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No Longer Left to Their Own Devices: Evaluating the Non-Traditional Medical Device Excise Tax

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Cover Page Footnote

* University of Notre Dame Law School, J.D. Candidate, May 2015. I would like to thank my faculty advisor, Professor Michael Kirsch, for his invaluable advice and guidance.

NOTES

NO LONGER LEFT TO THEIR OWN DEVICES: EVALUATING THE NON-TRADITIONAL MEDICAL DEVICE EXCISE TAX

KENSINGTON A. WOLGAMOTT*

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INTRODUCTION

When the United States federal government entered a shutdown in the fall of 2013, the budget crisis took center stage in the political debate. The Affordable Care Act (“ACA”) was one of the most contentious issues on the agenda, and among the bargaining chips in the discussion was the disputed issue of the medical device excise tax (“MDET”). The excise tax, imposed upon the sale of certain medical devices, has raised quite a bit of bipartisan opposition and has been up for repeal or reform over a dozen times to date. The increasing attention the tax has received since its inception, and especially since it became a part of the fiscal fight, has raised concerns from numerous sources over both the tax itself and its structure. The medical device industry is adamant that the MDET will have crippling effects on the

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industry, by forcing firms to cut jobs, spending on innovation, and in some cases, operations all together. The federal government, on the other hand, argues the MDET is a fair method of taxation, as the medical device industry will receive a windfall from the increase in revenue when the ACA requires millions of uninsured Americans to start buying health insurance.

This Note will present the issues raised by both sides of the debate, but will also posit that there are considerations missing from the discussion that, while indeterminable in their effects right now, must be present in the conversation in the future to determine if this use of an excise tax is an efficient and effective means of taxation. Most importantly, those discussions will be significantly affected by where the economic burden of the tax lands. In other words, when deciding the fate of the tax in the future, it will be crucial to know who is “paying” for the tax—the manufacturers, or the various consumers? However, until there is more of a consensus on the effects of the tax, none of the arguments presented by either side can be properly evaluated.

This Note starts in Part I by first defining what an excise tax is, and then moving into the more particular details of the MDET itself, including the legislation that enacted it, what qualifies for the tax (and what does not), and the purpose of the tax. Part I will close with a discussion of the relevance of the tax in the current political debate, before moving into a more in-depth discussion of the tax structure in Part II. Part II begins with a focus on the traditional rationales behind the excise tax structure and why the MDET does not fit these molds. It will then present the specific arguments for and against the MDET, as advocated by the medical device industry and the U.S. federal government. Finally, in Part III, this Note will take a forward-looking approach to the MDET by discussing the factors that will be important to include in later discussions about the future of the MDET.

I. BACKGROUND INFORMATION

A. *Excise Tax*

An excise tax is defined as a “direct and fixed charge placed on [specific] goods.”¹ It is typically levied against the manufacturer or producer for sale of the select product or good; because it is narrowly based, it is often described as a “selective sales tax.”² Excise taxes are applied on either a per unit or ad valorem basis;³ gasoline, alcohol and cigarette excise taxes, which are commonly associated with the classic structure of an excise tax, are applied on a per-unit basis.⁴ The excise tax structure is utilized by both federal and state governments, and is typically a large source of revenue for both.⁵

1. BLACK'S LAW DICTIONARY 417 (9th ed. 2009).

2. J. Fred Giertz, *Excise Taxes*, in THE ENCYCLOPEDIA OF TAXATION AND TAX POLICY 125, 125 (Joseph J. Cordes et al. eds., 2005).

3. *Id.*

4. *Id.*

5. *Id.* at 126.

Taxes, regardless of their form, are structured in a way designed to raise revenue, but often are justified in their use by specific reasons or rationales. Excise taxes are no different, and can be explained by a variety of traditional arguments. These will be explained in greater detail later in this Note,⁶ but for purposes of framing the tax, common justifications for the use of an excise tax are introduced here. The excise tax structure is often employed as an easily administered form with which to raise revenue, as the tax is applied to a narrowly-defined product base, usually in a structured marketplace.⁷ Traditionally, excise taxes have been described as a form of indirect taxation, which by definition means that the tax is collected from the manufacturer or producer of the good, but the burden, or economic incidence, of the tax is expected to be shifted to the consumer.⁸ For example, the ultimate economic burden of paying for an excise tax on cigarettes is passed on from the manufacturer to the consumer through an increase in the final sale price of the cigarettes. Unlike a sales tax, which appears as a separate line item on a consumer receipt, excise taxes are applied directly to the manufacturer as a percentage of their sales price, but are often passed onto the consumer by an increase in the final sale price of the good, making the tax less recognizable by the final consumer and thus more appealing to government officials who are generally opposed to raising taxes.⁹ Because of the traditional ease of shifting the economic burden of the tax to the final consumer, excise taxes are also very commonly known for their application when the government is seeking to change behavior.¹⁰ From the first excise tax in the United States, which was levied against whiskey distributors in 1791, to the current tax on cigarettes, alcohol, and airline travel, selective excise taxes have traditionally been applied to goods or services that are considered harmful or undesirable in an attempt to discourage consumption or punish the consumer; in this regard they are often referred to as “sin taxes.”¹¹ The one exception was the selective excise tax applied to crude oil in 1979—the Crude Oil Windfall Profit Tax Act of 1979. This excise tax was justified by the politicians who enacted it by using a windfall argument. In other words, it was stated that the oil companies ought to be taxed for their expected increases in revenue

6. *Infra* Part II.A.

7. See Giertz, *supra* note 2, at 125.

8. John H. Bowman, *Excise Taxation*, in HANDBOOK ON TAXATION 677, 677 (W. Bartley Hildreth & James A. Richardson eds., 1999); see also Giertz, *supra* note 2, at 125.

9. *How Sales and Excise Taxes Work*, INST. ON TAX'N AND ECON. POL'Y, at 2 (Aug. 2011); see also Jorge Martinez-Vazquez & Robert M. McNab, *Tax Systems in Transition Economics*, in HANDBOOK ON TAXATION 911, 922 (W. Bartley Hildreth & James A. Richardson eds., 1999) (stating that “[i]ndirect taxes are typically much easier to legislate in an acceptable format and also much easier to enforce than direct taxes”).

10. Richard Williams & Katelyn Christ, *Taxing Sins: Are Excise Taxes Efficient?*, 52 MERCATUS ON POLICY 1, 2 (2009).

11. Brenda Yelvington, *Excise Taxes in Historical Perspective*, in TAXING CHOICE: THE PREDATORY POLITICS OF FISCAL DISCRIMINATION 31, 52–53 (William F. Shughart II ed., 1997). Excise taxes have a long-standing historical tradition of being used to change or influence behavior in the United States.

generated by government decontrol of domestic oil prices.¹² The major difference between the windfall profit tax and the others was upon whom the government seemed to want to place the economic burden of the tax. This tension, even in the two rationales commonly associated with excise taxes, foreshadows the tension that will be identified in the MDET. While most excise taxes are typically explained by the traditional rationale of an indirect tax (i.e. one where the economic burden is expected to be passed to the consumer through an increase in the final price of the good), this is not true of the windfall profits excise tax,¹³ and may not be true of the MDET either. Rather, it remains a key tension in the rationale underlying the use of a selective excise tax, and one that will be crucial in the discussion of the MDET—who will ultimately “pay” for the tax?¹⁴ The answer to this question will help both in determining the future of the tax, and in substantiating the underlying rationales confirming the choice of an excise tax structure.

B. *The Medical Device Excise Tax*

Following the enactment of the Patient Protection and Affordable Care Act in January 2010 (“PPACA”),¹⁵ the Health Care and Reconciliation Act of 2010 (“HCERA”) established a 2.3 percent tax on all qualifying medical devices¹⁶ that was one of many additional revenue-raising provisions to finance the new health care reform.¹⁷ Pursuant to the new section 1405 of the HCERA, entitled “Excise Tax on Medical Device Manufacturers,”¹⁸ the Internal Revenue Code was amended to add Section 4191, which imposed a 2.3 percent excise tax on the sale of

12. *Id.* at 51. The windfall-profits tax was explained in a report to Congress in the following way: “The revenues resulting from these higher prices [due to deregulation of prices] would provide income to oil producers far in excess of what most of them originally anticipated. . . . Thus, the committee believes that the additional revenues received by oil producers . . . are an appropriate object of taxation.” *Id.*

13. The exception is the windfall-profits tax on oil, which was arguably meant to stick with the domestic manufacturers/producers of oil.

14. Even defining the actors is difficult—passing the economic burden of the tax along and away from the manufacturers only really tells part of the story. Multiple factors and numerous players can impact the outcome; for example, the slope of the demand curves may vary drastically depending on whether the party is a patient, an insurance company, or even a hospital group.

15. Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119 (2010).

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

17. The HCERA made important changes to the PPACA, but both laws were signed. Often, references to both the PPACA and HCERA are necessary, as is the case in the remainder of this Note. Thus, for the remainder of this Note, references will be made to the “Affordable Care Act” (“ACA”), which is often used as short hand or even as an unofficial title for the health care reform from the combined PPACA and HCERA. Beyond this section, the health care reform will be referred to as the ACA. See John McDonough, *ACA vs. ObamaCare: What’s In a Name?*, BOSTON.COM (Jan. 14, 2012, 11:54 AM), http://www.boston.com/lifestyle/health/health_stew/2012/01/aca_vs_obamacare_whats_in_a_name.html.

