusetts, and logic as to who purchases such devices, that increase appears to be slight, if any. Furthermore, the complicated nature of the distribution channels and types of devices in the industry make an excise tax an overly burdensome and costly tax to implement. These compliance costs are an

198. *Device Levy Hikes Medical Technology Tax Bill Dramatically*, MEDTECH (Nov. 14, 2012), <https://www.medtech.org/news/global.aspx?recid=3746>.

199. *See, e.g., id.*

200. ADVAMED STUDY, Sept. 2011, *supra* note 108, at 8 (citation omitted).

201. ERNST & YOUNG, *supra* note 197.

overall loss to society and ought to have been more thoroughly considered by Congress before enacting the MDET. Therefore, Congress needs to revisit this provision and either repeal the MDET or, at a minimum, revise some of the most onerous parts, possibly by exempting start-ups, exempting certain uses, adopting the interim guidance on convenience kits and constructive pricing as final, and allowing for revision of the tax rate based on data gathered during the tax's first few years of operation.

As it stands now, the MDET will continue to cost the United States high-paying manufacturing jobs and will slowly lead to decreased innovation in the medical device industry. Congress should designate the MDET as a priority in its 2014 discussions on tax reform in order to keep the U.S. medical device industry flourishing.