18. § 1405, 124 Stat. at 1064.

certain medical devices, to be collected from the manufacturer or importer of the device.¹⁹ The tax applies to the wholesale price of any taxable medical device when it is first sold, leased, rented, or used by the manufacturer or importer.²⁰ The MDET attaches to any sale made after December 31, 2012, with all penalties and reporting rules governed by the Internal Revenue Code (“IRS”).²¹

1. Definition: What Qualifies and What Does Not

Section 4191 of the Internal Revenue Code, although brief, imposes the MDET’s regulations as applied to the sale of certain medical devices. Based on the language of the statute, the MDET is “imposed on the sale of any taxable medical device by the manufacturer, producer, or importer” at a rate of 2.3 percent of the price for which the device is sold.²² The Code goes on to further define a “taxable medical device” as any “device,” defined in §201(h) of the Federal Food, Drug, and Cosmetic Act (“FFDCA”),²³ intended for humans.²⁴ Finally, there is a list of explicit exemptions from the taxable devices, which includes “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.”²⁵ The text is simple and uncomplicated, but the application is not; in response to many questions and comments, the Department of the Treasury and the IRS have issued final regulations seeking to explain the scope of the medical device tax, both in terms of its application and exclusions.²⁶

The details in application of the tax are still being reviewed in select grey areas, but it is important for this Note’s purpose to understand the general application of the tax, because some of the arguments raised in opposition to the MDET are unfortunately based on misunderstandings of its use. For example, one fear expressed by the general public and medical device lobbying firms alike is the fear of driving manufacturing and production of medical devices overseas to avoid the tax.²⁷ This fear, however, is completely unfounded because

19. I.R.C. § 4191 (West Supp. 2010).

20. *Implementing the Medical Device Excise Tax*, ERNST & YOUNG LLP (Nov. 21, 2012), [http://www.ey.com/Publication/vwLUAssets/Technical_Line_Implementing_the_medical_device_excise_tax/\\$FILE/TechnicalLine_BB2439_MedDeviceExcise_Tax_21November2012.pdf](http://www.ey.com/Publication/vwLUAssets/Technical_Line_Implementing_the_medical_device_excise_tax/$FILE/TechnicalLine_BB2439_MedDeviceExcise_Tax_21November2012.pdf).

21. *Medical Device Excise Tax: Frequently Asked Questions*, INTERNAL REVENUE SERVICE, <http://www.irs.gov/uac/Medical-Device-Excise-Tax:Frequently-Asked-Questions> (last updated Feb. 3, 2014).

22. I.R.C. § 4191(a).

23. 21 U.S.C. § 321 (2006).

24. I.R.C. § 4191.

25. § 4191(b)(2).

26. JANE G. GRAVELLE & SEAN LOWRY, CONG. RESEARCH SERV., R43342, *THE MEDICAL DEVICE EXCISE TAX: ECONOMIC ANALYSIS* (2013).

27. DIANA FURCHTGOTT-ROTH & HAROLD FURCHTGOTT-ROTH, ADVANCED MED. TECH. ASSOC., *EMPLOYMENT EFFECTS OF THE NEW EXCISE TAX ON THE MEDICAL DEVICE INDUSTRY 1, 7–9* (2011). The study sponsored by Advanced Medical Technology Association (“AdvaMed”), noted that, while it was impossible to predict the exact impact of the medi-

the text of the statute states that the MDET will be imposed on the “sale of any medical device by the manufacturer, producer, or importer of the device.”²⁸ In addition, devices produced in the United States for exports are exempt from the tax, thus dispelling any truth to the fear that the MDET will drive manufacturers overseas.²⁹

The guidance provided by both the IRS and Treasury Department on the application of I.R.C. § 4191 may be broken down into two broad areas of expressed concern regarding the implementation of the MDET. The first may be labeled as inquiries about the type of good to which the MDET attaches. As stated above, the 2.3 percent excise tax applies to the “sale of any taxable medical device,”³⁰ which is then defined further in I.R.C. section 4191(b).³¹ But the regulations do not list all applicable medical devices to which the tax applies; instead, they link the definition of “taxable medical device” to section 201(h) of the FFDCa with the caveat that the device must be intended for human use.³² This qualification is included because section 201(h) of the FFDCa provides generally that:

[T]he term “device” . . . means an instrument, apparatus . . . [that is] intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or intended to affect the structure or any function of the body of man . . . and which does not achieve its primary intended purposes through chemical action within or on the body of man . . . and which is not dependent upon being

cal device excise tax, “some manufacturing of medical devices may shift offshore as a result of the new excise tax to minimize losses.” *Id.* at 7. Then, without citing any additional sources other than their own study, it was estimated that they could make “a conservative assumption that 10% of manufacturing activities [will move] offshore.” *Id.* at 9.

28. I.R.C. § 4191(a); see also Christopher Flavelle, *How Much Will the Medical Device Tax Hurt?*, BLOOMBERG BUSINESSWEEK (Mar. 22, 2012), <http://www.businessweek.com/articles/2012-03-22/how-much-will-the-medical-device-tax-hurt>. This was just one of numerous articles that pointed out the overstatements or incorrect assumptions made by medical device firms and lobbyists, noting that the statute creates no incentive to move production overseas because the tax applies to all covered products sold in the U.S., regardless of origin of manufacture. In particular, the articles criticized a 2011 study by AdvaMed, a trade association representing over 80 medical technology firms in the United States, which has been continuously cited for numerous misstatements of tax, often used by others in the medical device industry. See FURCHTGOTT-ROTH & FURCHTGOTT-ROTH, *supra* note 27. The methodology and the corresponding results have been repeatedly questioned and criticized for overstating potential results of the MDET, in addition to making false claims with little to no justification behind such outcomes. See Paul N. Van de Water, *Excise Tax on Medical Devices Should Not be Repealed Industry Lobbyists Distort Tax’s Impact*, CTR. ON BUDGET AND POLICY PRIORITIES, <http://www.cbpp.org/cms/?fa=view&id=3684> (last updated Oct. 2, 2013) (noting that the tax will not cause manufacturers to shift overseas because “[t]he tax applies equally to imported and domestically produced devices,” also noting that the AdvaMed study is “not credible”).

29. See Van de Water, *supra* note 28 (competitiveness of U.S. medical technology firms will not be reduced by the tax, as the MDET only applies to the sale of devices in the United States, not the origin of production).

30. I.R.C. § 4191(a).

31. § 4191(b).

32. Taxable Medical Devices, 77 Fed. Reg. 72925 (Dec. 7, 2012) (to be codified at 26 C.F.R. pt. 48).

metabolized for the achievement of its primary intended purposes.³³

The text of I.R.C. section 4191 also includes a non-exclusive list of exemptions, including eyeglasses, contact lenses, hearing aids, and “any other medical device determined by the Secretary to be of a type that is generally purchased by the general public at retail for individual use,”³⁴ which is otherwise known as the “retail exemption.”³⁵ According to the final regulations, those devices that qualify under the retail exemption may be determined by one of several options; the final regulations include a safe harbor provision that identifies certain categories of medical devices that the IRS and the Treasury Department have determined fall within the exemption.³⁶ In addition, the final regulations have incorporated a facts and circumstances approach to evaluating whether a device is considered to be a type generally purchased by the public at retail for individual use, often known colloquially as items available for sale “over the counter.”³⁷ It follows that such an instrument qualifies as exempt if “(i) the device is regularly available for purchase and use by individual consumers who are not medical professionals, and (ii) the device’s design demonstrates that it is not primarily intended for use in a medical institution or office, or by medical professionals.”³⁸

33. 21 U.S.C. § 321 (2006) (emphasis added).

34. I.R.C. § 4191.

35. Taxable Medical Devices, 77 Fed. Reg. at 72927.

36. *Id.* The safe harbor includes items that qualify as “over the counter” products, as identified by the following three sources: *OTC—Over the Counter*, U.S. FOOD AND DRUG ADMIN., <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfIVD/Search.cfm> (last updated Jan. 20, 2014) (any devices listed in this database by the FDA qualify for the safe harbor from the MDET); *Product Classification*, U.S. FOOD AND DRUG ADMIN., <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm> (last updated Jan. 20, 2014) (qualifying devices include devices described as “OTC” or “over the counter” devices in the relevant FDA classification regulation heading); *Establishment Registration & Device Listing*, U.S. FOOD AND DRUG ADMIN., <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cf1/rl.cfm> (last updated Jan. 20, 2014) (any devices described as “OTC” or “over the counter” in this database, by product code name, the FDA’s classification regulation heading, or the classification name field in the FDA’s device registration and listing database).

37. Taxable Medical Devices, 77 Fed. Reg. at 72927.

38. *Id.* The proposed regulations, adopted as final, additionally set out a list of both positive and negative factors to be considered when determining whether a device qualifies as exempt from the MDET. The positive factors, which help determine if the device is regularly available for purchase and use by individuals posits a nonexclusive list of factors, which includes, but is not limited to the following:

(i) whether consumers who are not medical professionals can purchase the device through retail businesses that also sell items other than medical devices, including drug stores, supermarkets, and similar vendors; (ii) whether consumers who are not medical professionals can safely and effectively use the device for its intended medical purpose with minimal or no training from a medical professional; and (iii) whether the device is classified by the FDA under Subpart D of 21 CFR part.

Id. Negative factors to consider in determining if the design of a device demonstrates its primary intended use is in a medical institution or as by a medical professional, and thus not intended for individual consumer purchase, include, but again are not limited to:

(i) whether the device generally must be implanted, inserted, operated, or otherwise administered by a medical professional; (ii) whether the cost to acquire,

The second area broadly focused on by both the IRS and the Treasury Department, in their guidance on the application of the MDET, addresses the entity responsible for paying the MDET for a qualifying device. According to I.R.C. section 4191, the MDET is imposed on the “sale of any taxable medical device by the *manufacturer, producer, or importer* [at] a tax equal to 2.3 percent of the price for which so sold.”³⁹ A “manufacturer” is generally defined as “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.”⁴⁰ Anyone importing a taxable good into the United States is also liable for payment of the MDET, as an “importer.”⁴¹ The sale and price of the taxable article has been a hotly debated topic since the tax’s first introduction. They are defined, for purposes of the statute, in the definition of a sale, thereafter described as “an agreement whereby the seller transfers the property (that is, the title or the substantial incidents of ownership) in goods to the buyer for a consideration called the price, which may consist of money, services, or other things.”⁴² Many commenters submitted requests related to sale and price, but the guidance provided has largely denied attempts to create a blanket rule on

maintain, and/or use the device requires a large initial investment and/or ongoing expenditure that is not affordable for the average consumer; (iii) whether the device is a Class III device under the FDA system of classification; (iv) whether the device is classified by the FDA under certain enumerated parts or subparts of 21 CFR; and (v) whether the device qualifies as durable medical equipment (DME), prosthetics, orthotics, and supplies (collectively, DMEPOS) for which payment is available exclusively on a rental basis under the Medicare Part B payment rules and is an “item requiring frequent and substantial servicing” as defined in 42 CFR 414.222 890 (Physical Medicine Devices).

Id. The final regulations clarify that not every one of these factors must be met in the course of a facts and circumstances test, and that additional factors may also be relevant.

39. I.R.C. § 4191(a) (emphasis added).

40. 26 C.F.R. § 48.0-2(a)(4)(i) (2000). In responding to many of the comments submitted to the IRS, the IRS and Treasury Department staff noted that one commenter had requested the final regulations of section 4191 include a presumption such that a manufacturer merely be defined as anyone who lists a device with the FDA. However, the final regulations refused to adopt such a definition, instead responding that longstanding rules defining the terms “manufacturer” and “importer” for chapter 32 purposes had been built over the years through a combination of statutory and regulatory provisions, published guidance, and case law. Taxable Medical Devices, 77 Fed. Reg. at 72930.

41. 26 C.F.R. § 48.0-2(a)(4)(i) (adding that “[i]f the nominal importer of a taxable article is not its beneficial owner (for example, the nominal importer is a customs broker engaged by the beneficial owner), the beneficial owner is the ‘importer’ of the article for purposes of chapter 32 and is liable for tax on his sale or use of the article in the United States”); see also I.R.C. § 4219 (which, along with the regulations thereunder, covers any circumstances under which sales by persons other than the manufacturer or importer are subject to the manufacturers excise tax); 26 C.F.R. § 48.0-2(a)(4)(ii) (explaining that someone other than the person who actually manufactured or produced the taxable article might be considered the manufacturer for purposes of the tax, such as “where a person manufactures or produces a taxable article for another person who furnishes materials under an agreement whereby the person who furnished the materials retains title thereto and to the finished article. . .”).

42. 26 C.F.R. § 48.0-2(a)(5).

price setting, either to the favor of buyers or manufacturers.⁴³ Thus, the result has been that guidance provided on who qualifies as a manufacturer (and an importer or producer) has been largely flushed out, while determinations of price and defining a sale remain topics of conversation and debate which the IRS and Treasury Department are still issuing assistance on.

Other important topics have been addressed by final regulations and interim guidance related to the application of the MDET. A few of the clarifications important to point out include the following: replacement parts for qualifying taxable devices will be subject to the tax, even if listed separately as distinct devices by the FDA;⁴⁴ the tax will attach in the case of a sale made on credit, regardless of whether or not the purchase price is actually collected;⁴⁵ but the “donation of a taxable medical device by the manufacturer of the device to an *eligible donee* will not constitute a taxable use.”⁴⁶

2. Purpose

The major justification offered for the medical device tax is its revenue, which will help to offset the cost of health care reform, as established by the ACA.⁴⁷ According to the Joint Committee on Taxation,

43. Taxable Medical Devices, 77 Fed. Reg. at 72930-31. Concerns over the final sale price of taxable devices permeated the comments received by the IRS on section 4191. In response, the IRS and Treasury Department noted their awareness of implementation issues the medical device industry was likely to face from the tax, but the IRS expressed their intention to “work with stakeholders on compliance-related issues, such as the determination of price.” *Id.* at 72930. Many commenters requested that the principles of Revenue Ruling 80-273 be extended to taxable medical devices, which states that “when a manufacturer or importer sells a taxable article directly to an unrelated end user at retail, the excise tax may be based on a sale price of seventy-five percent of the retail sale price, after any adjustments under section 4216(a), such as for containers, packing, and transportation charges.” *Id.* However, revenue rulings are meant to only apply to a specific set of circumstances, and even then are not binding on the IRS, which gave them reason enough to deny that the reasoning of the Revenue Ruling be extended to taxable medical devices. The guidance on the regulations also made clear that strict rules used to determine transfer pricing under section 428 could not be directly applied to determine the sales price of taxable medical devices. *Id.*

44. Taxable Medical Devices, 77 Fed. Reg. at 72932 (explaining that the tax will be applied to the actual amount paid, if any, on products under warranty and if not under warranty, replacement and new parts, which are listed with the FDA under section 510(j) of the FFDCA and 21 CFR part 807, will generally be considered taxable).

45. 26 C.F.R. § 48.0-2(b)(3).

46. I.R.S. Notice 2012-77, 2012-52 I.R.B. 781. The IRS Notice provided interim rules governing the excise tax treatment of donations of taxable medical devices to certain organizations, which may be relied upon since the IRS and Treasury Department have not issued further guidance on the issue since the Internal Revenue Bulletin was issued on Dec. 27, 2012. The Notice provides that qualifying taxable medical devices, when donated to an organization qualifying for federal tax exemption under I.R.C. § 170(c) as a charitable organization, will not subject the manufacturer that is donating to the MDET. The manufacturer qualifying for this safe harbor will not be held liable for the tax, unless at the time of donation they knew or had reason to know that the organization receiving the donation was not an eligible donee (i.e. did not qualify as tax exempt under § 170(c)) or that the article donated was to be resold by the eligible donee.

47. ANDREW NOLAN, CONG. RESEARCH SERV., R42971, THE MEDICAL DEVICE EXCISE TAX: A LEGAL OVERVIEW (2013).

the MDET is estimated to raise \$20 billion by 2019,⁴⁸ with other sources estimating between \$20 to \$40 billion in the first ten years the tax will be in effect.⁴⁹

While the MDET has caused a lot of bipartisan tension, the tax actually only purports to raise about two percent of the revenue necessary to fund the health care reform.⁵⁰ Although the estimated budgets for the ACA continue to grow, Congress was careful to design the ACA so that it would not add to the already growing federal budget deficit. To help pay for the expansion of health care coverage to over 27 million uninsured Americans, the Congressional plan divided funds between two broad sources: cuts in government spending, and new provisions to raise revenue.⁵¹ Some of the new provisions, including the MDET, were justified as increases in taxes to industries that will benefit from the health care reform.⁵² Thus, the other significant justification for the tax is the argument that the medical device industry is among those commercial interests that arguably stand “to benefit from unanticipated profits as more individuals enroll in health care insurance.”⁵³ This justification of a “windfall” from the increased number of products will depend heavily on the impact of both the ACA, in terms of increas-

48. *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*, THE JOINT COMMITTEE ON TAX’N (Mar. 20, 2010), <https://www.jct.gov/publications.html?func=startdown&id=3672>.

49. GRAVELLE & LOWRY, *supra* note 26 (reporting that the MDET is projected to “collect approximately \$38 billion of excise tax revenues over the next 10 years, resulting in \$29 billion of net revenues, after accounting for offsets from other taxes”); *see also* Interview by Carey Goldberg with Brian Johnson, Publisher and Co-Founder of Mass-Device.com, in Washington, D.C. (Sept. 30, 2013, 1:40 PM), <http://commonhealth.wbur.org/2013/09/medical-device-tax-repeal> (estimating that the tax will generate about \$30 billion in income for the federal government over the next ten years); Heather Mayer, *Device Tax to Cut Jobs, Raise Prices, Survey Says*, DOTMED NEWS (May 6, 2010), <http://www.dotmed.com/news/story/12589/?lang=en> (MDET “slated to raise \$20 billion to help pay for health care reform”).

50. Sarah Kliff, *How Congress Paid for Obamacare (In Two Charts)*, WASH. POST (Aug. 30, 2012), <http://www.washingtonpost.com/blogs/wonkblog/wp/2012/08/30/how-congress-paid-for-obamacare-in-two-charts/>.

51. *Id.*

52. *See* Van de Water, *supra* note 28. Most famously, the “windfall” justification of an excise tax was used by Congress when they passed the Crude Oil Windfall Profit Tax in 1980 in response to the deregulation of oil prices. In a statement by the Joint Committee on Taxation, it was announced that “Congress believed that the large price increases resulting from the phased decontrol and extraordinary increase in world oil prices were an appropriate object of taxation.” JOINT COMMITTEE ON TAX’N, GENERAL EXPLANATION OF THE CRUDE OIL WINDFALL PROFIT TAX ACT OF 1980, 6 (1981). Although not on account of a deregulation of price control, this congressional justification for the MDET relies on the idea that a government imposed regulation (mandatory, universal health care coverage) will provide an increase in profits to the medical device industry, as more consumers of the devices enter the market. *See infra* note 54 for the counter arguments.

53. GRAVELLE & LOWRY, *supra* note 26. The medical device industry was not the only industry singled out for an increase in taxes; a wide range of other industries will also see an increase in taxes, including hospitals, home health agencies, clinical laboratories, health insurance providers, and drug companies. *See* Van de Water, *supra* note 28.

ing the potential consumer base for the medical devices covered by this tax, and who bears the ultimate economic burden of the tax.⁵⁴ It is still too early on to conclusively state that this purported windfall will smooth out or eliminate the possible negative externalities of the tax.⁵⁵ However, an increase in the demand for the products taxed by the MDET remains a justification for the tax imposed on the sale of medical devices.⁵⁶

3. How the MDET Made it to the Center of the Political Debate

From October 1–16, 2013, the U.S. federal government entered a shutdown and curtailed most routine operations after Congress failed to enact legislation appropriating funds for the fiscal year 2014.⁵⁷ Although it was originally proposed with limited public knowledge as a method of raising revenue for the ACA in 2010, the medical device tax grew in unpopularity to become one of several bargaining chips in the

54. See *supra* note 52, for reasons why the ACA may not actually increase the consumer base for the products taxed by the MDET. The economic burden of the tax will also impact the “windfall” justification of the MDET. We currently do not know who will maintain market power following the full implementation of the ACA (i.e. will the hospitals and insurance companies gain market power such that they can repel any attempts by the medical device industries to increase the price of their devices in response to the tax?), nor do we have a complete picture of the elasticities of the demand curves for each of the products being taxed. This is especially pertinent information, as it will effectively determine if the economic burden of the tax will stick with the manufacturers of the devices, or will be passed onto the hospitals, insurance groups or even the final patients through an increase in the cost of the devices or procedures as necessary compliments to the devices. There remains a significant amount of tension in such a discussion, as the ultimate economic impact of the tax will effectively determine if these discussions are moot. In other words, if the economic burden of the tax shifts from the manufacturer to another party down the chain of sales, is the MDET effectively justified by the “windfall” rationale?

55. While the justification remains strong, there are several points to make that may undercut the actuality of this justification. Opponents to this rationale for the tax argue that the “windfall” effect will be negligible for several reasons. First, a number of the items upon which the tax will be imposed are disproportionately used by Medicare patients because they address the consequences of aging. Second, they argue that those in need of big-ticket items are also those most likely to already have health insurance. In other words, the people who will be forced to obtain health insurance because of the mandatory requirements are not those that will be most inclined to need to purchase many of the items taxed by the MDET. And finally, other government influences in the health care system, including the new reforms, will increase the power of hospitals, thus increasing their market power and reducing the medical device industry’s ability to maintain price control in the market. See John R. Graham, *Obamacare’s Medical-Device Excise Tax: Early Evidence Suggests Significant Harm*, FORBES (Sept. 14, 2013, 8:13 AM), <http://www.forbes.com/sites/theapothecary/2013/09/14/obamacares-medical-device-excise-tax-early-evidence-suggests-significant-harm/>. Note that the negative externalities mentioned here include the purported job loss and elimination of R&D budgets the medical device industry cites as justifications for repeal of the MDET.

56. Michael Hiltzik, *Save Obamacare’s Medical Device Tax!*, L.A. TIMES (Oct. 3, 2013), <http://articles.latimes.com/2013/oct/03/business/la-fi-mh-device-tax-20131003>.

57. Brad Plumer, *Absolutely Everything You Need to Know About How the Government Shutdown Will Work*, WASH. POST (Sept. 30, 2013, 12:22 PM), <http://www.washingtonpost.com/blogs/wonkblog/wp/2013/09/30/absolutely-everything-you-need-to-know-about-how-the-government-shutdown-will-work/>.

budget crisis on the Hill during the 2013 shutdown.⁵⁸ Even prior to the shutdown, the tax had been up for Congressional repeal seventeen times between January 25, 2011 and September 29, 2013.⁵⁹ Its bipartisan opposition is attributed to the aggressive lobbying by the medical device industry.⁶⁰ The industry's lobbyists have been credited with heavily impacting the political debate surrounding implementation of the tax through numerous efforts to direct their congressional representatives towards estimated negative effects of the tax.⁶¹ But the tax has survived many attempts at repeal because it also has the most powerful friend in Washington: President Obama, who has promised to veto any bill containing a repeal of the tax.⁶² Despite this promise from the President, the tax remains a topic of conversation and of potential compromise on the Hill.⁶³

II. DISCUSSION—ANALYSIS OF THE TAX STRUCTURE

A. *Not Your Traditional Excise Tax—Theoretical Application of the Tax Structure*

Taxes on choice or specific goods are often defended by their proponents as devices intended merely to raise revenue. As noted earlier, the MDET itself is heavily defended by the amount of revenue it is anticipated to generate.⁶⁴ However, the desire, and even the need by

58. Peter Overby, *Why A Medical Device Tax Became Part of the Fiscal Fight*, NAT'L PUB. RADIO (Oct. 15, 2013, 5:56 PM) (downloaded at <http://www.npr.org/2013/10/15/234864058/why-a-medical-device-tax-became-part-of-the-fiscal-fight>).

59. NOLAN, *supra* note 47, at 11–12 (providing a list of all proposals to fully repeal the medical device excise tax during the 112th and 113th Congresses).

60. Tony Pugh, *Health Care Law, Medical Device Tax Survive Shutdown Debate*, McCLATCHY DC (Oct. 17, 2013), <http://www.mcclatchydc.com/2013/10/17/205740/health-care-law-medical-device.html> (noting that some congressmen in both the House and Senate, and on both sides of the aisle, have shifted their position on the tax as lobbying efforts have increased, the diverse impact attributable to the “sprinkling of device makers across a wide swath of states”). In fact, the industry lobbyists have already had a significant impact on the face of the tax, as their efforts are credited for an initial reduction in the percentage size of the tax, which halved the tax, taking it from 4.6 to 2.3 percent. *Id.*

61. *Id.* (quoting Mark Leahy, president and CEO of the Medical Device Manufacturers Association, “[m]ore and more members of the Senate and House of Representatives are learning about the devastating impact the medical device tax has on innovation, jobs and patient care,” in explaining why the efforts of his lobbyists will not let up); *cf.* Paul N. Van de Water, *More Bogus Economics from the Medical Device Industry*, CTR. ON BUDGET AND POLICY PRIORITIES (Mar. 30, 2012, 12:33 PM), <http://www.offthechartsblog.org/more-bogus-economics-from-the-medical-device-industry/> (one of numerous media sources highlighting the overdramatized effects of the MDET on the medical device industry, calling studies and overblown result expectations “not credible”).

62. Goldberg, *supra* note 49. Former Senator Max Baucus, Chairman of the Senate Finance Committee (D-Montana), is the father of the tax, having been involved in its inception in 2009. Senate Majority Leader Harry Reid (D-Nevada) is also notably invested and has no interest in bringing a repeal bill to a vote because he helped broker a deal to cut the tax in half in 2009.

63. Marc Heller, *Senate Finance Committee Oks Two-Year Extension of Most Expired Tax Provisions*, BLOOMBERG BNA (Apr. 9, 2014), <http://www.bna.com/senate-finance-committee-n17179889451/>.

64. NOLAN, *supra* note 47.

government to raise revenue, only tells part of the story behind decisions to tax. Both economic and political influences are involved in the ultimate decision on how to structure taxes; additional influences and rationale always underlie the tax structure chosen. An excise tax is no different, and as noted earlier, may be described by a host of traditional rationale.

Excise taxes are a prime example of what have traditionally been referred to as indirect taxes.⁶⁵ The tax, which is imposed on the sale of a select good, is indirect because the economic burden of the tax typically falls upon persons other than the one from whom the tax is directly collected from.⁶⁶ Thus, one of the common features of most selective excise taxes is that the tax's economic incidence (or ultimate economic burden of paying the tax) is often expected to be shifted from the original taxpayer to the consumer through an increase in price.⁶⁷ The crucial thing to understand is that the tax's economic incidence is not dependent on where the revenue is collected, but rather depends on the price elasticity of demand and supply of the good being taxed.⁶⁸ These concepts are best explained by looking at a streamlined example in the context of an excise tax. Elastic goods are goods with many substitutes; for simplified purposes, assume that an excise tax is levied against wine, while beer and liquor are considered to be adequate substitutes. If an excise tax was levied against the manufacturers of wine, the economic incidence of the tax would be borne by the manufacturer; if the manufacturer were to try to raise the price of wine to make up for the increase in cost it experiences because of the tax, consumers could just switch to any of the various substitutes, such as beer or liquor.⁶⁹ Thus, an elastic good can be identified by the fact that a

65. Giertz, *supra* note 2, at 125; see also Jorge Martinez-Vazquez et al., *Direct Versus Indirect Taxation: Trends, Theory, and Economic Significance* (Ga. State Univ. Andrew Young Sch. of Policy Studies, Working Paper No. 09-11, 2009), available at http://aysps.gsu.edu/isp/files/ispwp0911_updated.pdf (While direct taxes are often described as “those that may be adjusted to the individual characteristics of a taxpayer,” an indirect tax is described as “those that are levied on transactions irrespective of the circumstances of [the] buyer or seller.”).

66. MERRIAM WEBSTER DICTIONARY 257 (14th ed. 2010); see also Giertz, *supra* note 2, at 125 (noting that excise taxes may be collected at various stages, including the point of production, wholesale or retail levels, but that the tax is ultimately imposed on a transaction (such as the sale of the good), rather than a person or corporation directly (i.e. an income tax), but that there is traditionally expected to be a difference between the point of collection and who ultimately pays for the tax).

67. See generally Don Fullerton & Gilbert E. Metcalf, *Tax Incidence* 28 (Nat'l Bureau of Econ. Research, Working Paper No. 8829, 2002) (“[T]he standard assumption is that the burdens [of the tax] fall on the consumers of the taxed products (through higher prices).”).

68. Bowman, *supra* note 8, at 677–a.

69. Although this is not a perfect example, as beer and liquor are arguably not perfect substitutes for many people who prefer wine, it does have some basis grounded in historical context. In reviewing common reactions to sin taxes, substitution of similar nontaxed products reveals that the high tax on whiskey in the U.S. in the late 1800's caused many people simply to switch to beer, and others to opium and marijuana. Adam Gifford Jr., *Whiskey, Margarine, and Newspapers: A Tale of Three Taxes*, in *TAXING CHOICE: THE PREDATORY POLITICS OF FISCAL DISCRIMINATION* 57, 58 (William F. Shughart II ed., 1997).

slight change in price typically leads to a sharp change in the quantity demanded or supplied.⁷⁰ In contrast, goods that are said to be inelastic have relatively few substitutes—although simplified for purposes of this hypothetical, consider cigarettes to be the only satisfactory product that smokers are willing to buy. If the tax is again levied against the manufacturer, the cigarette manufacturer in this case has the ability to pass on the economic incidence of the tax to the final consumer by increasing the price of cigarettes. Because cigarettes are assumed to have no acceptable substitute, consumers would have to either buy the cigarettes at the new higher price, or change their consumption habits. Consumer habits can thus be affected by the shift in the economic burden of a tax on an inelastic good, especially if the good is not considered a “necessity.”⁷¹ Therefore, in the interest of raising revenue, excise taxes are arguably best applied to inelastic goods.

Based on the aforementioned reasons, imposing an excise tax on certain goods would seem like an effective method of raising revenue for the government, especially when the good is considered to be inelastic. But as noted above, the ability to raise revenue rarely constitutes the complete picture for justifying a certain tax structure. And yet it is important to first understand why application of an excise tax is most efficiently applied (in terms of revenue raising) to an inelastic good because the two possible outcomes of a price increase to an inelastic good (increasing the price of consuming the good/changing consumption habits) are also two of the strongest traditional rationales for choosing an excise tax structure. These are also the traditional justifications that have made excise taxes a popular tool for politicians; first, an excise tax that attaches to an inelastic good at the production level can typically be passed on to the consumer through an increase in the price of the good, without adding the additional cost as a separate line item on the consumer’s receipt, and second, because an excise tax levied against a good with few substitutes can be an effective method of changing consumer buying habits, an excise tax can be used to change consumption habits. This second rationale is captured in the concept of “sin taxes,” which classifies many of the goods chosen as targets of selective excise taxes as goods which the government has a motivation to decrease consumption of, usually justified by a health or moral concern.⁷² In other words, the use of selective excise taxes has been rationalized as a method of government intervention “required to align private costs more closely with social costs.”⁷³ Instead of an outright

70. ROBERT E. HALL & MARC LIEBERMAN, *MACROECONOMICS: PRINCIPLES AND APPLICATIONS* 102 (Jack W. Calhoun et al., eds., 4th ed. 2008).

71. *Id.* at 104.

72. Randall G. Holcombe, *Selective Excise Taxation from an Interest-Group Perspective*, in *TAXING CHOICE: THE PREDATORY POLITICS OF FISCAL DISCRIMINATION* 81, 81 (William F. Shughart II ed., 1997) (noting that one of the three clear rationales for excise taxes developed by economic theory is that “[a]n excise tax can be placed on goods whose consumption is considered to be undesirable . . . viewed as either a penalty for consuming the good, a tax on a negative externality . . . or both”).

73. William F. Shughart II, *Introduction and Overview*, in *TAXING CHOICE: THE PREDATORY POLITICS OF FISCAL DISCRIMINATION* 1, 3 (William F. Shughart II ed., 1997) (arguing

ban of the use of what the government considers an immoral or risky good, a selective excise tax seeks to change the consumer's behavior by raising the price and "provid[ing] consumers with incentives to curtail their purchases."⁷⁴

In summary, excise taxes have traditionally been justified as efficient and effective means of raising revenue when applied to inelastic goods. Traditionally, many of these goods have been selected as the object of the tax because the government has an underlying objective to change consumer behavior, being of the type that the government considers as posing a certain moral or health risk. However, these traditional rationales and justifications are in tension with each other; most selective excise taxes are traditionally levied against products considered to be harmful or immoral to society, so an increase in price is meant to change behavior. But, if this goal of the tax is successful and consumers do change their spending habits, the tax does not raise the revenue anticipated by government officials. This tradeoff makes it incredibly difficult to determine if an excise tax has "worked." In an effort to perhaps provide reasoning that functions despite the tension between those objectives, a final rationale has developed, which posits that an excise tax can be applied as a substitute for a user fee, with the proceeds earmarked for more desirable purposes (i.e. smokers pay extra for cigarettes as a "fee" for the health risks their decision imposes on the community). This rationale, commonly used to defend the use of an excise tax, justifies the traditional "sin tax" by holding that the money raised by the tax will be used to help curb the social or moral improprieties of the product itself, by earmarking it for such purposes.⁷⁵ "There is little doubt that taxpayers are more tolerant of a tax increase if the stated objective is to reduce activities that are widely frowned upon and to increase funding for projects or programs that are widely believed to promote worthy objectives."⁷⁶ For example, many of the state taxes on alcohol are earmarked for highway safety programs, an area directly impacted by the negative externalities of

that government action is required because of the assumption that without it, the consumption/use of certain products imposes costs on society that the consumer themselves does not bear and which they do not take into account when making consumption decisions; this is especially evident in the case of smokers, who do not necessarily think about the negative externalities they impose on others because of second-hand smoke, so the tax forces them to at least consider their decision to buy cigarettes and smoke because of the increase in price, and if they decide they will smoke regardless of the moral/health risks, they will bear the burden of their cost on society by bearing the burden of the tax).

74. *Id.*

75. See generally Dwight R. Lee, *Overcoming Taxpayer Resistance by Taxing Choice and Earmarking Revenues*, in *TAXING CHOICE: THE PREDATORY POLITICS OF FISCAL DISCRIMINATION* 105 (William F. Shughart II ed. 1997) (positing that because public desire for special interest spending lines up with public opposition to government taxation, thus giving both the government and public the general incentive to earmark revenues for purposes desired by the public).

76. *Id.* at 106. These earmarked funds have also been coined as a "user fee" for the consumer of the good.

drinking and driving.⁷⁷ This final rationale seems to attempt to strike a balance between the government's goal of raising revenue, and perhaps the slightly less attainable, but desirable effect, of shifting consumption. By earmarking funds from the tax for programs meant to curb the negative externalities of the select products' consumption, the government effectively takes a stance against the products' use, while also raising revenue—an arguably effective compromise between the traditionally conflicting rationales typically cited for an excise tax.

In light of these traditional justifications of selective excise taxation, however, the tax on medical devices is challenging to rationalize. While the tax will arguably effectively raise revenue, the extent of the demand curves determining the elasticity for many medical devices remain undetermined. Many of the devices are arguably without adequate substitutes in the market, making them inelastic goods by definition, but this does not completely tell the story in determining the elasticity of the entire demand curve. For example, if the manufacturers were to pass on the economic burden of the tax to the patient/final consumer, there are numerous situations where a patient might just elect to not have a procedure done, or might even wait until alternative options kick in, including Medicare coverage, cheaper prices, or other alternatives, such as experimental treatments.⁷⁸ This demand curve will vary based on the type of medical device in question and the options available to the consumer. Of course this also highlights the fact that it cannot yet be determined where the economic burden of the tax will land. Without good estimates of the relevant price elasticities, it remains uncertain if the MDET will follow the traditional path of an

77. *Id.* With regard to benefit taxes, such as the highway motor fuels tax, the Encyclopedia of Taxation & Tax Policy describes the rationale for earmarking them as follows: Earmarking finds its strongest equity rationale in the benefits connection, where it extends the quid-pro-quo concept (the accepted basis for private market transactions) into the tax-financed sector. Dedication of highway user tax revenues for highway purposes represents the benefit principle at its best (notwithstanding the tenuous relationship between taxes paid and benefits received by different categories of highway users). The equity rationale for earmarking general taxes finds its limit in the fact that there are very few services or facilities for which there is a corresponding "earmarkable" tax.

Frederick Stocker, *Earmarking of Taxes*, in THE ENCYCLOPEDIA ON TAXATION & TAX POLICY 89, 90 (Joseph J. Cordes et al., 2d ed. 2005). See also George R. Crowley & Adam J. Hoffer, *The Effects of Dedicating Tax Revenues*, 109 MERCATUS ON POLICY 1, 1 (2012) (positing that "[t]heoretically, the process of dedicating tax revenues to specific expenditures should have no impact on the composition of expenditures, because one dollar from one tax is perfectly substitutable for one dollar from another," but that the effects of earmarking tax revenues have strong policy implications and dedicating tax revenues to specific projects the public supports are popular methods used by policymakers to mask increases in government spending).

Other examples of earmarking include more broadly defined purposes, like revenues received by schools districts being dedicated to education purposes, but also things like gasoline and motor vehicle taxes, which are earmarked to fund road maintenance and the ever contentious social security payroll taxes, earmarked for elderly insurance purposes, but also for welfare/unemployment compensation.

78. This also raises the difficulty in defining the "consumer"—even if the economic burden of the tax is passed on, who would it fall on (i.e. the patient, the insurance companies, or the hospitals) and what would the demand curves for each look like?

excise tax in terms of being described as an indirect form of taxation (i.e. the economic incidence of the tax is easily shifted from the manufacturer to the “consumer”), or not.

The MDET is also not adequately justified by the traditional rationale of a “sin tax” or a tax imposed to change consumption habits. No one would argue that the MDET is being imposed to encourage people not to have medical procedures done or to discourage the use of beneficial medical devices. Many of these devices have helped save lives through preventative measures or other means, while the rest arguably have tended to produce only positive externalities.

Finally, in terms of earmarking funds, the argument is trickier. Because the MDET pretty clearly does not purport to be a “sin tax,” at least in the traditional sense of trying to change consumer behavior, negative externalities are harder to identify and define. In an attempt to do so, however, arguably it would be fair to look at what the funds were earmarked for. But problems arise here as well, since tracing the revenue raised by the MDET leads to a general fund managed by the United States Treasury Department.⁷⁹

Taken collectively, it remains challenging, if not impractical, to attempt to justify the MDET by the traditional rationales of an excise tax.

B. *Industry Concerns*

In addition to its lack of conformity with traditional justifications for selective excise taxation, the medical device industry has voiced a number of other concerns with the tax that go beyond the economic theories used to justify its structure. These practical concerns, communicated by industry lobbyists, must be discussed (and potentially addressed) in assessing the efficiency of the selective excise tax structure. Among the problems asserted by the medical device industry are the following, to be discussed below: (1) the demand for medical devices will drop if the price increases to reflect the MDET; (2) the increased cost of the MDET will force companies to (a) lay off workers and (b) reduce spending on innovation; (3) smaller companies will not be able to survive the cost increase of the tax; and (4) the costs of the tax on the industry will so substantially outweigh the benefits that it will have a crippling effect on the industry (i.e. driving firms overseas, forcing towns centered around these companies to disappear, etc.). In discussing the potential effects of the tax on the medical device industry, it must be noted that the final impact will depend largely on whom the economic burden of the tax falls upon. While a shift of the economic

79. This is not to say that a general fund in the Treasury Department cannot be earmarked to achieve the traditional goals of curbing the negative externalities or benefiting programs meant to do so. For example, social security payroll taxes are also deposited in a general fund at the Treasury. But from there, the funds are earmarked and made accessible to the states only when they have shown proof that the funds they receive will be used for one of the two primary purposes of social security taxes. No such earmarking has been established for the MDET at this time. *See generally* Ewan Clague & Joel Gordon, *Earmarking Tax Funds for Welfare Purposes*, 3 SOC. SEC. BULL. 10 (1940).

burden of the tax from manufacturers to consumers may mitigate many of the negative impacts discussed below, it does not negate the fact that these concerns must be addressed to fully answer the question of whether this tax structure is the “best” choice.

The medical device industry asserts that the demand for medical devices will drop if they are forced to raise the price of their goods. This argument assumes that the consumer, in experiencing an increase in the price of medical devices, would decrease their demand for such products. In other words, the assumption is based on the theory that the demand curve for medical devices is relatively elastic.⁸⁰ Yet economic research shows that healthcare related spending is relatively inelastic;⁸¹ in other words, when prices have increased, the demand only falls by a fraction of the price increase.⁸² This would seem to imply that even a large increase in the price of medical devices would have a relatively small effect on demand, since many medical devices arguably have few adequate substitutes and many are considered “necessary” for the patient.⁸³ However, even if the entire burden of the tax were to be shouldered by the consumer, the medical device industry arguably overstates the impact the price increase might have on consumer behavior, regardless of the slope of the demand curve, because the MDET actually tends to be a relatively small share of the price of the taxed product, especially relative to other excise taxes.⁸⁴ While the industry concerns are not unfounded (demand for some devices with adequate substitutes or those considered “optional” might decrease with an increase in price), their effect appears to be overstated, such that an increase in price of medical devices would not cause the devastating effect of a large shift in demand that the industry lobbyists have implied.

“The medical device tax is a tax on jobs.”⁸⁵ This leading argument by the medical device industry lobbyists posits that to offset the revenue loss due to the excise tax, manufacturers will have to lay off tens of

80. An elastic demand curve assumes that an increase in the price of a good will cause consumers to shift their consumption away from the product. This might typically be the case for products that have adequate and available substitutes, and are not considered necessities.

81. GRAVELLE & LOWRY, *supra* note 26, at 14.

82. A 2006 review of the economic literature by Mathematica Policy Research found the price elasticity of overall health services range from -0.04 to -0.75, but centered around -0.2; this translates to an indication that if health care costs were to increase by ten percent, customers/patients would be anticipated to only reduce their total health care spending by two percent. SU LIU & DEBORAH CHOLLET, MATHEMATICA POLICY RESEARCH, INC., PRICE AND INCOME ELASTICITY OF THE DEMAND FOR HEALTH INSURANCE AND HEALTH CARE SERVICES: A CRITICAL REVIEW OF THE LITERATURE 34 (2006).

83. Of course this would also vary depending on the device needed and the condition of the patient.

84. GRAVELLE & LOWRY, *supra* note 26, at 4 (“Federal cigarette taxes are estimated to be around 16% of the retail price, but if measured on the same basis as the medical device and other taxes (before state and local taxes and on price net of the tax) the tax is more than 36%.”).

85. Michael Ramlet et al., *The Economic Impact of the Medical Device Excise Tax*, AM. ACTION F. (June 4, 2012), http://americanactionforum.org/uploads/files/research/The_Economic_Impact_of_the_Medical_Device_Excise_Tax.pdf.

thousands of workers.⁸⁶ The industry itself is massive in the United States; in 2008 alone, the medical device industry employed 422,778 workers, who were paid over \$24.6 billion in earnings.⁸⁷ Although the actual impact remains to be determined, lobbyists have already begun pointing to companies who have laid off workers in the industry.⁸⁸ Others point to reports like the one by Diana Furchtgott-Roth, which estimated the tax would prompt the loss of 45,661 jobs,⁸⁹ or groups like the American Action Forum, which estimated around 14,500 jobs would be lost because of the tax.⁹⁰ The direct effect of the tax on industry jobs remains undetermined—some employers have cited the MDET as one of many reasons for laying off workers—but the numbers across the industry have remained low thus far and the reports that have estimated job loss in the tens of thousands have been found to use questionable methodology.⁹¹ Once again, while the argument is not

86. *Id.* It remains unclear if this argument is based on the assumption that the manufacturers will bear the burden of the excise tax or if it matters in the long run because the initial hit by the tax will have the same impact alleged. See also Devon Herrick, *The Job-Killing Medical Device Tax*, NAT'L CTR. FOR POL'Y ANALYSIS (Feb. 2012), <http://www.ncpa.org/pdfs/ib106.pdf>.

87. The Lewin Group, *State Economic Impact of the Medical Technology Industry*, ADVANCED MED. TECH. ASS'N (June 7, 2010), available at http://www.lewin.com/~media/Lewin/Site_Sections/Publications/StateEconomicImpactoftheMedicalTechnologyIndustry61510.pdf.

88. For example, Stryker Corporation was cited as one of the major medical device companies who announced in November 2011 that they would be laying off 1,000 workers, or about five percent of their workforce in anticipation of the tax. Numerous news sources reported that the layoffs were made solely in advance of the MDET, but the press release from Stryker cites other reasons, such as “continued investment in strategic areas and drive growth despite the ongoing challenging economic environment and market slowdown in elective procedures,” and it was well-known in the industry that the company was in financial trouble prior to any effects by the tax. Press Release, Stryker Corporation, Stryker Announces Actions to Drive Over \$100 Million in Annual Productivity Gains (Nov. 10, 2011), available at <http://phx.corporate-ir.net/phoenix.zhtml?c=118965&p=irol-newsArticle&ID=1629222>.

89. FURCHTGOTT-ROTH & FURCHTGOTT-ROTH, *supra* note 27, at 9, 21. The methodology of the report remains unclear and the data produced in this report has been questioned by numerous credible sources, but the information contained in the report continues to be cited.

90. Ramlet et al., *supra* note 85 (14,500 is based on estimations made by both the Joint Committee on Taxation and historical industry data).

91. See Van de Water, *supra* note 61. The article points out that studies like the one sponsored by AdvaMed and used to estimate the job loss total at 39,000 jobs due to the MDET was based on flawed methodology. It points out that Battelle, which carried out the study for AdvaMed, used an “input-output” model to conclude the hypothetical economic event (an estimated \$3 billion loss in revenues to the medical industry) would result in a little fewer than 40,000 jobs being lost. The problem is, there is no reason to think that the medical industry will actually lose \$3 billion in revenues, from a loss of sales of the devices themselves—this would only happen if the goods were completely elastic, which they are not. Based on an elasticity of 0.2 of medical devices, the report overestimates the revenues losses by a factor of five. In addition, a straight input-output model ignores important related changes like government’s fiscal or monetary policy, which would have a large impact.

unfounded, the estimated results of the tax on industry jobs appear to be grossly overstated.⁹²

The industry has emphasized that, in addition to a loss of jobs, the cost incurred by the MDET will force companies to reduce spending on innovation. Much the same as the argument reflecting job loss because of the tax, this concern posits that the increased cost of the tax on manufacturers will in turn cause them to cut or scale back their budgets for research and development (“R&D”). Reports, such as those from Benjamin Zycher, a senior fellow at the Pacific Research Institute, have estimated that the tax will force the medical device industry to cut spending on R&D by over \$2 billion a year.⁹³ This seems staggering in an industry that is known for its large R&D spending, but the truth of the impact seems to be similar to the job-loss argument; the tax could force companies to cut some R&D spending, but the estimated results by the industry appear to be largely overstated. Spending on R&D in recent years has slowed for reasons entirely unrelated to the tax. *The Economist* wrote “device companies have sustained themselves by making small improvements to existing products. Spending on R&D has so far failed to yield many truly innovative devices.”⁹⁴ Other sources have cited a general decrease in the amount of investment funds available for manufacturing firms,⁹⁵ as well as a wealth of inefficiencies in the healthcare market that have slowed R&D expenditures, prior to the tax.⁹⁶ But if the MDET is to join the ranks of other reasons for the cuts on spending in R&D, it will first have to be determined who is saddled with the burden of paying the tax.⁹⁷ Thus, the effect of the MDET on R&D spending will largely depend on who bears the economic burden of the tax. However, even if the burden remains fully with the manufacturer, the story about why spending on R&D may be cut is not fully told

92. Pugh, *supra* note 60. The article cited expert Eugene Kiely, director of Fact-Check.org, a nonpartisan, nonprofit government watchdog project of the Annenberg Public Policy Center of the University of Pennsylvania. Kiely noted that “[w]e couldn’t even come up with tens of thousands of jobs that are being lost here in the United States” in the context of the overblown job effects being cited.

93. Zycher’s report is no longer available online, but it is referenced in documents produced by the Advanced Medical Technology Association. See *Summaries of Key Device Tax Studies and Reports*, ADVANCED MED. TECH. ASS’N (May 22, 2012), <http://advamed.org/res.download/19>.

94. *Left to Their Own Devices: Medtronic and the Woes of America’s Medical-Technology Industry*, ECONOMIST, (Sept. 11, 2011), <http://www.economist.com/node/21528644> (hereinafter “Left to Their Own Devices”).

95. See *The U.S. Medical Device Industry in 2012: Challenges at Home and Abroad*, MED. DEVICE AND DIAGNOSTIC INDUS. (July 17, 2012); *Medical Technology Innovation Scorecard: The Race for Global Leadership*, PRICEWATERHOUSECOOPERS LLP (Jan. 2011), <http://pwhealth.com/cgi-local/hregister.cgi/reg/innovation-scorecard.pdf>; Ramlet et al., *supra* note 85.

96. *Left to Their Own Devices*, *supra* note 94 (listing numerous problems affecting the medical device industry, including, but not limited to, “recalls, stingy customers, [and] anxious regulators”); Michael E. Porter & Elizabeth Olmstead Teisberg, *Redefining Competition in Healthcare*, 82 HARV. BUS. REV. 65 (2004) (citing zero-sum competition, a focus on local markets, and inefficient strategies and structures as major issues within the medical device industry).

97. In other words, effects on small as well as large firms will likely be minimal if the tax is expected to be passed on in price and the decrease in demand would be negligible.

by the tax alone. Once again, it appears that giving a blanket amount of billions of dollars lost on innovation in the industry overstates and oversimplifies the problem.

Claims have been made that small firms in the medical device industry will be disproportionately affected by the excise tax. This argument, if true, would appear to be especially pertinent, given that a vast majority of the medical technology firms in the United States are considered small-sized firms; in 2007, seventy-three percent of the medical device companies in the U.S. had fewer than twenty employees,⁹⁸ and in 2011, eighty-five percent of the companies had fewer than twenty employees.⁹⁹ The medical device industry argues that these smaller business and startups in the medical device industry will have greater difficulty adapting to the excise tax burden because the structure of the tax favors larger companies who are better positioned to absorb the lost revenue as a result of lower fixed costs and larger cash reserves.¹⁰⁰ However, this argument presumes that these smaller companies are also those with narrower margins. Being small in size (i.e. number of employees, or devices, etc.) is not why a company will necessarily struggle with the tax. It will depend on the margins; the tax is applied to sales revenue, and not profits, so you can imagine a situation in which a small company, based on the number of employees, or the number of devices made, is making significant profit margins based on their investment in/production of one lucrative device. It is accordingly misleading to say that a small company, just for being small in size, will suffer disproportionately from the tax.

The medical device industry has relied on statistics, studies, and reports they have self-produced, to argue that the cost of the tax will have a crippling effect on the industry. News sites have run stories about the devastating effects the MDET could have on towns bolstered by the medical device industry. For example, Fox News ran a story in October 2013, on two medical device companies, Iconacy and OrthoPediatrics, whose CEOs were quoted saying “[t]here are estimates that over 40,000 jobs will be impacted” and that Warsaw, IN, where both companies were located “is known for its medical device companies, [and thus] the tax could also have a profound effect on both the community and the state of Indiana.”¹⁰¹ These reports, stories, and statements, however, should not be taken at face value. Many of the reports and studies have been undermined for their methodology, and many of the statistics have been found to be grossly overestimated.¹⁰² Although many of the problems identified by the medical device industry are

98. *2011 Annual Survey of Manufacturers*, U.S. CENSUS BUREAU (Dec. 17, 2013), http://factfinder2.census.gov/faces/tableservices/jsf/pages/productview.xhtml?pid=ASM_2011_31GS201&prodType=table (2011 is the most recent year in which this data is available).

99. *Id.*

100. Ramlet et al., *supra* note 85.

101. Gabrielle Karol, *Medical Device Leaders: Don't Hurt Job Growth with ObamaCare Tax*, FOX BUSINESS (Oct. 21, 2013), <http://www.foxbusiness.com/business-leaders/2013/10/21/medical-device-leaders-dont-hurt-job-growth-with-obamacare-tax/>.

102. Van de Water, *supra* note 61.

valid and may potentially have an impact on the industry itself, the extent of the effects cannot be predicted with complete accuracy. But just one year into the tax's implementation, it appears the estimated effects have been largely overstated. The tax is still new and in its early stages of application; it will take time before we know more determinative effects of the tax, but it should be reemphasized that while many of the arguments made above are valid, they will depend significantly on who bears the economic burden of the tax. And yet even without such knowledge, it appears that the predicted effects of the tax by the industry lobbyists have been largely overstated.

C. *The Federal Government's Response*

Determining if a tax is effective depends entirely on how you define the term. Most economists, especially those in public finance, find it preferable to raise revenue by taxing a broad base at a low rate in order to maximize the amount of revenue, while reducing the distortions to the economy.¹⁰³ The opposite of this broad-based tax structure, however, is a selective excise tax. Thus, effectiveness of an excise tax is often defined by its traditional rationales—in particular, excise taxes are often considered effective if they are able to change or affect the behavior of the consumer. In other words, (1) was the tax passed onto the consumer, and if so, (2) how much did consumption decrease? But as we have established above, the MDET is challenging to justify with such traditional rationales associated with an excise tax. It does not appear that the tax has been established to incentivize a change in consumer behavior. If we cannot effectively define the influences behind the use of an excise tax using traditional rationales, then it arguably does not make sense to try and define the tax's effectiveness based on such rationales. Based on this, how can the effectiveness of the tax be defined?

Many supporters of the MDET would label the tax as an effective one purely based on the amount of revenue it could raise for the healthcare reform. But the MDET was certainly not the only option proposed to raise funds for the ACA. In a congressional research report from 2009, alternative tax options were identified as potential revenue raisers, including many that came close to or exceeded the estimated \$39 billion in revenue from the MDET.¹⁰⁴ Ultimately Congress elected to fund the ACA through several sources of revenue; funding for the ACA will come from both cuts in government spending and new revenue sources, including the MDET.¹⁰⁵ The \$39 billion estimated in revenue from the MDET is merely a fraction of the estimated \$1.634

103. *Tax Policy Nuts and Bolts: Understanding the Tax Base and Tax Rate*, INST. ON TAX'N AND ECON. POL'Y (Aug. 2011), <http://www.itepnet.org/pdf/pb50bolts.pdf>.

104. JANE G. GRAVELLE, CONG. RESEARCH SERV., R40648, TAX OPTIONS FOR FINANCING HEALTH CARE REFORM (2010). The alternative tax options included, but were not limited to, excise taxes on alcohol and non-diet sweetened beverages, reducing the indexing of the rate brackets to the Consumer Price Index, increasing the capital gains tax, numerous financial accounting standards, payroll tax increases, or a new value-added tax.

105. Kliff, *supra* note 50.

trillion necessary for the funding of the healthcare reform.¹⁰⁶ This means that only about two percent of the revenue to fund the ACA will come from the revenue raised by the MDET over the next decade. Some would argue (primarily the medical device industry) that this small percentage could be raised in other ways less harmful to the medical device industry. On the other hand, without evidence of who the burden of the tax will fall upon, or what benefits the industry will gain from the additional healthcare coverage, it cannot be argued that the tax is not fairly placed on an industry that could benefit from the ACA.

Many proponents of the MDET rely on “fairness” in defining the effectiveness of the MDET. The argument here is three-fold. First, the biggest proponents of the MDET argue that the tax is “fair” because it purports to tax an industry that may receive quite a windfall from the additional customer base brought about by implementing the ACA. If such a windfall does occur, the effect of the tax on manufacturers may ultimately be negligible. Second, the supporters of the tax argue that in addition to the potential benefits the medical device industry may gain from the ACA, the industry is one that can afford the cost of the tax. The large profit margins of some of the most vocal companies certainly support this argument, but across the industry, this argument holds if the burden of the tax is able to be shifted from the manufacturer to the consumer. This brings us to the third justification for the “fairness” of the tax on the industry—imposed oversight of an industry that arguably operates with substantial, unchecked control over the pricing of their products in the market. The medical device industry, as discussed, supplies goods that generally have few, if any, adequate substitutes. Thus, the industry largely operates with a monopoly over the price in the market. Because of this market control, the medical device manufacturers may have an easier time passing the burden of the tax on by raising the price of the devices. While not much may be done about this ease in shifting the burden to the final consumer, the implementation of the necessary administrative and compliance costs related to the tax may open the market up to further regulation and/or oversight of the price control in the market. These arguments support the proposition that the tax is effective because it is being fairly administered to the medical device industry.

Ultimately, the effectiveness of the tax will not be fully determinable until several years after it has been introduced to the market. Only time will tell who bears the economic burden of the tax, and whether

106. *Id.* The other sources discussed in this article are broken into two groups: cuts in government spending and new provisions designed to generate revenue for the expansion in healthcare coverage. All of these charges are also discussed in a 2012 Congressional Budget office report. See Letter from Douglas W. Elmendorf, Director, Congressional Budget Office, to Honorable John Boehner, Speaker of the House, U.S. House of Representatives (July 24, 2012), available at <http://www.cbo.gov/sites/default/files/cbofiles/attachments/43471-hr6079.pdf>, whose information was later updated generally by U.S. CONGRESSIONAL BUDGET OFFICE, THE BUDGET AND ECONOMIC OUTLOOK: 2014 TO 2024 (2014), available at http://www.cbo.gov/sites/default/files/cbofiles/attachments/45010-Outlook2014_Feb.pdf (pay particular attention to Appendix B).

the government's predicted external benefits to the medical device industry become a reality.

III. DETERMINING THE FUTURE OF THE MDET

Based on the limited amount of data available at this time, it would be both impractical and perhaps misleading to make substantial claims regarding either the impact or the effectiveness of the MDET. The tax has survived numerous attempts at repeal¹⁰⁷ and appears to be sticking around, at least for the time being. Without making an argument either for or against repeal/reform at this time, this Note posits that the tax ought to be reassessed in the future to determine if the tax structure is appropriate or if there stands to reason certain justifications for reform or repeal.

There are two competing stories circulated about the MDET. To determine if the tax has been successful and/or efficient, or if it ought to be considered for reform or repeal, requires that one of the competing stories be adopted; either (1) the medical device industry is correct that the application of the MDET does more harm than good to the industry and that reform/repeal ought to be a serious consideration, or (2) the federal government will be correct in their prediction that a windfall from the ACA will balance the cost of the tax on the industry. Within each of these predictions exists the underlying tension mentioned throughout this Note; the impact of the MDET will depend heavily on who ultimately bears the economic burden of the tax. Thus, the success of each side's justifications for or against the tax depends heavily on who will "pay" for the tax.

The crux of the arguments made by both the federal government and the medical device industry appear to assume that the economic impact of the MDET will remain with the manufacturers. The federal government seems to assert that the cost of the MDET on the medical device manufacturers is justified by a windfall the industry will receive from the influx of patients mandated to receive healthcare insurance under the ACA; the medical device industry, on the other hand, alleges the MDET will have a crippling effect on the industry, by forcing firms to cut jobs, innovation and maybe their entire operation altogether.¹⁰⁸ If the economic burden is to remain with the manufacturer (i.e. the tax is not passed on by an increase in the price of the devices sold), then it remains to be seen whose prediction would ring true.¹⁰⁹

On the other hand, if the economic burden of the tax is shifted from the manufacturers to the consumers, both the arguments by the

107. NOLAN, *supra* note 47, at 11–12.

108. *See supra* Part II.B.

109. Arguably both sides have largely overstated the effect the MDET might have in this scenario, as presented through earlier evidence in this Note. The predictions from the medical device industry seem to be overblown, relying on misinformed and overestimated data, while the government's argument is undercut by arguments that the people mandated to retain health insurance through the ACA will not be the type of people who will need many of the devices covered by the MDET (and thus the ACA would not contribute to a windfall because no substantial increase in the patient numbers would occur).

federal government and the medical device industry could be potentially undermined. The federal government's windfall justification for the MDET would not be moot if the tax's economic burden were shifted to the consumer because the medical device industry could be earning a higher margin on their sales (which would be taxed by the MDET), but such a result could make it more difficult for the government to explain their decision to tax in this way. In other words, if the government uses the windfall justification as their reasoning to use a selective excise tax, then it would be difficult to explain why they structured the tax in such a way that it was not the manufacturers, those earning the windfall, who are paying for the tax, but rather the consumer (the people providing the windfall!). The medical device industry would also be faced with their argument being seriously undermined if the economic burden of the tax were shifted to the consumer. If the tax can merely be shifted by an increase in the price of the devices, the tax, in the long run, should have little to no negative effects on the industry itself, thus undermining their arguments that the tax unfairly burdens them.

In conclusion, a reassessment of the tax will depend heavily on where the economic burden of the tax falls. If the burden remains on the manufacturer, either the government or the medical device industry's arguments may be assessed to determine the fairness of the tax on the industry. But if the economic burden of the tax is shifted to the consumer, the reassessment of the tax becomes much trickier, for the following reasons: First, it would need to be determined to *whom* the economic burden of the tax has been passed; are the insurance companies paying the higher prices or are the patients facing the upturn in prices for both the devices and the procedures they involve? Second, the amount of the burden would need to be considered; in a relatively unregulated market, the manufacturers have a monopoly on production and thus could potentially raise prices. It would have to be determined how much prices had increased. And finally, it would need to be determined what effect the increase in prices was having. If the prices were so great for the individual consumer that they were electing not to have important procedures for cost-related reasons, that would be a justification for a reassessment of the tax structure.

It remains to be seen how the cost of the MDET will be divided among the affected parties; it will take time to determine where the economic burden of the tax lands and how that cost will affect all parties involved.

IV. CONCLUSION

Despite the adamant arguments from both the medical device industry and the U.S. federal government, determining the fate of the MDET is best left for future discussions. While both sides present valid arguments, it may be the case that neither is correct, or that both have overstated their positions. This discussion, however, is heavily dependent on where the economic burden of the tax falls. Thus, it will only

be once enough time has passed that we will know who is truly “paying” for the MDET. Only then may the effectiveness of each side’s arguments be properly addressed and the future of the MDET be known.